ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 06/02/08 for the Period Ending 06/02/08

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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): **June 2, 2008**

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 2, 2008, Acorda Therapeutics, Inc. issued a press release announcing the results of its second Phase 3 clinical study of Fampridine-SR on walking ability in people with 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 8.01.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated June 2, 2008.

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 2, 2008

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 2, 2008

Exhibit 99.1

For Immediate Release:

MEDIA:
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Acorda Therapeutics Announces Positive Data from Second Phase 3 Study of Fampridine-SR on Walking Ability in People with Multiple Sclerosis

- Company Plans to File New Drug Application (NDA) in First Quarter of 2009 -

- Investor Conference Call and Webcast Today at 8:30 a.m. ET -

Hawthorne, NY, June 2, 2008 - Acorda Therapeutics, Inc. (NASDAQ: ACOR) today announced positive results from its second Phase 3 clinical trial of Fampridine-SR (MS-F204) on walking ability in people with multiple sclerosis (MS). A significantly greater proportion of people taking Fampridine-SR in the trial had a consistent improvement in walking speed compared to people taking placebo (42.9% vs. 9.3%), as measured by the Timed 25-Foot Walk ($p < 0.001$). Consistent improvement in walking speed was the primary endpoint of the study as outlined in the Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA).

"With the success of this trial, we have achieved a critical milestone for Fampridine-SR. We have now completed two successful Phase 3 trials demonstrating improved walking ability in people with MS," said Ron Cohen, M.D., President and CEO of Acorda Therapeutics. "We believe that, subject to FDA review, the results of our two Phase 3 trials are adequate to support an NDA. We expect to submit this application in the first quarter of 2009 and plan to request priority review."

The study's only prospectively defined secondary outcome measure, leg strength, showed a statistically significant increase in the Fampridine-SR Timed Walk responders compared to placebo ($p = 0.028$). There was a small improvement in leg strength for Fampridine-SR Timed Walk non-responders compared to placebo that was not statistically significant.

Additional measures in this study were consistent with the results of the first Phase 3 Fampridine-SR trial. The average increase in walking speed over eight weeks of treatment compared to baseline was 24.7 percent for the Fampridine-SR Timed Walk responders compared to 7.7 percent for the placebo group. The 12-Item Walking Scale (MSWS-12), a self-rated assessment of walking disability, was improved in Timed Walk responders compared to non-responders. Also, an increased response rate on the Timed 25-Foot Walk was seen across all four types of MS. The Company intends to present comprehensive data from this trial at an upcoming medical meeting.

“Difficulties with walking are among the most pervasive and debilitating problems faced by people with MS. Walking disability affects their ability to accomplish daily tasks and limits their independence,” said Andrew Goodman, M.D., Director of the Multiple Sclerosis Center at the University of Rochester. “Because there are currently no therapies indicated to improve walking impairment in MS, clinicians are limited in their ability to address this aspect of the disease. The results of this study indicate that Fampridine-SR could represent an important new way to treat people with MS.”

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 primary endpoint of the study was response on the Timed 25-Foot Walk. A Fampridine-SR Timed Walk responder was defined as a study participant whose walking speed was faster at a majority of the four on-drug visits than any speed measured during the five off-drug visits. The trial, which enrolled 240 individuals at 39 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. Subjects were randomized to treatment with Fampridine-SR (n=120), at a dose of 10mg twice a day, or placebo (n=119), and the study was open to people with all four major types of MS: primary-progressive, secondary-progressive, relapsing-remitting and progressive-relapsing. Participants were permitted to remain on a stable regimen of their current medications, including immunomodulators.

