ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 10/22/09 for the Period Ending 10/22/09

Address	420 SAW MILL RIVER ROAD
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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): **October 22, 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 October 22, 2009, Acorda Therapeutics, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has extended the PDUFA goal date for its review of the New Drug Application (NDA) for Fampridine-SR to January 22, 2010.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated October 22, 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.

October 22, 2009

By: /s/ David Lawrence
Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated October 22, 2009.

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Extension of Fampridine-SR PDUFA Goal Date to January 22, 2010

HAWTHORNE, N.Y., October 22, 2009 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the U.S. Food and Drug Administration (FDA) has extended the PDUFA goal date for its review of the New Drug Application (NDA) for Fampridine-SR to January 22, 2010. The original Prescription Drug User Fee Act (PDUFA) date for this priority review application was October 22, 2009.

Following the Peripheral and Central Nervous System Drugs Advisory Committee meeting on Fampridine-SR, Acorda submitted additional information on its proposed Risk Evaluation and Mitigation Strategy (REMS) program. The FDA accepted this submission as a solicited major amendment to the Fampridine-SR NDA. The FDA has the option to extend the PDUFA goal date when a sponsor submits a major amendment that provides a substantial amount of new data not previously reviewed by the FDA.

“The REMS program is important to ensuring appropriate use of Fampridine-SR, if approved, and we are pleased that the FDA has accepted our amendment,” said Ron Cohen, M.D., President and CEO of Acorda Therapeutics. “We look forward to continuing to work with the FDA as it completes its review of the Fampridine-SR NDA.”

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 in the United States 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.