ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
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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): **June 8, 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 June 8, 2009, Acorda Therapeutics, Inc. (the "Registrant") issued a press release announcing that, in response to its eligibility application to the European Medicines Agency ("EMEA") for Fampridine-SR, the EMEA has notified the Registrant that Fampridine-SR is eligible to be submitted for a Marketing Authorization Application ("MAA") via the EMEA's Centralized Procedure. The Centralized Procedure provides for a single, coordinated review that is conducted by the EMEA on behalf of all European Union ("EU") member states.

The EMEA also designated Fampridine-SR as a New Active Substance ("NAS"); if approved, compounds designated as an NAS receive a 10-year market exclusivity period in EU member states.

A copy of the release is attached hereto as Exhibit 99.1 and is incorporated by reference into this item.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated June 8, 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.

June 8, 2009

By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated June 8, 2009.

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Eligibility of Fampridine-SR for Centralized Review in Europe

- EMEA Grants New Active Substance (NAS) Status for Fampridine-SR
- Small and Medium Enterprise (SME) Status Granted to Acorda
- Ex-U.S. Partnership Discussions Ongoing

HAWTHORNE, N.Y., June 8, 2009 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that, in response to its eligibility application to the European Medicines Agency (EMEA) for Fampridine-SR, the EMEA has notified the Company that Fampridine-SR is eligible to be submitted for a Marketing Authorization Application (MAA) via the Agency's Centralized Procedure. The Centralized Procedure provides for a single, coordinated review that is conducted by the EMEA on behalf of all European Union (EU) member states.

The EMEA also designated Fampridine-SR as a New Active Substance (NAS); if approved, compounds designated as an NAS receive a 10-year market exclusivity period in EU member states.

Ron Cohen, M.D., President and CEO of Acorda, noted: "Fampridine-SR potentially represents a novel and important therapeutic option for people with MS who have walking impairment. This confirmation by EMEA of Fampridine-SR's eligibility for a centralized MAA filing and its granting of NAS status are key steps in the process toward making Fampridine-SR available to patients in the EU who may benefit from it. We are advancing the European regulatory process as we continue our discussions with potential ex-U.S. marketing partners. Should these discussions result in a partnership, we plan to time the filing of the MAA to allow our partner to provide input before submission."

The EMEA additionally granted Acorda Small and Medium Enterprise (SME) status. The SME program is an EMEA initiative to assist small companies applying for approval of medicinal products. By being designated an SME, companies are eligible for elimination or reduction of certain fees, have access to scientific advice during the clinical development and application processes, and EMEA assumes responsibility for certain required translations as long as they stay under the 250 employee limit .

The U.S. Food and Drug Administration (FDA) is currently reviewing a New Drug Application (NDA) for Fampridine-SR. The NDA was assigned Priority Review and 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.