ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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SIC Code	2836 - Biological Products, Except Diagnostic Substances
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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): **February 2, 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 February 2, 2009, Acorda Therapeutics, Inc. (the "Registrant") issued a press release announcing the submission of a New Drug Application to the U.S. Food and Drug Administration on January 30, 2009 for Fampridine-SR. The Company also announced that it has discussed Fampridine-SR with regulatory authorities in Europe and believes that the current data are sufficient to file a centralized Marketing Authorization Application (MAA) with the European Medicines Agency, and that it plans to file the MAA when it has determined the commercialization pathway that maximizes the value of Fampridine-SR outside the U.S. The Registrant's press release is filed as Exhibit 99.1 hereto and incorporated by reference into this item 8.01.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated February 2, 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.

February 2, 2009 *By:* */s/ David Lawrence*

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated February 2, 2009

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

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

- Acorda Submitted New Drug Application (NDA) for Fampridine-SR on January 30, 2009
- No Current Therapies Indicated to Improve Walking Ability in People with MS

HAWTHORNE, N.Y., February 2, 2009 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced the submission of a New Drug Application to the U.S. Food and Drug Administration (FDA) on January 30, 2009 for Fampridine-SR, a novel therapy being developed to improve walking ability in people with multiple sclerosis (MS). The Company expects that the NDA filing, if accepted, will be subject to standard review, which would provide a target for the FDA to complete its review within ten months from receipt of the submission.

"This NDA filing is a major milestone for Acorda and our Fampridine-SR development program," said Acorda Therapeutics President and CEO Ron Cohen, M.D. "Walking impairment is one of the most pervasive and alarming aspects of MS for patients, their families and their health care providers. There are no medicines currently indicated to improve walking ability in people with MS, and Fampridine-SR therefore may represent an important new approach to MS therapy. We are excited to have taken this major step toward potentially making Fampridine-SR available to help people with MS."

Approximately 400,000-500,000 people in the Unites States have MS, and recent studies indicate that between 64-85% of people with MS have walking disability(1),(2). Fully 70% of people with MS who have walking disability report it to be the most challenging aspect of their disease (1).

The Fampridine-SR NDA submission is based on data from a comprehensive development program assessing the safety and efficacy of Fampridine-SR, including two Phase 3 trials that involved 540 people with MS and were conducted under Special Protocol Assessments (SPAs) from the FDA. The safety and efficacy profile of Fampridine-SR was consistent across Phase 2 and Phase 3 trials. Overall, the NDA filing included more that 50 clinical studies of Fampridine-SR. The total exposure to Fampridine-SR in MS studies filed as part of the NDA was over 1,200 patient-years. Additionally, more than 450 people are currently enrolled in Fampridine-SR extension trials, with treatment duration ranging from seven months to almost five years.

The Company also has discussed Fampridine-SR with regulatory authorities in Europe and believes that the current data are sufficient to file a centralized Marketing Authorization Application (MAA) with the European Medicines Agency (EMEA). The Company plans to file the MAA when it has determined the commercialization pathway that maximizes the value of Fampridine-SR outside the U.S.

(1) Harris Interactive poll, April 2008
(2) NARCOMS patient database

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. As of June 2008, the Company completed two successful Phase 3 clinical trials to evaluate the safety and efficacy of Fampridine-SR in improving walking ability in people with MS.

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. In June 2008, Acorda's lead clinical product, Fampridine-SR, completed a second Phase 3 clinical trial to evaluate its safety and efficacy in improving walking ability in people with MS. 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.