ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 08/25/09 for the Period Ending 08/25/09

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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Symbol	ACOR
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
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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): **August 25, 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 August 25, 2009, Acorda Therapeutics, Inc. (the "Registrant") issued a press release announcing that the U.S. Food and Drug Administration's Peripheral and Central Nervous System Drugs Advisory Committee will review the Registrant's New Drug Application for Fampridine-SR on October 14, 2009. The Registrant also announced that is has received preliminary approval for the proposed trade name Amaya from the U.S. Food and Drug Administration.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated August 25, 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.

August 25, 2009

By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated August 25, 2009.

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Date of FDA Advisory Committee Review of Fampridine-SR for Improvement of Walking Ability in People with MS

- ***Peripheral and Central Nervous System Drugs Advisory Committee to Hold Meeting on October 14, 2009***
- ***Proposed Trade Name for Fampridine-SR, if approved, is Amaya™***

HAWTHORNE, N.Y., August 25, 2009 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the U.S. Food and Drug Administration (FDA) has confirmed that its Peripheral and Central Nervous System Drugs Advisory Committee will review the Company's New Drug Application (NDA) for Fampridine-SR on October 14, 2009. The meeting will take place at the Inn and Conference Center, University of Maryland University College (UMUC), Marriott Conference Centers, 3501 University Blvd. East, Adelphi, MD. Information related to the meeting is available on the U.S. Office of the Federal Register web site at: http://edocket.access.gpo.gov/2009/pdf/E9-20380.pdf

The Company also announced that it has received preliminary approval for the proposed trade name Amaya from the FDA.

Fampridine-SR is a novel therapy being studied as a potential treatment to improve walking ability in people with multiple sclerosis. The Fampridine-SR NDA was accepted by the FDA on May 5, 2009 and assigned Priority Review status. At that time, the FDA set a Prescription Drug User Fee Act (PDUFA) date of October 22, 2009; the PDUFA date is the target date for the FDA to complete its review of Fampridine-SR.

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 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.