ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 05/06/09 for the Period Ending 05/06/09

Address	420 SAW MILL RIVER ROAD
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Telephone	914-347-4300
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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): **May 6, 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 May 6, 2009, Acorda Therapeutics, Inc. issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has accepted the Fampridine-SR New Drug Application ("NDA") for filing, assigning 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 the Fampridine-SR NDA. A copy of the release is attached hereto as Exhibit 99.1 and incorporated by reference into this item.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated May 6, 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.

May 6, 2009

By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated May 6, 2009.

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces FDA Acceptance of Fampridine-SR New Drug Application for Filing

- FDA Assigns Priority Review and PDUFA Date of October 22, 2009
- No Current Therapies Indicated to Improve Walking Ability in People with MS

HAWTHORNE, N.Y., May 6, 2009 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the U.S. Food and Drug Administration (FDA) has accepted the Fampridine-SR New Drug Application (NDA) for filing, assigning 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 the Fampridine-SR NDA.

"I am pleased that we were able to work quickly to address the comments from the FDA and resubmit our NDA approximately three weeks from having received the Refuse to File letter on our initial NDA submission, and that the FDA accepted the filing less than two weeks later," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "We are also encouraged that the FDA has elected to assign Priority Review status to the Fampridine-SR NDA."

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.

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 Fampridine-SR, using one of their proprietary Oral Controlled Release Technologies, the MXDAS ® (MatriX Drug Absorption System) Technology. Products developed by EDT aim to deliver clinically meaningful benefits to patients by using their extensive experience and proprietary delivery technologies in partnership with pharmaceutical companies. 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 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.