ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 05/20/11 for the Period Ending 05/20/11

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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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): **May 20, 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 May 20, 2011, Acorda Therapeutics, Inc. (“Acorda”) issued a press release announcing that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) has recommended conditional marketing authorization of FAMPYRA ® (prolonged-release fampridine 10 mg tablets) for the improvement of walking in adult patients with multiple sclerosis with walking disability (Expanded Disability Status Scale of 4-7). This oral therapy was developed and is commercialized by Acorda in the United States under the trade name AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg. FAMPYRA is being developed and marketed by Biogen Idec outside the United States under a licensing agreement from Acorda. 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 May 20, 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.

May 20, 2011

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 20, 2011

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Statement on CHMP Positive Opinion on Marketing Authorization Application for FAMPYRA ® in Europe

- Recommended as Treatment to Improve Walking in Adult Patients with Multiple Sclerosis Who Have Walking Disability
- Marketing Approval in Europe Would Trigger $25 Million Payment to Acorda from Biogen Idec

HAWTHORNE, NY, May 20, 2011 – The Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) has recommended conditional marketing authorization of FAMPYRA ® (prolonged-release fampridine 10 mg tablets) for the improvement of walking in adult patients with multiple sclerosis with walking disability (Expanded Disability Status Scale of 4-7). This oral therapy was developed and is commercialized by Acorda Therapeutics, Inc. in the United States under the trade name AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg. FAMPYRA is being developed and marketed by Biogen Idec outside the United States under a licensing agreement from Acorda.

Based on the CHMP recommendation, Biogen Idec expects that a conditional marketing authorization for FAMPYRA should be granted within 67 days.

“AMPYRA is the first and only medication indicated to improve walking in people with MS, and has been shown to be effective in all major types of MS. Many thousands of people with MS have experienced improvement in their walking ability after initiating treatment with AMPYRA, and we are pleased that the CHMP decision should soon allow patients in Europe to have access to this medication,” said Ron Cohen, M.D., Acorda’s President and CEO. “We will continue working with our partner, Biogen Idec, to make this therapy available in Europe and other markets worldwide.”

In May 2011, FAMPYRA was approved for use in Australia by the Australian Therapeutic Goods Administration (ATGA).

As part of the license agreement between Acorda and Biogen Idec, European Medicines Agency (EMA) approval in Europe triggers a $25 million milestone payment to Acorda from Biogen Idec. Acorda may receive additional payments of up to $375 million based on the successful achievement of future regulatory and sales milestones. Under Acorda’s existing agreements with

Elan Pharma International Limited, a subsidiary of Elan Corporation plc, Acorda will pay Elan seven percent of the milestone payments that Acorda receives from Biogen Idec.

Acorda will also receive a double-digit royalty from Biogen Idec based on net sales of FAMPYRA in all markets outside the United States.

Under the provisions of the conditional marketing authorization for FAMPYRA, Biogen Idec will be required to provide further data to the CHMP. A conditional marketing authorization is renewable annually.

AMPYRA was approved by the U.S. Food and Drug Administration on January 22, 2010 based on safety and efficacy data from 56 clinical trials that enrolled more than 2,000 people, over 1,000 of whom were diagnosed with MS. The drug was launched commercially in the U.S. on March 1, 2010 and, as of December 2010, approximately 7,000 U.S. physicians had prescribed AMPYRA to approximately 40,000 people with MS. Acorda entered into a collaboration with Biogen Idec in June 2009 in which Biogen Idec licensed rights from Acorda to develop and commercialize fampridine in all markets outside the United States.

For more information, visit www.ampyra.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. 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), which was previously called fampridine, and remains known by that name outside the US. In laboratory studies, dalfampridine 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 United States by Acorda Therapeutics, and by Biogen Idec in markets outside the U.S. based on a licensing agreement with Acorda. AMPYRA is manufactured globally by Elan based on a supply agreement with Acorda.

AMPYRA is now 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 Unites 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 Elan’s Matrix Drug Absorption System (MXDAS ®) technology and is manufactured by Elan 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 and to successfully market Zanaflex Capsules; 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; failure to protect Acorda Therapeutics’ 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 our 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. 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.