ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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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): **January 22, 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 January 22, 2010, Acorda Therapeutics, Inc. issued a press releasing announcing that it has received marketing approval from the U.S. Food and Drug Administration for AMPYRA™ (dalfampridine).

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated January 22, 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.

January 22, 2010

By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated January 22, 2010.

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces FDA Approval of AMPYRA™ (dalfampridine) to Improve Walking in People with Multiple Sclerosis — Demonstrated by Increases in Walking Speed

- *First and Only FDA-Approved Therapy Addressing Walking Impairment*
- *AMPYRA Previously Referred to as Fampridine-SR*
- *AMPYRA Expected to be Available by Prescription in March 2010*
- *Acorda Conference Call Today at 5:30 p.m. Eastern Time*

HAWTHORNE, N.Y., January 22, 2010 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that it has received marketing approval from the U.S. Food and Drug Administration (FDA) for AMPYRA™ (dalfampridine), an oral treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed. AMPYRA demonstrated efficacy in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). AMPYRA can be used alone or with existing MS therapies, including immunomodulator drugs.

“The approval of AMPYRA marks an important milestone for the many people with MS who suffer walking impairment. Difficulty walking is often cited by those with MS as one of the most pervasive and challenging aspects of their disease,” said Ron Cohen, M.D., President and CEO of Acorda Therapeutics, adding “We are enormously gratified to have achieved approval for the only medication indicated to improve walking in people with MS, and we thank all of the clinicians, people living with MS and medical and patient support organizations who joined in this effort over the past decade. Reaching this milestone underscores Acorda’s ongoing commitment to develop innovative therapies for people with neurological diseases.”

“Walking impairment affects a large majority of people with MS, and we are very pleased that the FDA has approved a new treatment that addresses this aspect of the disease,” said John Richert, M.D., Executive Vice President for Research & Clinical Programs at the National Multiple Sclerosis Society. “Continuing to

advance clinical research and expand the range of therapeutic options for people with MS, including treatments for the most debilitating symptoms and challenges associated with the disease, is critical to helping people with MS."

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. The FDA granted AMPYRA orphan drug status, which will provide seven years of market exclusivity for the drug. In addition, Acorda has several issued patents that cover the formulation and use of AMPYRA.

AMPYRA is administered as a 10 mg tablet twice daily, approximately 12 hours apart. The primary measure of efficacy in its two Phase 3 MS trials was walking speed (in feet per second) as measured by the Timed 25-foot Walk (T25FW), using a responder analysis. A responder was defined as a patient who showed faster walking speed for at least three visits out of a possible four during the double-blind period than the maximum speed achieved in the five non-double-blind, no treatment visits (four before the double-blind period and one after).

A significantly greater proportion of patients taking AMPYRA 10 mg twice daily were responders compared to patients taking placebo, as measured by the T25FW (Trial 1: 34.8% vs. 8.3%; Trial 2: 42.9% vs. 9.3%). The increased response rate in the AMPYRA group was observed across all four major types of MS.

During the double-blind treatment period, a significantly greater proportion of patients taking AMPYRA 10 mg twice daily had increases in walking speed of at least 10%, 20%, or 30% from baseline, compared to placebo. In both trials, the consistent improvements in walking speed were shown to be associated with improvements on a patient self-assessment of ambulatory disability, the 12-item Multiple Sclerosis Walking Scale (MSWS-12), for both drug and placebo treated patients. However, a drug-placebo difference was not established for that outcome measure.

"Walking impairment makes life more difficult for many of my patients," said Dr. Andrew Goodman, M.D., Director of the Multiple Sclerosis Center at the University of Rochester. "With the approval of AMPYRA, we will have the first treatment option shown to improve walking speed in people with MS."

Acorda expects AMPYRA to be commercially available in the United States in March 2010. AMPYRA will be distributed exclusively through a network of specialty pharmacies and coordinated by AMPYRA Patient Support Services. Dedicated and experienced customer care agents will be available to help healthcare professionals process prescriptions, work with insurance carriers to facilitate coverage, and help patients to access benefits available through reimbursement assistance and patient assistance programs.

AMPYRA Patient Support Services can be reached at 888-881-1918 for more information about AMPYRA.

The FDA approved AMPYRA with a risk evaluation and mitigation strategy (REMS) program comprising a medication guide and communication plan. The goals of the communication plan are to inform patients about the serious risks, including seizures, associated with use of higher than recommended doses of AMPYRA therapy, and the change of the established name from fampridine to dalfampridine.

AMPYRA will be marketed in the United States by Acorda's established commercial organization, which successfully launched ZANAFLEX CAPSULES® (tizanidine hydrochloride). The Company plans to double the number of field- based sales professionals to approximately 100 by the time of commercial availability in March.

Under Acorda's existing license and supply agreement with Elan Pharma International Limited, a subsidiary of Elan Corporation, plc (NYSE: ELN), AMPYRA will be manufactured by Elan Drug Technologies using one of their Oral Controlled Release Technologies, the MXDAS™ (MatriX Drug Absorption System) technology.

"We are delighted that AMPRYA will now be available to help people with MS. This approval represents another significant milestone in our successful collaboration with Acorda Therapeutics," announced Shane Cooke, Executive Vice President and Head of Elan Drug Technologies. "The approval is the culmination of an enormous amount of work and effort over many years and is the second product in which we have collaborated with Acorda. We hope to find additional opportunities to work together in the future."

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 to 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 prescribing information, please visit: www.AMPYRA.com.

Conference Call

Acorda will hold a conference call and audio webcast on January at 5:30 p.m. ET. To participate in the conference call, please dial 800-573-4752 (domestic) or 617-224-4324 (international) and reference the access code 51443395. The presentation will be available via a live webcast at:

http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2697617

A replay of the call will be available from 8:30 p.m. ET on January 22, 2010 until midnight on February 22, 2010. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 14061810. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at http://www.acorda.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 an existing supply agreement with Acorda.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, usually progressive disease in which the immune system attacks and degrades the function of nerve fibers in the brain and spinal cord. More than 400,000 Americans have MS . Most people living with MS are diagnosed between the ages of 20 and 50, and women are affected two to three times more often than men. Worldwide, MS may affect an estimated 2.5 million people.

Research indicates 64%-85% of people with MS have difficulty walking, and 70% of people with MS who have difficulty walking report it to be the most challenging aspect of their MS. Within 15 years of an MS diagnosis, 50% of people with MS often require assistance walking and, in later stages, up to a one third are unable to walk.

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), as 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.

About Elan Drug Technologies

Elan Drug Technologies (EDT) is the world's leading drug delivery company and is a business unit of Elan (NYSE:ELN). EDT developed dalfampridine, using one of their proprietary Oral Controlled Release Technologies, the MXDAS ™ (MatriX Drug Absorption System) technology. EDT aim to deliver clinically meaningful benefits to patients by using their extensive experience and proprietary delivery technologies in partnership with pharmaceutical companies. Products enabled by their technologies are used by millions of patients each day. More information is available at *www.elandrugtechnologies.com.*

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 Amypra, 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.