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ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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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): **May 22, 2007**

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 22, 2007, Acorda Therapeutics, Inc. (the "registrant") issued a press release announcing that it has reached agreement with the U.S. Food and Drug Administration on a Special Protocol Assessment for a second Phase 3 trial of Fampridine-SR in Multiple Sclerosis. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item.

The information in this Item 8.01 of Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated May 22, 2007

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 22, 2007

By: /s/ David Lawrence

Name: David Lawrence, M.B.A.
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated May 22, 2007

Exhibit 99.1

CONTACTS:

Erica Wishner
Acorda Therapeutics
(914) 347-4300 ext. 162
ewishner@acorda.com

FOR IMMEDIATE RELEASE

Acorda Therapeutics and FDA Reach Agreement on Special Protocol Assessment for Second Phase 3 Study of Fampridine-SR in Multiple Sclerosis

HAWTHORNE, NY, May 22, 2007 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for a second Phase 3 trial of Fampridine-SR in Multiple Sclerosis (MS). An SPA is a process in which the FDA provides evaluation and guidance on clinical trial protocols for Phase 3 trials. T he objective of the study is to show that individuals treated with Fampridine-SR are significantly more likely to have consistent improvements in their walking than those treated with placebo. Pending clinical results, the FDA has agreed that this trial, MS-F204, together with the company's first Phase 3 trial, MS-F203, would be adequate to support a New Drug Application (NDA) for Fampridine-SR.

"We are pleased to have reached this agreement with the FDA, and are already working closely with our team of 35 MS centers to begin the study," said Ron Cohen, M.D., President and CEO. "Currently, there are no approved therapies that improve mobility in people with MS and physicians and patients regularly rate walking as one of the areas of greatest unmet medical need for this condition."

MS-F204 Trial Design

The primary outcome measure for the study will be a walking response, defined as a consistent improvement in walking speed as measured by the Timed 25-Foot Walk . Efficacy will be based solely on the achievement of statistical significance in the primary outcome measure. The secondary outcome measure for this study is the Lower Extremity Manual Muscle Test (LEMMT). Additional outcome measures, such as the Ashworth score for spasticity, a Clinician Global Impression and a Subject Global Impression, are included to allow an integrated efficacy analysis across studies. A visit at the conclusion of the study will provide pharmacodynamic information. Approximately 35 MS centers in the U.S. and Canada are expected to participate in the trial, and the trial is designed to enroll approximately 200 participants.

The design of MS-F204 is fundamentally similar to Acorda's first Phase 3 trial of Fampridine-SR in MS, MS-F203. However, the current study protocol will require 14 weeks of patient participation compared to 21 weeks in MS-F203.

About Fampridine-SR

Fampridine-SR is a sustained-release tablet formulation of the investigational drug fampridine (4-aminopyridine, or 4-AP). Data collected in laboratory studies found that fampridine can improve the communication between damaged nerves, which may result in increased neurological function.

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 Acorda Therapeutics' ability to successfully market and sell Zanaflex Capsules, the risk of unfavorable results from future studies of Fampridine-SR, delays in obtaining or failure to obtain FDA approval of Fampridine-SR, competition, the ability to obtain additional financing to support Acorda Therapeutics' operations, unfavorable results from its preclinical programs, and failure to protect its intellectual property or to defend against the intellectual property claims of others. 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.

About Acorda Therapeutics

Acorda Therapeutics is a biotechnology company developing therapies for SCI, MS and related nervous system disorders. The Company's marketed products include Zanaflex Capsules™ (tizanidine hydrochloride), a short-acting drug for the management of spasticity. For full prescribing information, please go to www.zanaflexcapsules.com. Acorda's lead clinical stage product, Fampridine-SR, recently completed a Phase 3 study 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.