ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 03/31/09 for the Period Ending 03/30/09

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): **March 30, 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 March 31, 2009, Acorda Therapeutics, Inc. (the "Registrant") issued a press release announcing that the Registrant had received a refuse to file letter from the U.S. Food and Drug Administration regarding its New Drug Application for Fampridine-SR for improvement of walking ability in people with multiple sclerosis. 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 March 31, 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.

March 31, 2009

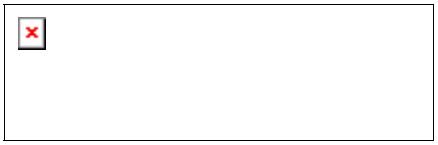
By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated March 31, 2009.

Exhibit 99.1



CONTACT:

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

FOR IMMEDIATE RELEASE

Acorda Therapeutics Receives Refuse to File Letter from FDA on Fampridine-SR NDA

— Company to Host Conference Call at 8:30 a.m. Eastern Time Today—

HAWTHORNE, N.Y., March 31, 2009 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) announced today that the Company received a refuse to file letter from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for Fampridine-SR, a novel therapy being developed to improve walking ability in people with multiple sclerosis (MS).

The FDA has raised what it termed "format issues" regarding the eCTD (electronic) submission, requesting that some of the data in the NDA be reformatted, as well as requesting that some additional supporting information be included in the filing. The FDA has not requested or recommended additional clinical or other studies.

"We are surprised by this development," stated Ron Cohen, M.D., President and CEO of Acorda Therapeutics, "We plan to address the issues raised in this letter with FDA expeditiously as we believe Fampridine-SR is potentially an important, first in class treatment option for people suffering with MS."

The Company plans to request a meeting with FDA as soon as possible to discuss its comments on the NDA filing.

Conference Call and Audiocast
Acorda will host a conference call Tuesday, March 31, 2009 at 8:30 a.m. Eastern Time. To participate, please dial 866-783-2143 (domestic) or 857-350-1602 (international) and reference the access code 85118409. To access the audio webcast, please go to the Investor Relations "Calendar of Events" section of the Acorda website at www.acorda.com, or you may use the link: http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2150210.

A replay of the call will be available from 11:30 a.m. Eastern Time on March 31, 2009 until April 30, 2009. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 59152215. The archived teleconference will be available for 30 days in the Investor Relations section of the Acorda website at http://phoenix.corporate-ir.net/phoenix.zhtml?c=194451&p=irol-irhome.

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 Statement

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.