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): **April 11, 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 April 11, 2011, Acorda Therapeutics, Inc. issued a press release announcing data analyses showing that people with multiple sclerosis (MS) who responded to AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg had comparable improvements in their walking regardless of baseline walking speed or overall level of MS-related disability. In addition, AMPYRA responders, regardless of baseline disability, showed clinically meaningful improvement on the 12-Item MS Walking Scale (MSWS-12), a patient-based questionnaire that measures the impact of MS on the patient's reported ability to perform daily activities related to walking. 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 April 11, 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.

April 11, 2011

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated April 11, 2011

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Presents New AMPYRA ® (dalfampridine) Data Analyses on Walking Improvement in Multiple Sclerosis at AAN Annual Meeting

- AMPYRA Shown to Provide Clinically Meaningful Improvement in Walking for People with Multiple Sclerosis Regardless of Baseline Walking Speed or EDSS Score

HAWTHORNE, NY, April 11, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced data analyses showing that people with multiple sclerosis (MS) who responded to AMPYRA™ (dalfampridine) Extended Release Tablets, 10 mg had comparable improvements in their walking regardless of baseline walking speed or overall level of MS-related disability [1] . In addition, AMPYRA responders, regardless of baseline disability, showed clinically meaningful improvement on the 12-Item MS Walking Scale (MSWS-12), a patient-based questionnaire that measures the impact of MS on the patient's reported ability to perform daily activities related to walking. These and other post hoc analyses of AMPYRA clinical trial and extension study data will be presented at the 63 rd American Academy of Neurology (AAN) Annual Meeting being held April 9-16 in Honolulu, Hawaii.

"Walking impairment is one of the most common and serious functional deficits caused by MS, but often people with MS and their physicians do not discuss walking issues until the level of impairment is severe," said Ron Cohen, M.D., Acorda's President and CEO. "These new analyses of our clinical data highlight that people with MS can experience a meaningful benefit with AMPYRA across all degrees of walking impairment. This also applies to patients with walking difficulties that may be less obvious and not immediately appreciated by others."

As part of this analysis, 394 participants who received 10 mg twice daily in AMPYRA Phase 2 and Phase 3 clinical trials were stratified by two separate criteria: baseline Expanded Disability Status Scale (EDSS) score (five sub-groups: 1.5-3.5; 4.0-4.5; 5.0-5.5; 6.0; and >6.0) and baseline walking speed as measured by the number of seconds required to complete the Timed 25 Foot Walk (T25FW) (five sub-groups: 5.16-8.95; 8.98-10.61; 10.64-13.29; 13.33-18.38; 18.40-71.57).

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[1] *Improvement in Walking Speed Across a Wide Range of Baseline EDSS Scores and Walking Speeds From Trials of Dalfampridine Extended Release Tablets in Patients with MS* (P07.164) available for viewing on April 14 from 2-6:30 p.m. HAST

A Timed Walk responder was defined as a person who walked faster on at least three of four on-treatment assessments compared to the fastest of five off-treatment assessments as measured by the T25FW. When stratified by severity of EDSS score, both the rate of response and the average percent improvement in walking speed among AMPYRA Timed Walk responders were comparable across the five subgroups and were consistently greater than changes in both AMPYRA non-responders and patients receiving placebo.

A separate analysis of pooled data from two placebo-controlled AMPYRA Phase 3 clinical trials demonstrated that AMPYRA responders transitioning from the placebo-controlled trials into open-label studies experienced a rapid loss of walking improvement after discontinuing therapy during the transition period [2] . Re-initiation of therapy resulted in recovery of walking speed improvement among previous responders by the first open-label study visit, which occurred 2 weeks after restarting treatment. The average walking speed improvement among responders was 27.7% from baseline at the conclusion of the placebo-controlled trials; after withdrawal from therapy, responder walking speed decreased to 4.3% above baseline. Following re-initiation of therapy, responders showed an average 24.3% increase from the original baseline. This indicates that responders can return to the level of walking improvement experienced before interruption of therapy. The study also found that the safety profile observed in the long-term extension trials was consistent with that seen in double-blind clinical trials; no new safety signals emerged in the open label extension. Approximately 94% of participants who completed the placebo-controlled clinical trials elected to enroll in the extension study. Participants in the extension study were followed for up to 3.5 years on therapy for this analysis.

Another analysis of AMPYRA clinical trial data indicated that the FDA-approved dose of 10 mg taken twice daily is the optimal dose for AMPYRA. Data showed that dosage strengths above of 10 mg twice daily did not result in an increase in either responder rates or change in walking speed among responders, but did increase overall adverse events (AEs) and central nervous system AEs [3] . In a placebo-controlled Phase 2 clinical trial (MS-F202) that evaluated the safety and efficacy of AMPYRA dosed at 10, 15 and 20 mg twice daily, data showed that there was no statistically significant difference in the proportion of patients who met the criteria for AMPYRA Timed Walk responders across the three dosages relative to placebo (35.3% for 10 mg; 36.0% for 15 mg; 38.6% for 20 mg; 8.5% for placebo). The same study showed comparable changes between the three twice daily dosages in terms of improvement of walking speed among responders (27.6% for 10 mg; 29.6% for 15 mg; 24.6% for 20 mg). The overall rate of adverse events in the MS-F202 was higher among patients receiving 15 and 20 mg twice daily compared to those receiving 10 mg twice daily (86.5% for 10 mg; 94.0% for 15 mg; 91.2% for 20 mg; 80.9% placebo), as was the incidence of central nervous system AEs (38.5% for 10 mg; 50.0% for 15 mg; 63.2% for 20 mg; 44.7% placebo). Additional data presented in this analysis showed that improvements in the percent change in walking speed were correlated to drug levels in the blood below the average minimum level with the 10 mg dose, indicating that doses lower than 10 mg twice daily would not be expected to maintain therapeutic plasma concentrations without more frequent dosing.

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[2] *Change in Walking Speed in Transition From Double-Blind to Open-Label Clinical Trials of Dalfampridine Extended Release Tablets, 10 mg Twice Daily, in Patients With MS* (P07.165) available for viewing on April 14 from 2-6:30 p.m. HAST

[3] *Doses of Dalfampridine Extended Release Tablets Greater Than 10 mg Twice Daily Are Associated With Increased Adverse Events but not Increased Efficacy* (P03.236) available for viewing on April 12 from 2-6:30 p.m. HAST

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 .

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.