ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 10/21/11 for the Period Ending 10/21/11

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): **October 21, 2011**

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 October 21, 2011, Acorda Therapeutics, Inc. ("Acorda") issued a press release announcing data from two new analyses of AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, presented at the 5 th Joint Triennial Congress of the European and Americas Committees for Treatment and Research in Multiple Sclerosis (ECTRIMS and ACTRIMS), being held in Amsterdam, the Netherlands. One poster presented an analysis of safety and efficacy data from open-label extension trials that included patients taking AMPYRA for up to five years; a second poster analyzed one year of post-market safety data from AMPYRA in the United States. 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	*Description*
99.1	Press Release dated October 21, 2011

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.

October 21, 2011

By: /s/ David Lawrence
Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated October 21, 2011

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Data on AMPYRA ® Presented at 5 th Joint Triennial Congress of ECTRIMS and ACTRIMS

HAWTHORNE, NY, October 21, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced data from two new analyses of AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, presented at the 5 th Joint Triennial Congress of the European and Americas Committees for Treatment and Research in Multiple Sclerosis (ECTRIMS and ACTRIMS), being held in Amsterdam, the Netherlands. One poster presented an analysis of safety and efficacy data from open-label extension trials that included patients taking AMPYRA for up to five years; a second poster analyzed one year of post-market safety data from AMPYRA in the United States. AMPYRA is known as prolonged-, modified, or sustained-release fampridine (FAMPYRA ®) in some countries outside the United States.

“Several hundred people with MS participated in AMPYRA clinical trial extension studies, and more than 50,000 people living with MS in the United States have tried AMPYRA since launch in March 2010. We are closely following patients’ experience to learn more about the long-term efficacy and safety of this medication to improve walking,” said Ron Cohen, M.D., Acorda’s president and CEO. “Analysis of walking speed data from the extension studies showed that people who responded to AMPYRA had sustained improvement compared to non-responders for up to five years on treatment. Just as importantly, safety data from the extension studies and from one year of real-world use showed that the long-term safety profile of AMPYRA was consistent with that observed in clinical trials, with no new safety signals emerging.”

The first poster presentation, entitled “Updated Analysis of Open-Label Extension Studies of Dalfampridine Extended Release Tablets in Multiple Sclerosis” (poster 566), analyzed long-term efficacy of AMPYRA in 348 patients who were classified as AMPYRA responders in one of two Phase 3 clinical trials (MS-F203 and MS-F204). A responder was defined as a person who walked faster on at least three of four on-

treatment assessments compared to the fastest of five off-treatment assessments as measured by the Timed 25-Foot Walk. In the extension trials, all participants received AMPYRA 10 mg twice daily for up to five years.

Walking speed among patients who responded to AMPYRA in the Phase 3 clinical trials remained improved throughout the duration of the extension studies when compared to non-responders.

The poster also presented safety findings from all 483 participants who enrolled in extension studies after participating in either MS-F203 or MS-F204. The tolerability profile reported in the extension studies was similar to that seen in Phase 3 placebo-controlled trials of AMPYRA, with the most common adverse events being urinary tract infection, falls, MS relapse, arthralgia, and peripheral edema. In a sub-analysis of the 348 extension study participants treated with AMPYRA in the Phase 3 trials , four seizure-related events were reported.

The second poster, entitled “Dalfampridine Extended Release Tablets: One Year of Post-Marketing Safety Experience in the United States” (poster 508), analyzed all spontaneously reported adverse events in the United States from March 1, 2010 through March 31, 2011. This analysis included more than 46,000 patients treated with AMPYRA, representing approximately 14,500 patient-years of experience.

During the first year of marketing, the most frequently reported adverse events included dizziness, insomnia, balance disorder, headache, nausea, urinary tract infection, asthenia, and back pain, which were previously observed in AMPYRA clinical trials.

There is a known risk of seizure with dalfampridine. The seizure rate of approximately 5.7/1000 patient-years observed in the post-marketing population, reflecting seizures that have been either reported or confirmed by a healthcare practitioner, was not substantially different from the rate observed in AMPYRA clinical trials.

Acorda is developing and commercializing AMPYRA in the United States. Biogen Idec has licensed the rights from Acorda to develop and commercialize FAMPYRA outside the United States. Biogen Idec presented additional clinical data on prolonged-release fampridine at the congress.

The analysis of open-label dalfampridine studies was presented by Dr. Andrew Goodman, Director of the Multiple Sclerosis Center at the University of Rochester, on behalf of the MS-F203, MS-F204 and extension study investigators, and funded by Acorda Therapeutics, Inc. The analysis of post-marketing safety data on AMPYRA was funded by Acorda Therapeutics, Inc.

Important Safety Information
AMPYRA can cause seizures; the risk of seizures increases with increasing AMPYRA doses. AMPYRA is contraindicated in patients with a prior history of seizure. Discontinue AMPYRA use if seizure occurs.

AMPYRA is contraindicated in patients with moderate or severe renal impairment (CrCl≤50 mL/min); the risk of seizures in patients with mild renal impairment (CrCl 51–80 mL/min) is unknown, but AMPYRA plasma levels in these patients may approach those seen at a dose of 15 mg twice daily, a dose that may be associated with an increased risk of seizures; estimated CrCl should be known before initiating treatment with AMPYRA.

AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

Urinary tract infections were reported more frequently as adverse reactions in patients receiving AMPYRA 10 mg twice daily compared to placebo.

The most common adverse events (incidence ≥2% and at a rate greater than the placebo rate) for AMPYRA in MS patients were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain.

For full U.S. Prescribing Information and Medication Guide for AMPYRA, please visit: www.AMPYRA.com .

About AMPYRA (dalfampridine)
AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed. AMPYRA, which was previously referred to as Fampridine-SR, is an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), and is known as prolonged-, modified, or sustained-release fampridine (FAMPYRA ®) in some countries outside the United States (U.S).

In laboratory studies, dalfampridine extended release tablets has been found to improve impulse conduction in nerve fibers in which the insulating layer, called myelin, has been damaged. AMPYRA is being developed and commercialized in the U.S. by Acorda Therapeutics; FAMPYRA is being developed and commercialized by Biogen Idec in markets outside the U.S. based on a licensing agreement with Acorda. AMPYRA and FAMPRYA are manufactured globally by Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, based on a supply agreement with Acorda.

AMPYRA is available by prescription in the United States. For more information about AMPYRA, including patient assistance and co-pay programs, healthcare professionals and people with MS can contact AMPYRA Patient Support Services at 888-881-1918.

AMPYRA Patient Support Services is available Monday through Friday, from 8:00 a.m. to 8:00 p.m. Eastern Time at 888-881-1918. For full U.S. Prescribing Information and Medication Guide, please visit: www.AMPYRA.com .

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company developing therapies for multiple sclerosis, spinal cord injury and related nervous system disorders. The Company is commercializing and marketing AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, in the United States. AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS); this was demonstrated by an improvement in walking speed. AMPYRA was developed using Alkermes' Matrix Drug Absorption System (MXDAS ®) technology and is manufactured by Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, based on a supply agreement with Acorda.

Acorda also markets 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 Acorda Therapeutics' ability to successfully market and sell Ampyra in the United States; third party payors (including governmental agencies) may not reimburse for the use of Ampyra at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of Ampyra outside of the United States and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of anticipated potential generic competition on Zanaflex Capsules revenues; failure to protect Acorda Therapeutics' intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; the ability to obtain additional financing to support Acorda Therapeutics' operations; and, unfavorable results from our research and development 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. Forward-looking statements made in this release are made only as of the date hereof, and 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.