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): **November 17, 2010**

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 November 17, 2010, Acorda Therapeutics, Inc. issued a press release announcing that data from the second of two pivotal dalfampridine extended release tablets Phase 3 clinical trials in multiple sclerosis were published in the October 2010 edition of *Annals of Neurology* . 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 November 17, 2010.

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.

November 17, 2010

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated November 17, 2010

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Additional Phase 3 Clinical Trial Data Published in *Annals of Neurology* Showing Dalfampridine Extended Release Tablets Improved Walking Ability in People with Multiple Sclerosis

HAWTHORNE, N.Y., November 17, 2010 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that data from the second of two pivotal dalfampridine extended release tablets Phase 3 clinical trials in multiple sclerosis (MS) were published in the October 2010 edition of *Annals of Neurology* . The study, which included 239 participants at 39 leading MS centers in the U.S. and Canada, demonstrated that a significantly greater proportion of people with MS taking dalfampridine extended release tablets had a consistent improvement in walking speed compared to those receiving placebo tablets (42.9 percent vs. 9.3 percent; $p < 0.0001$). These results were consistent with data from the first pivotal Phase 3 clinical trial, which were published in the February 29, 2009 edition of *The Lancet* .

“Data from this Phase 3 clinical trial involving 239 people with MS confirmed prior study results that a statistically significant proportion of those who receive dalfampridine extended release tablets experience a consistent improvement in their walking speed, and that this improvement is clinically meaningful,” said the paper’s lead author Andrew Goodman, M.D., Director of the Multiple Sclerosis Center at the University of Rochester Medical Center [1] .

AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg was approved by the U.S. Food and Drug Administration (FDA) on January 22, 2010 as a treatment to improve walking in people with MS. This was demonstrated by an increase in walking speed.

“Walking is an essential function of daily life. Published surveys have shown that over 60 percent of MS patients have walking impairment at any given time, and that people with MS cite walking impairment as one of the most upsetting aspects of their disease. AMPYRA is the only therapy approved to improve walking in MS, and it can provide a significant benefit for those who respond to treatment,” said Ron Cohen, M.D., President and CEO of Acorda Therapeutics. “Since the launch of AMPYRA in March 2010, we have been gratified by the positive feedback we have received from patients, as well as their family members and health care providers. We are continuing to work with these communities to provide information about the appropriate use of AMPYRA.”

Primary data from this clinical trial were first presented at the 2008 European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting. Data from this study are included in the approved package insert for AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg.

Data Demonstrate Improvement in Walking Speed
A significantly greater proportion of people taking dalfampridine (42.9 percent vs. 9.3 percent) were classified as “Timed Walk Responders,” defined as subjects with a faster walking speed in at least three of the four on-drug clinical visits compared to the fastest walking speed during five off-drug visits, as measured by the Timed 25-Foot Walk. The average increase in walking speed over the 9-week treatment

[1] Dr. Goodman is a consultant to Acorda Therapeutics.

period compared to baseline was 24.7 percent for the Timed Walk Responders in the drug group vs. 7.7 percent for the placebo group; the increase in speed was maintained across the entire treatment period and seen across all four major types of MS.

In addition, the study measured improvement in leg strength using the Lower Extremity Manual Muscle Test (LEMMT). There was an improvement seen in the dalfampridine Timed Walk Responders ($p=0.028$) compared to placebo. The mean improvement among dalfampridine Timed Walk Non-responders was not significantly different from either the dalfampridine Timed Walk Responder or placebo groups.

Validating the Clinical Meaningfulness of Walking Improvement
The study included several validation measures in order to assess the clinical meaningfulness of consistently improved walking speed (i.e the Timed Walk Response). The 12-Item MS Walking Scale (MSWS-12) was used as the primary measure to validate the clinical meaningfulness of the Timed Walk Response. The MSWS-12 is a self-rated scale in which the patient rates the extent to which their MS has affected 12 activities related to walking over the preceding two weeks, There was a significantly greater average improvement from baseline among Timed Walk Responders compared to Non-responders ($p<0.001$).

A Subject Global Impression (SGI) and a Clinician Global Impression (CGI) were used as secondary validation measures. Significant improvements were seen on these measures among Timed Walk Responders compared to Timed Walk Non-responders.

Safety Profile
In this study, adverse events were largely consistent with the safety profile observed in previous studies of dalfampridine extended release tablets in people with MS. Eight patients, including four from each treatment group (3.3 percent dalfampridine, 3.4 percent placebo) withdrew from the study due to adverse events. There was one reported seizure-related event in the placebo group (complex partial seizure) and no seizure-related events reported in the dalfampridine group.

Following is a list of adverse events reported in the clinical trial that occurred in greater than 5 percent of patients taking dalfampridine (percentages represent the dalfampridine treatment group vs. the placebo group): urinary tract infection (17.5 percent vs.8.4 percent), falls (11.7 percent vs.16.8 percent), insomnia (10.0 percent vs. 1.7 percent), headache (9.2 percent vs. 0.8 percent), asthenia (8.3 percent vs. 4.2 percent), dizziness (8.3 percent vs. 4.2 percent), nausea (8.3 percent vs. 0.8 percent), back pain (5.8 percent vs. 2.5 percent), balance disorder (5.8 percent vs. 1.7 percent), upper respiratory tract infection (5.8 percent vs. 6.7 percent), arthralgia (5.0 percent vs. 4.2 percent), nasopharyngitis (5.0 percent vs. 4.2 percent) and paresthesia (5.0 percent vs. 1.7 percent).

Clinical Trial Design
The double-blind, placebo-controlled clinical trial was designed to evaluate the safety and efficacy of dalfampridine in improving walking ability in people with MS. The study randomized 239 patients between 18 and 70 years old with a definite diagnosis of MS and some degree of walking disability. The study was open to people with all types of MS, including primary-progressive, secondary-progressive, relapsing-remitting and progressive-relapsing. Participants were permitted to remain on a stable regimen of their current medications, including immunomodulators, such as interferons. Subjects were randomized to 9 weeks of treatment with dalfampridine ($n=120$) or placebo ($n=119$), a 1:1 ratio of drug to placebo.

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 ($CrCl \leq 50$ 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.