

ACORDA THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 05/20/13 for the Period Ending 05/20/13

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| 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): **May 20, 2013**

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.)

**420 Saw Mill River Road,
Ardsley, NY**
(Address of principal executive offices)

10502
(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 May 20, 2013, Acorda Therapeutics, Inc. issued a press release announcing that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent Application No. 8,440,703 (“the ‘703 patent”) entitled “Methods of Using Sustained Release Aminopyridine Compositions.” The ‘703 patent includes claims directed to methods of improving lower extremity function and walking and increasing walking speed in patients with multiple sclerosis (MS) by administering less than 15 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. The ‘703 patent is set to expire in 2025. This patent is eligible for listing in the U.S. Food and Drug Administration (FDA) Orange Book. The ‘703 patent is separate from the two AMPYRA method of use patents issued by the USPTO in 2011 and 2013 that are set to expire in 2027 and 2026, respectively. 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, 2013

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, 2013

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

EXHIBIT INDEX

Exhibit No.

Description

99.1

Press Release dated May 20, 2013

**CONTACT:**

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Acorda Therapeutics
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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Issuance of Additional U.S. Patent for AMPYRA[®] Covering a Range of Dosage Strengths

ARDSLEY, NY, May 20, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent Application No. 8,440,703 (“the ‘703 patent”) entitled “Methods of Using Sustained Release Aminopyridine Compositions.” The ‘703 patent includes claims directed to methods of improving lower extremity function and walking and increasing walking speed in patients with multiple sclerosis (MS) by administering less than 15 mg of sustained release 4-aminopyridine (dalfampridine) twice daily.

The ‘703 patent is set to expire in 2025. This patent is eligible for listing in the U.S. Food and Drug Administration (FDA) Orange Book.

The ‘703 patent is separate from the two AMPYRA method of use patents issued by the USPTO in 2011 and 2013 that are set to expire in 2027 and 2026, respectively.

AMPYRA is approved 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 known as prolonged-, modified-, or sustained-release fampridine (FAMPYRA[®]) in some countries outside the United States.

Important New Safety Information

Do not take AMPYRA if you are allergic to dalfampridine (4-aminopyridine), the active ingredient in AMPYRA.

Important Safety Information

Do not take AMPYRA if you have ever had a seizure, or have certain types of kidney problems, or are allergic to dalfampridine (4-aminopyridine), the active ingredient in AMPYRA.

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. Stop taking Ampyra and call your doctor right away or get emergency medical help if you have shortness of breath or trouble breathing, swelling of your throat or tongue, or hives.

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 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 Actavis, Inc. under its agreement with Acorda.

Acorda has one of the leading pipelines in the industry of novel neurological therapies. The Company is developing Diazepam Nasal Spray for treatment of certain epileptic seizures. It is also studying AMPYRA to improve a range of functional impairments caused by MS, as well as its potential for 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, GGF2 for treatment of heart failure and rHlgM22, a remyelinating monoclonal antibody, for the treatment of MS. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and peripheral nerve damage. Chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury, is in preclinical development.

Acorda 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 or our other products 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 Diazepam Nasal Spray or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market Diazepam Nasal Spray or other products under development; 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; failure 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 & Exchange Commission. Acorda 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 disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this release.

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