ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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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): **June 6, 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 June 6, 2007, Acorda Therapeutics, Inc. (the "registrant") issued a press release announcing that it has begun a second Phase 3 clinical study of Fampridine-SR in multiple sclerosis, with the randomization of its first patient into the treatment phase of the study. 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 June 6, 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.

June 6, 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 June 6, 2007

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Begins Second Phase 3 Clinical Trial of Fampridine-SR in Multiple Sclerosis

Hawthorne, NY June 6, 2007 - Acorda Therapeutics (Nasdaq: ACOR) announced today that it has begun a second Phase 3 clinical study of Fampridine-SR in multiple sclerosis (MS), with the randomization of its first patient into the treatment phase of the study. The study is expected to enroll approximately 200 patients at 35 leading MS clinical centers in the United States and Canada. Fifteen centers have been initiated and are in the process of screening subjects for the trial.

The MS-F204 study, which is conducted under a Special Protocol Assessment (SPA) issued by the Food and Drug Administration (FDA), will evaluate the safety and efficacy of Fampridine-SR in improving walking ability in people with MS. An SPA is a process in which the FDA provides guidance on a Phase 3 clinical trial whose data will form the primary basis for an efficacy claim. Pending clinical results from MS-F204, FDA has agreed that this study together with the previous Phase 3 study would be adequate to support a New Drug Application (NDA) for Fampridine-SR.

The primary outcome measure for the study will be a walking response criterion, defined as a consistent improvement in walking speed as measured by the Timed 25-Foot Walk. The secondary outcome measure for this study is the Lower Extremity Manual Muscle Test (LEMMT). Individuals who are interested in learning about study enrollment may call, **877-617-2494** toll-free, weekdays from 10:00am to 4:00pm Eastern Time.

“As a clinician I see how impaired walking affects my patient’s ability to conduct even the most routine tasks,” said Lauren Krupp, M.D., Professor of Neurology and Psychology, Stony Brook University. “A drug that could improve walking ability would be a significant contribution to the treatment of people with MS.”

Ron Cohen, M.D., President and CEO of Acorda Therapeutics, said, “Walking impairment in MS is pervasive and seriously debilitating in this patient population. We are proud to be working towards an important treatment that potentially may help to address this major unmet medical need.”

About MS

Multiple sclerosis is a chronic, usually progressive disease of the central nervous system in which the immune system attacks and destroys the structure, and therefore degrades the function, of nerve cells. Approximately 400,000 Americans have MS, and every week about 200 people are newly diagnosed. Most are between the ages of 20 and 50, and women are affected two to three times as much as men. Worldwide, MS may affect 2.5 million individuals.

According to the National Multiple Sclerosis Society (NMSS), the direct costs of medical care for MS patients in the United States exceed $6 billion annually. Additionally, a recent NMSS analysis estimated the total cost of MS, including medical and non-medical care, production losses, and informal care, at more than $47,000 per U.S. patient per year. Complications from MS may make it harder for people to work and may interfere with their ability to perform common, daily activities.

For most people with MS, the disease slowly progresses with a series of unpredictable flare-ups, also called relapses or exacerbations. But for some, the progression of the disease is rapid. Each relapse tends to lead to increasing disabilities such as walking impairment, muscle weakness or speech or vision impairments. Approximately 80 percent of people with MS experience some form of walking disability. Within 15 years of an MS diagnosis, 50 percent of patients often require assistance walking and in later stages, about a third of patients are unable to walk. According to the NARCOMS (North American Research Committee on Multiple Sclerosis) patient registry, approximately 80 percent of people with MS experience some degree of walking impairment. Additionally, mobility issues tend to worsen over time and seem to be independent of the type of MS diagnosed.

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.

Fampridine-SR Mechanism of Action

A nerve cell has one extension, called an axon, which it uses to communicate via electrical signals to other nerve cells. All but the smallest axons have a special covering of a fatty substance called myelin that acts as insulation to preserve and speed these nerve signals, much like the insulating cover of an electrical cord helps preserve the transmission of electricity.

In MS, the myelin becomes damaged and the axon cannot effectively transmit electrical impulses. Specifically, the damaged myelin exposes channels in the membrane of the axon, which allow potassium ions to leak from the axon, dissipating the electrical current. Fampridine-SR blocks these exposed channels, and helps the electrical signals to pass through areas of damage.

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(TM) (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.