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): **June 6, 2011**

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 June 6, 2011, Acorda Therapeutics, Inc. ("Acorda") issued a press release announcing that an analysis of pooled clinical trial results showed patients who were responders to AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg demonstrated clinically relevant improvements in walking ability as measured by patient self-report on the 12-Item Multiple Sclerosis Walking Scale (MSWS-12), regardless of either their baseline Expanded Disability Status Scale (EDSS) score or baseline walking speed. The data were presented at the 2011 Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting, held June 1-4 in Montreal, Canada. 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 June 6, 2011

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.

June 6, 2011

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated June 6, 2011

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

New Clinical Data Analysis of AMPYRA ® (dalfampridine) Shows Improvement of Patient-Reported Walking Ability Across a Range of Walking Impairment

- *Analysis of Clinical Trial Data Presented at 2011 Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting*

HAWTHORNE, NY, June 6, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced an analysis of pooled clinical trial results showed patients who were responders to AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg demonstrated clinically relevant improvements in walking ability as measured by patient self-report on the 12-Item Multiple Sclerosis Walking Scale (MSWS-12), regardless of either their baseline Expanded Disability Status Scale (EDSS) score or baseline walking speed. The data were presented at the 2011 Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting, held June 1-4 in Montreal, Canada. AMPYRA is an oral medication approved by the U.S. Food and Drug Administration (FDA) as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

"People with MS often experience a progressive decline in their walking ability that can begin early in their disease course. However, in many cases patients and their healthcare providers do not discuss walking impairment until it is so severe that it requires physical support from canes or walkers," said Ron Cohen, M.D., Acorda's President and CEO. "These data show that people with MS, even those with less obvious walking impairment, can potentially experience meaningful clinical benefit from treatment with AMPYRA."

The poster presentation, entitled "Impact of Dalfampridine on MSWS-12 Score Change in MS Patients" (poster S70), examined improvements in walking ability as measured by the MSWS-12 when patients were stratified using two separate criteria: EDSS score and baseline walking speed as measured by the Timed 25-Foot Walk (T25FW). The MSWS-12 is a patient-reported questionnaire that assesses the impact of MS on various aspects of walking ability in everyday life . The presentation was based on a pooled analysis of data from one Phase 2 and two Phase 3 clinical trials of dalfampridine, which were the

pivotal trials included in the New Drug Application that formed the basis of the U.S. Food and Drug Administration approval of the drug.

When stratified by baseline EDSS score (≤4.5, 5.0-5.5, ≥6.0), improvements in MSWS-12 scores among AMPYRA responders were clinically relevant and substantially greater compared to non-responders and placebo-treated patients across all three EDSS groups. Responders were defined as patients whose walking speed was faster on at least 3 of 4 on-treatment visits than their fastest speed at any of 5 off-treatment visits .

Similarly, when patients were stratified into four groups by baseline walking speed, AMPYRA responders experienced clinically relevant improvements across all four groups.

A second poster on AMPYRA data presented at the CMSC meeting, "UTI Incidence Among MS Patients Treated with Dalfampridine 10 mg Twice Daily" (poster S157), analyzed the incidence of urinary tract infection (UTI) reported by MS patients treated with AMPYRA in clinical trials, extension studies, and postmarketing safety reports. Approximately 80% of newly diagnosed MS patients and up to 96% of patients who have had MS for 10 years or more normally experience some bladder dysfunction, and UTI is a frequent complication of this dysfunction [1] .

In the pooled Phase 2 and Phase 3 clinical trial data of 400 patients receiving AMPYRA twice daily and 238 patients receiving placebo referenced above, 14.5% of AMPYRA-treated patients reported experiencing a UTI compared to 9.2% of placebo-treated patients over treatment observations periods of 9 to 14 weeks. The incidence of serious UTIs was similar across the AMPYRA and placebo groups; there were no discontinuations in the clinical trials due to UTI as an adverse event. Neither urinalysis nor culture was required for a UTI diagnosis in the clinical trials, which was usually based on symptoms. Among 483 patients who enrolled in AMPYRA open-label extension studies, UTI was reported in 33.1% of patients, with observation periods ranging from 1-182 weeks.

Postmarketing safety reports showed that 0.5% of AMPYRA-treated patients reported symptoms suggestive of a UTI (238/46,000 patients; data through April 2011); less than 10% of these reported UTIs were confirmed by urinalysis or culture, suggesting that most diagnoses were based on symptoms rather than recommended diagnostic criterion.

AMPYRA is marketed in the United States by Acorda Therapeutics, Inc. It is approved in the Unites States as a treatment to improve walking in people with MS. This was demonstrated by an increase in walking speed. For more information, visit www.ampyra.com.

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[1] Foster HE. Bladder symptoms and multiple sclerosis. *MSQR-Multiple Sclerosis Quarterly Report* . 2002;21(1):5-8

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≤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 ≥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), which was previously called fampridine, and remains known by that name outside the US. In laboratory studies, dalfampridine 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 United States by Acorda Therapeutics, and by Biogen Idec in markets outside the U.S. based on a licensing agreement with Acorda. AMPYRA is manufactured globally by Elan based on a supply agreement with Acorda.

AMPYRA is now 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 developing therapies for multiple sclerosis, spinal cord injury and related nervous system disorders. The Company is commercializing and marketing AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, in the Unites States. AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS); this was demonstrated by an improvement in walking speed. AMPYRA was developed using Elan's Matrix Drug Absorption System (MXDAS ®) technology and is manufactured by Elan based on a supply agreement with Acorda.

Acorda also markets ZANAFLEX CAPSULES ® (tizanidine hydrochloride), a short-acting drug for the management of spasticity. The Company's pipeline includes a number of products in development for the treatment, regeneration and repair of the spinal cord and brain.

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 Acorda Therapeutics' ability to successfully market and sell Ampyra in the United States and to successfully market Zanaflex Capsules; third party payors (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; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of Ampyra outside of the United States and our dependence on our collaboration partner Biogen Idec in connection therewith; competition; failure to protect Acorda Therapeutics' intellectual property or to defend against the intellectual property claims of others; the ability to obtain additional financing to support Acorda Therapeutics' operations; and, unfavorable results from our preclinical programs. 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 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.