ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 09/15/09 for the Period Ending 09/15/09

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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): **September 15, 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 15, 2009, Acorda Therapeutics, Inc. issued a press release indicating that data from two long-term open-label extension studies of Fampridine-SR show that 86.0% of participants remained on therapy after a maximum treatment time of 15 months in study MS-F204EXT, and 69.5% remained on therapy after a maximum treatment of 36 months in study MS-F203EXT. The average treatment time for all patients was 10 months in the MS-F204EXT study and 26 months in the MS-F203EXT study, both inclusive of dropouts. The poster presentation at the 13 th Congress of European Federation of Neurological Societies (EFNS) inadvertently reported maximum treatment times for both studies as the median treatment times. The type of adverse events reported in the two extensions were consistent with the expected adverse event profile in people with more advanced multiple sclerosis (MS) and were similar between the two studies. These extension studies followed double-blind, placebo-controlled Phase 3 studies of Fampridine-SR, MS-F203 and MS-F204, in people with MS to improve walking ability. The data were presented on Sunday, September 13 th at the 13 th Congress of the EFNS in Florence, Italy.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated September 15, 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 15, 2009

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 September 15, 2009.

Exhibit 99.1

CONTACTS:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Data on Retention Rates and Safety from Two Phase 3 Fampridine-SR Extension Studies

- Data Presented at 13th Congress of the European Federation of Neurological Societies (EFNS)

HAWTHORNE, NY, September 15, 2009 — Data from two long-term open-label extension studies of Fampridine-SR show that 86.0% of participants remained on therapy after a maximum treatment time of 15 months in study MS-F204EXT, and 69.5% remained on therapy after a maximum treatment time of 36 months in study MS-F203EXT. The average treatment time for all patients was 10 months in the MS-F204EXT study and 26 months in the MS-F203EXT study, both inclusive of dropouts. The EFNS poster presentation inadvertently reported maximum treatment times for both studies as the median treatment times. The types of adverse events reported in the two extensions studies were consistent with the expected adverse event profile in people with more advanced multiple sclerosis (MS) and were similar between the two studies. These extension studies followed double-blind, placebo-controlled Phase 3 studies of Fampridine-SR, MS-F203 and MS-F204, in people with MS to improve walking ability.

The data were presented on Sunday, September 13th at the 13th Congress of the European Federation of Neurological Societies (EFNS) in Florence, Italy. Additional safety and efficacy data from the MS-F203 extension study were presented on September 10th at the 25th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).

The cut-off date for the EFNS analysis was November 30, 2008, which was the cut-off for the analyses used in Acorda's New Drug Application (NDA) filing for Fampridine-SR earlier this year. As of this date, the approximate total exposure to Fampridine-SR was 565 patient-years in the MS-F203 extension study and 193 patient-years in the MS-F204 extension study.

In the MS-F203 extension study, there were 82 discontinuations (30.5%), 28 of which were due to adverse events (10.4%). There were 30 discontinuations (14.0%) in the MS-F204 extension study, four of which were due to adverse events (1.9%).

The most commonly reported adverse events in the MS-F203 extension study were: urinary tract infection (34.6%), MS relapse (31.2%), fall (29.7%), arthralgia (16.4%) and asthenia (16.0%). The most common adverse events in the MS-F204 extension study were: fall (26.2%), urinary tract infection (20.6%), MS relapse (18.7%), asthenia (9.3%) and balance disorder (9.3%). Serious adverse events occurred in 23.4% of participants in the MS-F203 extension study and 7.9% of participants in the MS-F204 extension study. The most frequent serious adverse event in both studies was MS relapse (4.1% in the MS-F203 extension study and 1.9% in the MS-F204 extension study).

There were four seizure-related events reported in the MS-F203 extension study at the 10 mg twice daily dose, consisting of one complex partial seizure and three patients with convulsion. There were no seizure-related events reported in the MS-F204 extension study. The incidence of seizure at the 10 mg twice daily dose from a pooled analysis of all three ongoing extension studies of Fampridine-SR, including MS-F202EXT, MS-F203EXT and MS-F204EXT, 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).

Trial Design
All participants who had completed the Phase 3 placebo-controlled trial were eligible to enroll in the extension study of their respective trial; 269 participants of the MS-F203 trial and 214 participants of the MS-F204 trial elected to enroll. All participants in the extension studies were treated with Fampridine-SR at 10 mg twice daily, including participants who received placebo during the placebo-controlled trial. Baseline demographics of the participants of both studies were similar. More than half of the study participants in the MS-F203 and MS-F204 extension studies were diagnosed with secondary-progressive MS (52.8% and 50.0% respectively), with the remainder of diagnosed with relapsing-remitting MS (28.6% and 34.6% respectively), primary-progressive MS (14.9% and 11.2% respectively) or progressive relapsing MS (3.7% and 4.2% respectively).

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, 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,

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

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.