ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 05/02/07 for the Period Ending 05/02/07

Address	420 SAW MILL RIVER ROAD
	ARDSLEY, NY 10502
Telephone	914-347-4300
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): **May 2 , 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 2, 2007, Acorda Therapeutics, Inc. issued a press release describing its presentation of data from its MS-F203 Phase 3 clinical study of Fampridine-SR in multiple sclerosis at the American Academy of Neurology Meeting. 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 May 2, 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 2, 2007 *By:* */s/ Jane Wasman*

Name: Jane Wasman
Title: Executive Vice President, General Counsel and Corporate Secretary

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated May 2, 2007

Exhibit 99.1

Contact:
Erica Wishner
Director, Corporate Communications
Cell: (914) 282-0836
ewishner@acorda.com

Media:
Sean Leous
Rooney and Associates Communications
Cell: (917) 715-3765
sleous@rooneyco.com

Acorda Therapeutics Presents Data from its Phase 3 Study of Fampridine-SR in Multiple Sclerosis at the American Academy of Neurology Meeting

Boston, MA May 2, 2007 - Acorda Therapeutics, Inc. (Nasdaq: ACOR) today presented data from a Phase 3 clinical trial of Fampridine-SR in people with multiple sclerosis (MS) at the American Academy of Neurology meeting. Andrew Goodman, M.D., Director of the Multiple Sclerosis Center at the University of Rochester, presented top-line results on walking ability, leg strength, spasticity and clinician and subject global impressions. Dr. Goodman also presented a review of safety data.

Presentation Highlights
The prospectively-designed analysis plan for the study was based on a responder criterion, defined as a consistent improvement in walking speed, as measured with the Timed 25 Foot Walk. A significantly greater proportion of people taking Fampridine-SR were Timed Walk Responders compared to people taking placebo (34.8 percent vs. 8.3 percent, $p < 0.0001$). Increased response rate with treatment was seen across all four major (relapsing and progressive) types of MS.

The mean increase in walking speed, compared to pre-treatment, for Fampridine-SR treated Timed Walk Responders was significantly greater at every visit during the treatment period, compared to both Fampridine-SR Timed Walk Non-Responders and placebo treated patients ($p < 0.0001$). The average increase in walking speed over the treatment period, compared to baseline, was 25.2 percent for the drug treated Timed Walk Responders vs. 4.7 percent for the placebo group. In follow-up visits, at two and four weeks after the end of the treatment period, Responder and Non-responder groups returned to their baseline walking speeds.

The clinical significance of the consistent response on the timed walk was validated in the trial primarily by the 12-Item Multiple Sclerosis Walking Scale (MSWS-12), a patient self-assessment of walking disability. There was a statistically significant improvement in the MSWS-12 score for walking Responders compared to Non-responders ($p < 0.001$). In addition, the mean scores on all 12 questions in the MSWS-12 were better for the Responder group than the Non-responder group.

Subject Global Impression and Clinician Global Impression scales were used as secondary validators of clinical meaningfulness. Both measures also showed statistically significant

improvement among Responders compared to Non-responders ($p = 0.0010$ and $p < 0.0001$, respectively).

Statistically significant increases in leg strength, as measured by the Lower Extremity Manual Muscle Test (LEMMT), were seen in both the drug-treated Timed Walk Responders ($p = 0.0002$) and the drug-treated Non-responders ($p = 0.046$), compared to placebo-treated patients.

In an unplanned, direct comparison of Fampridine-SR vs. placebo-treated groups, the following measures were significantly improved in the Fampridine-SR-treated group: mean change in walking speed ($p = 0.0004$), mean change in the Lower Extremity Manual Muscle Test ($p = 0.0029$), and mean change in the Ashworth score for spasticity ($p = 0.021$).

Andrew Blight, Ph.D, Chief Scientific Officer of Acorda Therapeutics, commented, “Walking impairment is one of the most pervasive and serious disabilities afflicting people with MS, and there are no currently approved therapies that are indicated to improve walking in this population. Fampridine-SR, if approved, may offer a novel treatment for improving walking ability in people with MS, one that may be complementary to currently available therapies. In this study, we also saw improvements in measures of leg strength and spasticity compared to the placebo group. In particular, even the Fampridine-SR group that did not show a consistent walking improvement still showed a statistically significant improvement in leg strength compared to the placebo group. Further clinical studies would be required to determine whether such additional improvements may be clinically significant.”

Study discontinuations due to adverse events occurred in 11 (4.8%) of the 229 Fampridine-SR-treated patients, and none of the 72 patient placebo group. Three of these events were considered serious: influenza, sepsis and anxiety. The anxiety was considered probably related to treatment. A focal seizure, observed during the sepsis, was considered possibly related to treatment. An additional 13 patients in the Fampridine-SR-treated group experienced various serious adverse events but none of these led to discontinuation from treatment and none was considered related to treatment. Most non-serious adverse events were rated as mild to moderate in intensity and observed at similar rates in Fampridine-SR and placebo groups. Some events were seen more frequently in the Fampridine-SR group (insomnia, fatigue, back pain, balance disorder) while upper respiratory infection was more common in the placebo group. Overall, the safety data were consistent with previous experience.

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 immunomodulators. Secondary endpoints for the trial included the Lower Extremity Manual Muscle Test, the Ashworth Score for spasticity, and Subject and Clinician Global Impressions. 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. The safety measures in this trial included a physical examination and vital signs at each study visit, ECG, laboratory tests, and tests of drug plasma concentration in addition to adverse event monitoring.

Key inclusion criteria for the study included the ability to complete the Timed 25 Foot Walk twice at screening with times averaging between 8 and 45 seconds, having a confirmed diagnosis of MS and having a stable condition. Key exclusion criteria included a history of seizures, having previous treatment with fampridine or having an MS exacerbation within 60 days of screening.

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.

Over time, MS tends to lead to increasing disabilities such as walking impairment, muscle weakness, problems with cognition, 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. These complications may make it harder for people to work and may interfere with their ability to perform common, daily activities.

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.

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.

Webcast
Acorda will hold a webcast this evening at 7p.m. Eastern Time. Study data will be presented and members of the Acorda management team will be available for a question and answer session. To access the webcast please log on to http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=1529938

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.

###