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): **September 25, 2006**

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 September 25, 2006, Acorda Therapeutics, Inc. issued a press release announcing the results from its MS-F203 Phase 3 clinical study of Fampridine-SR. A copy of the release is attached hereto as Exhibit 99.1 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 September 25, 2006

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.

September 25, 2006

By: /s/ David Lawrence

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated September 25, 2006

Exhibit 99.1

For Immediate Release:

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Acorda Therapeutics Announces Positive Results of Phase 3 Study of Fampridine-SR on Walking in People with Multiple Sclerosis

Statistical significance achieved on all three efficacy criteria set forth in SPA

Conference Call and Webcast at 8:30 a.m. Eastern Time on September 25, 2006

Hawthorne, NY September 25, 2006 - Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced positive results from its Phase 3 clinical trial of Fampridine-SR on walking in people with multiple sclerosis (MS). Statistical significance was achieved on all three efficacy criteria defined in the Special Protocol Assessment (SPA) by the Food and Drug Administration (FDA). A significantly greater proportion of people taking Fampridine-SR had a consistent improvement in walking speed, the study's primary outcome, compared to people taking placebo (34.8 percent vs. 8.3 percent) as measured by the Timed 25-Foot Walk ($p<0.001$). In addition, the effect was maintained in this study throughout the 14-week treatment period ($p<0.001$) and there was a statistically significant improvement in the 12-Item MS Walking Scale (MSWS-12) for walking responders vs. non-responders ($p<0.001$).

The average increase in walking speed over the treatment period compared to baseline was 25.2 percent for the drug group vs. 4.7 percent for the placebo group. Increased response rate on the Timed 25-Foot Walk was seen across all four major types of MS. In addition, statistically significant increases in leg strength were seen in both the Fampridine-SR Timed Walk responders ($p<0.001$) and the Fampridine-SR Timed Walk non-responders ($p=0.046$) compared to placebo. The Company intends to present comprehensive data at an upcoming medical meeting.

"We are delighted with the results from this trial, which are consistent with Acorda's prior Phase 2 study in people with MS. We will request a meeting with the FDA as soon as possible to discuss next steps for the Fampridine-SR program," said Ron Cohen, M.D., President and CEO. "Acorda is committed to the development of therapies that will improve the function and lives of people with MS, and we wish to thank the physicians and people with MS who participated in this trial."

"Many people with MS experience nerve damage that eventually impairs walking. Currently, no therapies are indicated to improve neurological function, such as loss of mobility, in MS," said Andrew Goodman, M.D., Director of the Multiple Sclerosis Center at the University of Rochester. "Based on the results of this trial, Fampridine-SR could represent a new way to treat people with MS. In this study, a significantly higher proportion of subjects experienced a consistent improvement in walking speed with Fampridine-SR than with placebo, and this was accompanied by a reduction in the degree of disability that the subjects reported in their daily activities related to mobility."

Special Protocol Assessment (SPA)
This clinical trial was conducted under an SPA from the FDA. The efficacy criteria set forth in the SPA included three elements:

- To show that there were significantly more responders in the Fampridine-SR treated group than in the placebo group, as measured by the Timed 25-Foot Walk, a standard neurological test. A responder was defined as someone whose walking speed on the Timed 25-Foot Walk was consistently greater during at least three of four on-drug visits than the person's fastest speed on any of the five off-drug visits.

- To demonstrate statistically significant improvement in walking speed on the last on-drug visit for the Fampridine-SR-treated responders compared to the placebo group.

- To show that responders reported a significantly greater improvement than non-responders on the MSWS-12, a self-rated assessment of walking disability. This step was meant to validate the clinical meaningfulness of consistent improvement on the Timed 25-Foot Walk.

Study Design
The double-blind, placebo-controlled trial was designed to evaluate the safety and efficacy of Fampridine-SR in improving walking ability in people with MS. The trial, which enrolled 301 individuals at 33 MS centers in the United States and Canada, recruited patients between 18 and 70 years old with a definite diagnosis of MS and some degree of walking disability. The study was open to people with all types of MS, including primary-progressive, secondary-progressive, relapsing-remitting and progressive-relapsing. Participants were permitted to remain on a stable regimen of their current medications, including interferons. Secondary endpoints for the trial included measurements of leg strength. Subjects were randomized to 14 weeks of treatment with Fampridine-SR (n=229) or placebo (n=72), a 3:1 ratio of drug to placebo.

Safety Statement
In this study, adverse events were largely consistent with the safety profile observed in previous studies of Fampridine-SR in people with MS, including an increased risk of seizures that appears to be dose related. Following is a list of the most common adverse events reported in the study, with percentages representing the Fampridine-SR treatment group vs. the placebo group: falls (15.8 percent vs.15.3 percent), urinary tract infection (13.6 percent vs.13.9 percent), dizziness (8.3 percent vs. 5.6 percent), insomnia (8.3 percent vs. 4.2 percent), fatigue (6.1 percent vs. 2.8 percent), nausea (6.1 percent vs. 4.2 percent), upper respiratory tract infection (6.1 percent vs. 9.7 percent), asthenia (5.7 percent vs. 6.9 percent), back pain (5.7 percent vs. 0 percent), balance disorder (5.7 percent vs. 2.8 percent) and headache (5.7 percent vs. 5.6 percent).

Two serious adverse events that were judged potentially related to treatment and led to discontinuation were anxiety in one subject and a seizure in another subject that was observed during an occurrence of sepsis associated with a urinary tract infection. No deaths occurred during the study. One death was reported for a subject five weeks after the last on-drug study visit. This death occurred outside of the protocol time window for reporting adverse reactions and the cause of death is not known at this time.

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.

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.

Conference Call and Webcast
Acorda will hold a conference call and webcast today at 8:30 am ET to discuss the top-line results from the trial. To access the call, please dial 866-510-0704 (domestic) or 617-597-5362 (international) five minutes prior to the start time, and provide the access code 20529997. A replay of the call will be available from 10:30 a.m. Eastern Time on September 25, 2006 until 11:59 p.m. Eastern Time on October 25, 2006. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international), and provide the access code 88067926. An audio webcast of the call can also be accessed from the Company's website, at http://www.acorda.com, for the next 30 days.

Patient Information Line
Patients with questions regarding the results of this study, or, who want to join Acorda's mailing list to be kept informed of future company news, may call 877-223-5212, toll-free, weekdays from 10:00am to 5:00pm ET.

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 indicated for the management of spasticity. For full prescribing information, please go to www.zanaflexcapsules.com. The Company's pipeline includes a number of products in development for the treatment, regeneration and repair of the spinal cord and brain.

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