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 10, 2009**

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 10, 2009, Acorda Therapeutics, Inc. issued a press release indicating that data from a long-term open label extension study from the first Phase 3 Fampridine-SR trial, known as MS-F203, showed that 24.9% of extension study participants met the criteria as Extension Timed Walk Responders (ETWR) after one year of treatment and demonstrated improved walking speed over a two year period. The data were presented today at the 25 th Congress of the European Committee for Multiple Sclerosis (ECTRIMS) in Dusseldorf, Germany.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated September 10, 2009.

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 10, 2009

By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated September 10, 2009.

Exhibit 99.1

CONTACTS:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Interim Analysis of Two-Year Efficacy and Safety Data from Phase 3 Fampridine-SR Extension Study

- Retention Rate in the Open-Label Study was 82.9% After One Year and 75% After Two Years
- Sustained Walking Speed Improvement Seen After Two Years in Responder Group

HAWTHORNE, NY, September 10, 2009 — Data from a long-term open-label extension study from the first Phase 3 Fampridine-SR trial, known as MS-F203, showed that 24.9% of extension study participants with multiple sclerosis (MS) met the criteria as Extension Timed Walk Responders (ETWRs) after one year of treatment and demonstrated improved walking speed over a two year period. In addition, the safety profile of Fampridine-SR observed over two years in this study was consistent with previous placebo-controlled trials. The data were presented today at the 25 th Congress of the European Committee for Multiple Sclerosis (ECTRIMS) in Düsseldorf, Germany.

"Long-term data for Fampridine-SR are important because this medicine is potentially a chronic therapy for people with multiple sclerosis," said Andrew Goodman, M.D., Director of the Multiple Sclerosis Center at the University of Rochester, who presented the data. "The data suggest that Fampridine-SR can produce a sustained, clinically meaningful improvement in walking speed for a subset of people with MS over a two year period."

Trial Design

In the 14-week placebo-controlled portion of the MS-F203 study, 34.8% of subjects were defined as Timed Walk Responders in the Fampridine-SR group compared to 8.3% of subjects in the Placebo group. Following the placebo-controlled study, 269 of the 283 participants who completed the study, including those defined as Timed Walk Responders, Non-Responders and participants from the Placebo group, enrolled in the open-label extension study. All participants in the extension study were treated with Fampridine-SR at 10 mg twice daily, and assessed in the clinic at 2, 14, 26, 52, 78 and 104 weeks.

Timed walk response in the extension study was defined as walking faster in the majority of the first four open-label visits (2, 14, 26 and 52 weeks) compared to the fastest off-treatment speed, which was measured at seven separate time points during the placebo-controlled trial and at screening for the extension study. Walking speed was measured using the Timed 25-Foot Walk (T25FW).

As of the cut-off date for this analysis (November 30, 2008), participants had been treated with Fampridine-SR for up to 3 years, with an average exposure of 2.1 years and a total exposure of 565 patient-years. More than half of the study participants were diagnosed with secondary-

progressive MS (52.8%), with the remainder of diagnosed with relapsing-remitting MS (28.6%), primary-progressive MS (14.9%) or progressive relapsing MS (3.7%).

Safety and Efficacy Results

A total of 187 of the 269 (69.7%) subjects who enrolled in the extension trial were still enrolled at the time of the analysis, with an average exposure of 2.1 years. There were 82 discontinuations (30.5%), 29 of which were due to adverse events (10.8%). The most commonly reported adverse events in the study were: urinary tract infection (34.6%), MS relapse (31.2%), fall (29.7%), arthralgia (16.4%) and asthenia (16.0%). Over two years of treatment, 63 study participants (23.4%) experienced at least one serious adverse event. The most frequent serious adverse events were; MS relapse (4.1%), cellulitis (1.9%) and convulsion (1.1%).

There were four seizure-related events reported in the MS-F203 extension trial, including one complex partial seizure and three patients with convulsion. The incidence of seizure at 10 mg twice daily dose from a pooled analysis of all three ongoing extension studies of Fampridine-SR was 0.41 per 100 patient-years. The expected incidence of first seizure in the general MS population is approximately 0.35 (± 0.15) per 100 patient-years(1).

A total of 66 of 269 (24.9%) study participants were Extension Timed Walk Responders (ETWRs) after one year of treatment with Fampridine-SR 10 mg twice daily. ETWRs showed a mean improvement of >30% in walking speed visit after 12 months of treatment and 22% improvement at 24 months compared to their baseline speed (the average speed of their first four off-drug visits during the placebo-controlled study). Extension Timed Walk Non-Responders showed a decline in mean walking speed of 8% over 24 months. There were also statistically significant improvements in patient and clinician global impression scales for ETWRs compared to Non-Responders ($p<0.005$).

Among participants previously defined as Timed Walk Responders in the placebo-controlled trial, 42.9% met the criteria for ETWRs after one year in the extension study. In addition, 19.7% of participants defined as Timed Walk Non-Responders in the placebo-controlled trial met the criteria as ETWRs and 16.2% of subjects receiving placebo in the placebo-controlled trial met the criteria for ETWRs.

All study participants were evaluated for overall disability using the Expanded Disability Status Scale (EDSS) at the beginning of the placebo-controlled trial, and then reassessed after two years in the extension study. The mean EDSS score at baseline was 5.76, representing significant disability. After two years in the extension study, the change from EDSS baseline in ETWRs was -0.1 compared to +0.4 in non-responders ($p=0.018$). Increases in EDSS scores indicate a worsening of disability.

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 and commercialized by Acorda Therapeutics in the United States. A New Drug Application (NDA) for Fampridine-SR has been filed and assigned priority review by the U.S. Food and Drug Administration (FDA). The FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of October 22, 2009; the PDUFA date is the target date for FDA to complete its review of Fampridine-SR. In markets outside of the United States,

(1) Eriksson M, et al. Mult Scler. 2002;8:495-499.

Fampridine-SR will be developed and commercialized by Biogen Idec under a license from Acorda Therapeutics. Biogen Idec expects to file for approval by the European Medicines Agency (EMEA) in early 2010.

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. The Company's pipeline includes a number of products in development for the treatment, regeneration and repair of the spinal cord and brain.

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 Fampridine-SR, if approved, and 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. Therapeutics' ability to successfully market and sell Fampridine-SR, if approved, and 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.