ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
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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): **August 13, 2012**

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.)

420 Saw Mill River Road, Ardsley, NY	**10502**
(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 August 13, 2012, Acorda Therapeutics, Inc. issued a press release announcing t op line results from a post-marketing commitment study evaluating a 5mg dose of dalfampridine-ER to improve walking in people with multiple sclerosis (MS). The study failed to confirm efficacy of the 5mg dose. 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 August 13, 2012

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.

August 13, 2012

By: /s/ Andrew Blight
Name: Andrew Blight
Title: Chief Scientific Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated August 13, 2012

EXHIBIT 99.1

CONTACT:

Jeff Macdonald
Acorda Therapeutics, Inc.
(914) 326-5232
jmacdonald@acorda.com

FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Top Line Results of Post-Marketing Commitment Study Exploring 5 mg Dose of Dalfampridine-ER

ARDSLEY, N.Y. – August 13, 2012 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced top line results from a post-marketing commitment study evaluating a 5mg dose of dalfampridine-ER to improve walking in people with multiple sclerosis (MS). The study failed to confirm efficacy of the 5mg dose.

The study randomized 430 participants across three treatment arms: placebo, 5 mg or the currently marketed dose of 10 mg of dalfampridine-ER, twice daily. Baseline characteristics were measured at a single visit after randomization, following a qualifying screening visit. Study drug was then given for 4 weeks. Participants returned after 2 weeks on study drug for interim measurements (Visit 2), and again at 4 weeks (Visit 3).
The primary outcome was the change in walking speed (feet/second) on the Timed 25-Foot Walk (T25FW) test at Visit 3, measured at the time of peak plasma drug concentration, versus baseline.

Improvements in the primary outcome for the 5 mg dose (0.423 ft/sec, p=0.457) and the 10 mg dose (0.478 ft/sec, p=0.107) at Visit 3 were not statistically significant compared to placebo (0.363 ft/sec). The AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg registration studies used a consistent response analysis to allow for the variability in MS-related symptoms, including walking ability. The design of the current study required a single endpoint analysis that had not been used previously in the AMPYRA development program. In a post-hoc analysis, T25FW data were analyzed with methods similar to those used in the pivotal studies, combining all measures prior to treatment as the baseline and all measures on treatment as the on-drug value. The average change from baseline in walking speed was significantly greater for the 10 mg group compared to placebo (0.443 vs. 0.303 ft/sec, p=0.014) but not for the 5 mg group (0.366 vs. 0.303 ft/sec, p=0.292).

In addition, using a responder definition of average improvement in walking speed of at least 20% from baseline, similar to an analysis presented in the AMPYRA prescribing

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information, the 10 mg group showed significantly more responders than the placebo group (44% vs. 27%, p=0.004). The 5 mg group did not show a significant increase in response over placebo (32% vs. 27%, p=0.366).

A planned secondary outcome measure of improvement in walking, the 6-Minute Walk Test, was applied at Visit 2 in a subset of the study participants (approximately 50 randomized per treatment arm). The 10 mg dose, but not the 5 mg dose, showed a significant improvement compared to placebo (10 mg +129 ft vs. placebo +42 ft, p=0.014; 5 mg +77 ft vs. placebo +42 ft, p=0.308).

Changes in perceived effect of MS on walking-related activities, as measured by the self-reported 12-Item MS Walking Scale (MSWS-12), showed improvements for the 10 mg and 5 mg groups that were not significant compared to placebo (10 mg -11.1, p=0.286; 5 mg -9.7, p=0.866; placebo -8.4). A negative change represents reduced perceived disability.

“We believe the current study, together with the AMPYRA registration studies, continue to show that 10 mg twice daily is the appropriate, safe and effective dose. The 5mg twice daily dose of dalfampridine-ER failed to show efficacy over placebo on the primary or secondary measures. The 10 mg twice daily dose, which has consistently shown efficacy in our well-controlled clinical trials, did not meet the previously untested primary outcome measure selected for this study. We believe that this was due to increased patient variability, related to the study design. However, the 10 mg dose showed significant improvements in the 6-Minute Walk and in responder analyses of the Timed 25-Foot Walk,” said Enrique Carrazana, M.D., Acorda’s Chief Medical Officer. “We are particularly encouraged by the 6-Minute Walk result, as this marks the first time that data on AMPYRA’s effects have been assessed on this measure.”

