ACORDA THERAPEUTICS INC
Form 8-K
October 15, 2010
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): October 15, 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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 October 15, 2010, Acorda Therapeutics, Inc. (the "registrant") issued a press release announcing that a new analysis of AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg data examining walking improvement in treatment responders has been presented at the 26th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). 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. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference into this item.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated October 15, 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.

October 15, 2010

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated October 15, 2010.

EXHIBIT 99.1

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Data on AMPYRA® (dalfampridine) Presented at 26th Congress of European Committee for Treatment and Research in Multiple Sclerosis

- Responders to AMPYRA Showed Clinically Significant and Meaningful Improvement in Walking Ability Based on Recent Consensus Expert Group Criteria

HAWTHORNE, N.Y., October 15, 2010 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that a new analysis of AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg data examining walking improvement in treatment responders has been presented at the 26th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). 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.

Using recently published consensus expert group criteria[1], an independent analysis of pooled AMPYRA Phase 3 trial data showed that the statistically significant improvement in Multiple Sclerosis Walking Scale (MSWS-12) score reported in the pivotal studies is also clinically significant and meaningful for people with MS. This new analysis indicates that the MSWS-12 score differences, 7.30 points between AMPYRA responders and placebo, and 7.02 points between AMPYRA responders and all non-responders, exceed the consensus expert group criteria and thereby satisfy the requirements for clinically significant and meaningful differences.

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1 Dworkin et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain 2008 Feb;9(2):105-121.

An AMPYRA responder was defined as a person who walked faster on the Timed 25-Foot Walk at 3 of 4 on-treatment assessments than at any of the 5 off-treatment assessments.

“Walking is a critical function, and walking disability is often cited by people with MS as the most concerning aspect of their disease,” said Ron Cohen, M.D., President and CEO of Acorda Therapeutics. “This study highlights that the MSWS-12 is an important tool in evaluating how walking improvements can translate into real world benefit to patients, and that patients who respond to AMPYRA can experience a clinically meaningful improvement in their walking.”

Acorda is developing and commercializing AMPYRA in the United States. Biogen Idec has licensed the rights to develop and commercialize prolonged-release fampridine tablets outside the United States from Acorda Therapeutics, Inc. Biogen Idec is presenting additional clinical data on prolonged-release fampridine at ECTRIMS.

This study was conducted by Dr. Jeremy Hobart, Peninsula College of Medicine and Dentistry (Devon, UK) and funded by Acorda Therapeutics, Inc.

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. 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's marketed products include AMPYRA® (dalfampridine), 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; and 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, 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. 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.