ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 04/23/09 for the Period Ending 04/23/09

Address	420 SAW MILL RIVER ROAD
	ARDSLEY, NY 10502
Telephone	914-347-4300
CIK	0001008848
Symbol	ACOR
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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): **April 23, 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 April 23, 2009, Acorda Therapeutics, Inc. (the "Registrant") issued a press release announcing that the Registrant had resubmitted its New Drug Application ("NDA") for Fampridine-SR to the U.S. Food and Drug Administration (the "FDA"). Fampridine-SR is a novel therapy being developed to improve walking ability in people with multiple sclerosis. The Registrant had previously received a Refuse to File letter (the "RTF Letter") on March 30, 2009, which cited the need to correct "format issues" and requested additional supporting information before the NDA could be accepted for review. Based on subsequent discussions with the FDA, the Registrant believes that all of the FDA's comments related to the RTF Letter have been addressed. 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 April 23, 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.

April 23, 2009

By: */s/ David Lawrence*

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated April 23, 2009.

Exhibit 99.1

CONTACT:

Jeff Macdonald
Acorda Therapeutics
(914) 347-4300 ext. 232
jmacdonald@acorda.com

FOR IMMEDIATE RELEASE

Acorda Therapeutics Resubmits New Drug Application for Fampridine-SR for Improvement of Walking Ability in People with Multiple Sclerosis

HAWTHORNE, N.Y., April 23, 2009 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced the resubmission of its New Drug Application (NDA) for Fampridine-SR to the U.S. Food and Drug Administration (FDA). Fampridine-SR is a novel therapy being developed to improve walking ability in people with multiple sclerosis (MS).

Acorda received a Refuse to File (RTF) letter for the Fampridine-SR NDA on March 30, 2009, which cited the need to correct "format issues" and requested additional supporting information before the NDA could be accepted for review. Based on subsequent discussions with the FDA, Acorda has resubmitted the Fampridine-SR NDA and believes that all of the Agency's comments related to the RTF have been addressed.

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.