ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 04/13/10 for the Period Ending 04/13/10

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Symbol	ACOR
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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 13, 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 April 13, 2010, Acorda Therapeutics, Inc. (the "registrant") issued a press release announcing that four new analyses of clinical trial data on AMPYRA™ (dalfampridine) Extended Release Tablets 10 mg are being presented at the 62 nd American Academy of Neurology (AAN) Annual meeting. AMPYRA is an oral medication approved by the U.S. Food and Drug Administration (FDA) on January 22, 2010 as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an improvement 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

99.1 Press Release dated April 13, 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.

April 13, 2010

By: /s/ Jane Wasman

Name: Jane Wasman
Title: Executive Vice President,
General Counsel and Secretary

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated April 13, 2010.

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Data on AMPYRA™ (dalfampridine) Presented at American Academy of Neurology Meeting

- Responders to AMPYRA Treatment Showed Improvement in Average Walking Speed Compared to their Average Baseline for Up to 2.5 Years in Open-Label Studies
- Pooled Data from Phase 2 and 3 Placebo-Controlled Studies Showed 37% of AMPYRA-Treated Patients Demonstrate Consistent Walking Improvement and 25% Average Increase in Walking Speed
- Pooled Phase 2 and 3 Data Also Showed AMPYRA Improves Walking Speed Across the Range of Baseline Walking Speeds Studied and Response is Independent of Patient Demographics and Concomitant Immunomodulator Use

HAWTHORNE, N.Y., April 13, 2010 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that four new analyses of clinical trial data on AMPYRA™ (dalfampridine) Extended Release Tablets 10 mg are being presented at the 62 nd American Academy of Neurology (AAN) Annual meeting. AMPYRA is an oral medication approved by the U.S. Food and Drug Administration (FDA) on January 22, 2010 as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an improvement in walking speed.

“AMPYRA is a new therapy, the first ever with an indication to improve walking in MS.” said Ron Cohen, M.D., President and CEO of Acorda Therapeutics. “The data being presented at the AAN meeting include analyses of large numbers of patients receiving therapy for up to two and a half years, providing new information on the safety and efficacy of the drug during chronic use.”

Two platform presentations on AMPYRA data are included in today’s Scientific Session on Multiple Sclerosis:

Platform Presentation - Extension Studies
The first presentation is an analysis of long-term data from open-label extension studies of two completed Phase 3 trials as of November 30, 2008, the cut-off

date for the safety update for the New Drug Application (NDA) of AMPYRA. Patients receiving AMPYRA in the placebo-controlled trials were classified as either Timed Walk responders or non-responders based on their walking speed change as measured by the Timed 25-Foot Walk. A Timed Walk responder was defined as a patient who showed faster walking speed for at least 3 of 4 visits while taking AMPYRA compared to the fastest of 5 off-drug visits.

In the longer of the two extension studies, AMPYRA Timed Walk responders as a group continued to show improvement over their average baseline walking speed after 2.5 years, while Timed Walk non-responders did not. Both Timed Walk responders and non-responders showed a gradual and similar decrease in walking speed over time. Similar results were seen in the shorter extension study after 1.2 years. In both extension studies, the safety profile of AMPYRA was similar to that observed in double-blind trials lasting up to 14 weeks.

In the longer of the two extension trials, the approximate total exposure to Ampyra was 565 patient-years as of the cut-off date and there were four seizure-related events, with a fifth patient experiencing a seizure 22 days after discontinuation of study drug. There were no reports of seizure in the shorter of the two extension trials as of the cut-off date, with 193 patient-years of exposure to Ampyra.

Platform Presentation - Double Blind Studies
The second platform presentation is a pooled efficacy analysis of 631 patients who participated in one Phase 2 and two Phase 3 AMPYRA clinical trials (394 patients received AMPYRA 10 mg twice daily; 237 received placebo). Across the three studies, 37.3% of patients who received AMPYRA qualified as Timed Walk responders compared to 8.9% of patients who received placebo. The AMPYRA-treated responders showed an average improvement in walking speed of 25.3%.

In addition, AMPYRA-treated patients who did not respond to therapy experienced changes from baseline that were similar to those in the placebo group, indicating the trial design effectively separated treatment effects from unrelated changes in disease course.

Poster Presentations
The pooled Phase 2 and Phase 3 data were also analyzed in two separate poster presentations that will be presented on Thursday, April 15. The first analysis showed that response to AMPYRA was independent of gender, age, body mass index, MS type, baseline disability score as measured by the Expanded Disability Status Scale (EDSS), or disease duration. Response rate was also independent of treatment with common immunomodulator drugs. Among patients who responded to AMPYRA, 36.8% were taking interferons, 37.1% were taking glatiramer acetate and 27.3% were taking natalizumab; 39.8% were not taking immunomodulator therapy.

A second analysis compared response to AMPYRA in patients based on baseline walking speed, which ranged from 0.3-4.8 feet per second. The

responder rate and percent improvement in walking speed in patients treated with AMPYRA were similar across the entire range of baseline walking speeds represented in the studies.

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 $\geq$ 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 other 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.