Safety Statement

In this study, adverse events were generally mild to moderate and largely consistent with the safety profile observed in previous studies of Fampridine-SR in people with MS. The most common adverse events reported in the Fampridine-SR treatment group compared to the placebo group included: urinary tract infection (17.5% vs. 8.4%), falls (11.7% vs. 16.8%), insomnia (10.0% vs. 1.7%), headache (9.2% vs. 0.8%), asthenia (8.3% vs. 4.2%), dizziness (8.3% vs. 0.8%), nausea (8.3% vs. 0.8%), back pain (5.8% vs. 2.5%), balance disorder (5.8% vs. 1.7%), upper respiratory tract infection (5.8% vs. 6.7%), arthralgia (5.0% vs. 4.2%), nasopharyngitis (5.0% vs. 4.2%) and paraesthesia (5.0% vs. 1.7%).

There were three serious adverse events (SAEs) that led to discontinuation: two in the placebo group and one in the Fampridine-SR group. In the placebo group, one participant experienced a possible complex partial seizure and another experienced a combination of chest tightness and gastric reflux. Both of these events were judged by investigators, who were blinded at the time, to be possibly related to treatment. In the Fampridine-SR group, one participant had a patellar fracture, which was judged not to be treatment related. In addition, one participant treated with Fampridine-SR experienced an episode of syncope (fainting) one day after completing the treatment phase of the study. This was judged to be possibly related to treatment, but the participant was not discontinued from the trial. Follow-up assessment by the clinical investigators determined that these SAEs resolved completely with no residual effects. No deaths occurred during the study.

As of June 2, 2008, the total exposure in our MS studies to Fampridine-SR at 10mg twice a day, including both double-blind and open-label studies, is approximately 1,100 patient years. The incidence of seizures in these studies at the 10mg dose has been within the rates reported for placebo-treated groups in long-term controlled studies of immunomodulator drugs in MS patients. These rates have ranged up to two percent of patients in a two-year study, or one seizure per 100 patient years. The overall incidence of seizure appears to be dose-related.

About MS

Multiple sclerosis is a chronic, usually progressive disease in which the immune system attacks and degrades the function of nerve fibers in the brain and spinal cord. Over 400,000 Americans have MS, and someone is newly diagnosed with MS every hour in the United States. 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 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. 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 85 percent of people with MS experience some form of walking impairment. Within 15 years of an MS diagnosis, 50 percent of patients often require assistance walking and, in later stages, up to 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). 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 and manufactured by Elan Corporation plc.

Fampridine-SR and MS

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. In published studies, fampridine has been shown to block these exposed channels and help the electrical signals to pass through areas of damage.

Conference Call and Audio Webcast

Acorda will hold a conference call and audio webcast today at 8:30 a.m. ET to discuss the top-line results from the trial. To access the call, please dial 866-578-5801(domestic) or 617-213-8058 (international) and provide the access code 57594133. To access the audio webcast, please go to the Investor Relations “Calendar of Events” section of the Acorda website at www.acorda.com, or you may use the link: http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=1866966.

A replay of the call will be available from 10:30 a.m. ET on June 2, 2008 until 11:59 p.m. ET on July 2, 2008. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international), and provide the access code 37448849. An archived version of the webcast will be available for 90 days on the Acorda website in the Investor Relations section.

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 877-617-2494 , toll-free, weekdays from 10:00 a.m. to 5:00 p.m. ET.

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. Acorda’s lead clinical product, Fampridine-SR, has completed two Phase 3 clinical

trials to evaluate its safety and efficacy to improve 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 nervous system.

About Elan Drug Technologies

Elan's Drug Technologies group has developed Fampridine-SR tablets using one of its proprietary Oral Controlled Release Technologies, the MXDAS™ (MatriX Drug Absorption System) Technology. Elan Drug Technologies (EDT) is an established, profitable and growing specialty pharmaceutical business unit of Elan Corporation plc. For nearly 40 years, EDT has been applying its skills and knowledge to enhance the performance of dozens of drugs that have been marketed worldwide. EDT is focused on using its extensive experience, proprietary drug delivery technologies and licensing capabilities to develop innovative products that deliver clinically meaningful benefits to patients. More information about EDT's broad range of technologies including their Oral Controlled Release and NanoCrystal ® Technology Platforms, their patent estate and range of services is available at www.elan.com/EDT.

Acorda Therapeutics, Inc. 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 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.

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