ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 10/16/12 for the Period Ending 10/16/12

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): **October 16, 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 October 16, 2012, Acorda Therapeutics, Inc. ("Acorda") issued a press release announcing that the U.S. Patent and Trademark Office (USPTO) has determined that U.S. Patent No. 5,540,938 ("the '938 patent") is entitled to a full five year patent term extension under the patent restoration provisions of the Hatch Waxman Act. The claims of the '938 patent relate to methods for treating a neurological disease, such as multiple sclerosis (MS), and cover the use of a sustained release dalfampridine formulation, such as AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg for improving walking in people with MS. With a five year patent term extension, the '938 patent would expire in 2018. Acorda also has a granted U.S. patent and an allowed U.S. patent application covering the use of AMPYRA in improving walking in people with MS. The granted U.S. patent will expire in 2027, and the allowed U.S. patent application, once granted, is expected to expire in 2025 plus any additional term determined by the USPTO based on patent term adjustment provisions. 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 October 16, 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.

October 16, 2012

By: David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated October 16, 2012

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Hatch-Waxman Extension of AMPYRA ® (dalfampridine) Sustained-Release Formulation Patent

ARDSLEY, N.Y. – October 16, 2012 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the U.S. Patent and Trademark Office (USPTO) has determined that U.S. Patent No. 5,540,938 ("the '938 patent") is entitled to a full five year patent term extension under the patent restoration provisions of the Hatch Waxman Act. The claims of the '938 patent relate to methods for treating a neurological disease, such as multiple sclerosis (MS), and cover the use of a sustained release dalfampridine formulation, such as AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg for improving walking in people with MS. With a five year patent term extension, the '938 patent would expire in 2018.

Acorda also has a granted U.S. patent and an allowed U.S. patent application covering the use of AMPYRA in improving walking in people with MS. The granted U.S. patent will expire in 2027, and the allowed U.S. patent application, once granted, is expected to expire in 2025 plus any additional term determined by the USPTO based on patent term adjustment provisions.

AMPYRA is approved by the U.S. Food and Drug Administration (FDA) as a treatment to improve walking in patients with MS. This was demonstrated by an improvement in walking speed.

Important Safety Information
Do not take AMPYRA if you have ever had a seizure or have certain types of kidney problems.

Take AMPYRA exactly as prescribed by your doctor.

You could have a seizure even if you never had a seizure before. Your chance of having a seizure is higher if you take too much AMPYRA or if your kidneys have a mild decrease of function, which is common after age 50.

Your doctor may do a blood test to check how well your kidneys are working, if that is not known before you start taking AMPYRA.

AMPYRA may cause serious allergic reactions, including rare occurrence of anaphylaxis.

AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

The most common adverse events for AMPYRA in MS patients were urinary tract infection, trouble sleeping, dizziness, headache, nausea, weakness, back pain, and problems with balance.

Before taking AMPYRA tell your doctor if you are pregnant or plan to become pregnant. It is not known if AMPYRA will harm your unborn baby.

Tell your doctor if you are breast-feeding or plan to breast-feed. It is not known if AMPYRA passes into your breast milk. You and your doctor should decide if you will take AMPYRA or breast-feed. You should not do both.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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 post-stroke deficits. 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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