# ACORDA THERAPEUTICS INC

## FORM 8-K
(Current report filing)

Filed 07/25/11 for the Period Ending 07/25/11

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|---|---|
| Address | 420 SAW MILL RIVER ROAD<br>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): **July 25, 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 July 25, 2011, Acorda Therapeutics, Inc. ("Acorda") issued a Statement, posted in the “Investors” and “News & Events” sections of its corporate website (www.acorda.com), regarding Biogen Idec’s announcement the same day that it has received conditional approval from the European Commission for FAMPYRA ® (prolonged-release fampridine tablets) to improve walking in adult patients with multiple sclerosis (MS) who have walking disabilities (EDSS 4-7). FAMPYRA is the trade name in Europe for the product developed and commercialized in the U.S. by Acorda 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. As part of its ex-U.S. license agreement, Biogen Idec will pay Acorda royalties based on ex-U.S. net sales, and milestones based on new indications and ex-U.S. net sales. These milestones include the current $25 million payment for successful license of the product in the European Union. 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.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

| *Exhibit No.* | *Description* |
|---|---|
| 99.1 | Statement dated July 25, 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.**

*July 25, 2011*

*By:* /s/ Jane Wasman
*Name: Jane Wasman*
*Title: Executive Vice President, General Counsel and Corporate Secretary*

**EXHIBIT INDEX**

| *Exhibit No.* | *Description* |
| --- | --- |
| 99.1 | Statement dated July 25, 2011 |


**CONTACT:**

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FOR IMMEDIATE RELEASE

**Acorda Therapeutics Statement on European Union Approval of FAMPYRA ®**

HAWTHORNE, NY, July 25, 2011 – Biogen Idec (Nasdaq: BIIB) today announced that it has received conditional approval from the European Commission for FAMPYRA ® (prolonged-release fampridine tablets) to improve walking in adult patients with multiple sclerosis (MS) who have walking disabilities (EDSS 4-7). FAMPYRA is the trade name in Europe for the product developed and commercialized in the U.S. by Acorda Therapeutics, Inc. (Nasdaq: ACOR) 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.

Biogen Idec expects FAMPYRA will be available in Europe, on a country-by-country basis, beginning in September 2011.

“Walking impairment is one of the most common and devastating aspects of MS; studies have shown that even small degrees of walking impairment can have a major negative impact on the patient. AMPYRA has been shown to improve walking ability across a wide range of impairment, from mild to severe,” said Ron Cohen, M.D., Acorda’s President and CEO. “Since its launch in the United States, AMPYRA has been prescribed for tens of thousands of people with MS. The European approval of FAMPYRA allows people with MS in the European Union to have access to this novel and important medication. We will continue to work with our partner Biogen Idec to make dalfampridine available in other markets around the world.”

As part of their ex-US license agreement, Biogen will pay Acorda royalties based on ex-US net sales, and milestones based on new indications and ex-US net sales. These milestones include the current $25 million payment for successful license of the product in the European Union.

AMPYRA is being developed and marketed in the United States by Acorda Therapeutics, Inc. It was approved by the U.S. Food and Drug Administration (FDA) on January 22, 2010 as a treatment to improve walking in people with MS. This was demonstrated by an increase in walking speed. The FDA approval was 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.

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 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, 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 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.