

ACORDA THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 08/10/11 for the Period Ending 08/10/11

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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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): **August 10, 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 August 10, 2011, Acorda Therapeutics, Inc. (“Acorda”) issued a Press Release announcing that the United States Patent and Trademark Office (USPTO) has allowed U.S. Patent Application No. 11/102,559 entitled “Method of Using Sustained Release Aminopyridine Compositions.” The claims of the patent application relate to methods to improve walking, walking speed, lower extremity muscle tone and lower extremity muscle strength in patients with multiple sclerosis (MS) by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent application is separate from the AMPYRA[®] method of use patent application which was allowed by the USPTO in April 2011. 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

<i>Exhibit No.</i>	<i>Description</i>
99.1	Press Release dated August 10, 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.

August 10, 2011

Acorda Therapeutics, Inc.

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

EXHIBIT INDEX

<i>Exhibit No.</i>	<i>Description</i>
99.1	Press Release dated August 10, 2011

**CONTACT:**

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Allowance of Second U.S. Patent Application for AMPYRA[®] Covering Methods of Use for Improving Walking in Multiple Sclerosis

HAWTHORNE, NY, August 10, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the United States Patent and Trademark Office (USPTO) has allowed U.S. Patent Application No. 11/102,559 entitled “Method of Using Sustained Release Aminopyridine Compositions.” The claims of the patent application relate to methods to improve walking, walking speed, lower extremity muscle tone and lower extremity muscle strength in patients with multiple sclerosis (MS) by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent application is separate from the AMPYRA[®] method of use patent application which was allowed by the USPTO in April 2011.

“The allowance of this patent application further strengthens our patent protection for AMPRYA and enhances our ability to continue exploring potential new uses and indications, both in MS and other diseases,” said Ron Cohen, M.D., President and CEO of Acorda Therapeutics. “The discoveries we made during our development of AMPYRA, several of which are reflected in this patent, were critical to receiving FDA approval and making this therapy available to people with MS who have walking impairment. We are pleased that the UPTO has recognized these findings as innovative and valuable contributions to medicine.”

The patent issuing from Application No. 11/102,559 is currently set to expire in April 2025, but is also eligible for patent term adjustment, to be determined by the USPTO based on the prosecution history. This patent is eligible for listing in the U.S. Food and Drug Administration (FDA) Orange Book.

Sustained release 4-aminopyridine is marketed in the United States under the trade name AMPRYA[®] (dalfampridine) Extended Release Tablets, 10 mg. AMPYRA is an oral medication approved by the FDA as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

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 ($\text{CrCl} \leq 50 \text{ mL/min}$); the risk of seizures in patients with mild renal impairment ($\text{CrCl} 51\text{--}80 \text{ mL/min}$) 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 $\geq 2\%$ and at a rate greater than the placebo rate) for AMPYRA in MS patients were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, 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 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®) 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 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.

