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): **October 14, 2009**

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 October 14, 2009, Acorda Therapeutics, Inc. issued a press release indicating that the U.S. Food and Drug Administration (FDA) Peripheral and Central Nervous System Drugs (PCNSD) Advisory Committee voted 12 to 1 that clinical data on Fampridine-SR 10 mg twice daily demonstrated substantial evidence of effectiveness as a treatment to improve walking in people with multiple sclerosis (MS) and voted 10 to 2 (1 abstention) that it is clinically meaningful and can be safe for use.

The Committee also recommended by a vote of 12 to 1 that Acorda be required to evaluate the effects of doses lower than 10 mg twice daily, but by a 10 to 2 vote (1 abstention) that these studies not be required prior to approval.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated October 14, 2009.

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 14, 2009

By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated October 14, 2009.

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Positive Vote by FDA Advisory Committee for Fampridine-SR

- Committee Views Fampridine-SR as Safe, Effective and Clinically Meaningful for Improving Walking in People with Multiple Sclerosis
- Conference Call Scheduled for Thursday, October 15 at 8:00 a.m. Eastern Time

HAWTHORNE, N.Y., October 14, 2009 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced the U.S. Food and Drug Administration (FDA) Peripheral and Central Nervous System Drugs (PCNSD) Advisory Committee voted 12 to 1 that clinical data on Fampridine-SR 10 mg twice daily demonstrated substantial evidence of effectiveness as a treatment to improve walking in people with multiple sclerosis (MS) and voted 10 to 2 (1 abstention) that it is clinically meaningful and can be safe for use.

“We are pleased with the outcome of today’s Advisory Committee meeting. People with MS have an urgent need for therapies to improve their walking, which is essential to conducting their activities of daily life. If approved, Fampridine-SR would be the first medicine to improve walking in people with MS,” said Ron Cohen, M.D., Acorda Therapeutics President and CEO. “This Advisory Committee meeting is an important milestone in the development of Fampridine-SR, and we look forward to working with the FDA as it completes its review of Acorda’s New Drug Application.”

The Committee also recommended by a vote of 12 to 1 that Acorda be required to evaluate the effects of doses lower than 10 mg twice daily, but by a 10 to 2 vote (1 abstention) that these studies not be required prior to approval.

At the request of the FDA, the Committee discussed possible conditions for use, including for patients with renal impairment or history of seizure. Acorda has proposed a Risk Evaluation and Mitigation Strategy (REMS) program, which could include healthcare professional and patient education around appropriate use of Fampridine-SR.

The FDA seeks the advice of an advisory committee such as the PCNSD when evaluating a potential new treatment, but is not required to follow its recommendation. The current Fampridine-SR Prescription Drug User Fee Act (PDUFA) date set by the FDA is October 22, 2009; the PDUFA date is the target date for the FDA to complete its review of Fampridine-SR.

Conference Call
Acorda will hold a conference call and audio webcast on Thursday, October 15, 2009 at 8:00 a.m. ET to discuss the outcome of the Advisory Committee meeting. To participate in the conference call, please dial 866-700-6979 (domestic) or 617-213-8836 (international) and reference the access code 85689772. The presentation will be available via a live audio webcast at:

http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2484252

A replay of the call will be available from 11:00 a.m. ET on October 15, 2009 until midnight on November 14, 2009. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 45457470. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at http://www.acorda.com.

About Fampridine-SR
Fampridine-SR is a sustained-release tablet formulation of the investigational drug fampridine (4-aminopyridine or 4-AP). In laboratory studies, fampridine has been found to improve impulse conduction in nerve fibers in which the insulating layer, called myelin, has been damaged. Fampridine-SR is being developed by Acorda Therapeutics and manufactured by Elan Corporation plc.

About MS
Multiple sclerosis 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 between the ages of 20 and 50, with women affected two to three times more than men. Worldwide, MS may affect 2.5 million individuals.

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

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company developing therapies for spinal cord injury, multiple sclerosis and related nervous system disorders. The Company's marketed products include 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 delays in obtaining or failure to obtain FDA approval of Fampridine-SR, the risk of unfavorable results from future studies of Fampridine-SR, Acorda Therapeutics' ability to successfully market and sell Fampridine-SR, if approved, and Zanaflex Capsules, competition, failure to protect its 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 its 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.