No new safety signals were observed in this study. No seizures were reported. Two participants experienced serious adverse events in each of the 5 mg and the 10 mg treatment groups, including loss of consciousness in one patient in the 10 mg group who had discontinued dalfampridine-ER four days prior to the event. Adverse events that occurred in the combined dalfampridine-ER group at a rate of at least 2% greater than the placebo group included: urinary tract infection (8.0% vs. 5.6% placebo), nausea (7.7% vs. 3.5% placebo), dizziness (7.7% vs. 2.1% placebo), insomnia (6.3% vs. 4.2% placebo) and upper respiratory tract infection (2.8% vs. 0.7% placebo). Overall, adverse events were consistent with the U.S. Food and Drug Administration (FDA)-approved product labeling.

The study results will be provided to the FDA and presented in peer-reviewed scientific forums. The Company is continuing to analyze data from the study.

AMPYRA is currently approved by the FDA as a treatment to improve walking ability in people with MS. This was demonstrated by an increase in walking speed. The only approved dosage strength of AMPYRA is 10 mg, which is taken twice daily. As specified in the product labeling, AMPYRA tablets should not be split, crushed, chewed or

otherwise compromised, as doing will compromise the extended release properties of the tablet.

WEBCAST AND CONFERENCE CALL
Ron Cohen, President and Chief Executive Officer, Enrique Carrazana, Chief Medical Officer and Andrew Blight, Chief Scientific Officer, will host a conference call today at 8:30 a.m. ET to review the study results.

To participate in the conference call, please dial 866-730-5769 (domestic) or 857-350-1593 (international) and reference the access code 83883059. The presentation will be available via a live webcast on the Investor section of www.acorda.com.

A replay of the call will be available from 10:30 a.m. ET on August 13, 2012 until midnight on September 13, 2012. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 35919782. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at www.acorda.com.

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. The majority of seizures occurred at the recommended dose and in patients without a history of seizures, and generally within days to weeks of starting therapy. Discontinue AMPYRA use if seizure occurs.

AMPYRA is contraindicated in patients with moderate or severe renal impairment (CrCl less-than or equal to 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 and monitored at least annually during 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 greater-than or equal to 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. For full U.S. Prescribing Information and Medication Guide, please visit: www.AMPYRA.com.

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with MS, spinal cord injury and other neurological conditions.

Acorda markets AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, in the United States as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an improvement in walking speed. AMPYRA is marketed outside the United States as FAMPYRA® (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda. AMPYRA and FAMPYRA are manufactured under license from Alkermes Pharma Ireland Limited.

The Company also markets ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity. Acorda also receives sales royalties on tizanidine hydrochloride capsules, an authorized generic version of ZANAFLEX CAPSULES distributed by Watson Pharmaceutics, Inc. under its agreement with Acorda.

Acorda is developing an industry-leading pipeline of novel neurological therapies. The Company is studying AMPYRA to improve a range of functional impairments caused by MS, as well as its use in other neurological conditions, including cerebral palsy and chronic stroke. In addition, Acorda is developing clinical stage compounds AC105 for

acute treatment of spinal cord injury and GGF2 for treatment of heart failure. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and spinal cord injury. Additional preclinical programs include rHIgM22, a remyelinating monoclonal antibody for the treatment of MS, and chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury.

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 our ability to successfully market and sell Ampyra in the U.S.; third party payers (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 or from our other research and development programs, including any acquired or in-licensed programs; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of generic competition on Zanaflex Capsules revenues; failure to protect our 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; f ailure to comply with regulatory requirements could result in adverse action by regulatory agencies; and the ability to obtain additional financing to support our operations. 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 press 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.

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