

# ACORDA THERAPEUTICS INC

## FORM 8-K (Current report filing)

Filed 01/21/11 for the Period Ending 01/21/11

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): **January 21, 2011**

**Acorda Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-50513**  
(Commission  
File Number)

**13-3831168**  
(I.R.S. Employer  
Identification No.)

**15 Skyline Drive, Hawthorne, NY**  
(Address of principal executive offices)

**10532**  
(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))
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**Item 8.01 Other Events**

On January 21, 2011, Acorda Therapeutics, Inc. issued a Statement, posted in the “Investors” and “News & Events” sections of its corporate website ([www.acorda.com](http://www.acorda.com)), regarding the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) decision against approval of FAMPYRA<sup>®</sup> (prolonged-release fampridine 10 mg tablets) to improve walking ability in adult patients with multiple sclerosis (MS). FAMPYRA is the proposed trade name in Europe for the product commercialized in the U.S. by Acorda Therapeutics under the trade name Ampyra<sup>®</sup> (dalfampridine) Extended Release Tablets, 10 mg. A copy of the Statement is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item.

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**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Statement dated January 21, 2011

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## 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.

*January 21, 2011*

**Acorda  
Therapeutics, Inc.**

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

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Exhibit Index

Exhibit No.

Description

99.1 Statement dated January 21, 2011

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**CONTACT:**

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FOR IMMEDIATE RELEASE

**Acorda Therapeutics Statement on European CHMP Decision on FAMPYRA<sup>®</sup>**

HAWTHORNE, N.Y., January 21, 2011 – Biogen Idec (Nasdaq: BIIB) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) decided against approval of FAMPYRA<sup>®</sup> (prolonged-release fampridine 10 mg tablets) to improve walking ability in adult patients with multiple sclerosis (MS). FAMPYRA is the proposed trade name in Europe for the product commercialized in the U.S. by Acorda Therapeutics, Inc. (Nasdaq: ACOR) under the trade name AMPYRA<sup>®</sup> (dalfampridine) Extended Release Tablets, 10 mg.

Biogen Idec intends to appeal this opinion and request a re-examination of the decision by the CHMP.

"As of September 30, 2010, approximately 31,000 people with MS had received this medication in the U.S. We have been gratified by the extent of positive feedback from both physicians and people with MS about the benefits of AMPYRA," said Ron Cohen, M.D., Acorda's President and CEO. "We will work closely with Biogen Idec during the appeal process, with the goal of making this important medication available to MS patients in Europe."

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 September 30, 2010, approximately 6,300 U.S. physicians had prescribed AMPYRA to approximately 31,000 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.

**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 ( $\text{CrCl} \leq 50$  mL/min); the risk of seizures in patients with mild renal impairment ( $\text{CrCl}$  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  $\text{CrCl}$  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  $\geq 2\%$  and at a rate greater than the placebo rate) for AMPYRA in MS patients were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia,

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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](http://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](http://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<sup>®</sup> (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 Elan's Matrix Drug Absorption System (MXDAS<sup>®</sup>) technology and is manufactured by Elan based on a supply agreement with Acorda.

Acorda also markets ZANAFLEX CAPSULES<sup>®</sup> (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.

