ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 12/19/13 for the Period Ending 12/19/13

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): **December 19, 2013**

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 (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))

Item 8.01 Other Events

On December 19, 2013, Acorda Therapeutics, Inc. issued a press release announcing that the European Patent Office (EPO) Opposition Division has upheld amended claims covering a sustained release formulation of fampridine (known under the trade name FAMPYRA®), also known as dalfampridine or 4-aminopyridine, for increasing walking speed in patients with MS through twice daily dosing at 10 mg. The decision of the Opposition Division is open to appeal. 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 December 19, 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.

December 19, 2013

By: /s/Jane Wasman
Name: Jane Wasman
Title: President, International, General Counsel and Corporate Secretary

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated December 19, 2013

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces European Patent Office Upholds Fampridine (FAMPYRA ®) Patent
European Patent Office Upholds Fampridine (FAMPYRA ®) Patent

ARDSLEY, N.Y. – December 19, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the European Patent Office (EPO) Opposition Division has upheld amended claims covering a sustained release formulation of fampridine (known under the trade name FAMPYRA ®), also known as dalfampridine or 4-aminopyridine, for increasing walking speed in patients with MS through twice daily dosing at 10 mg. The decision of the Opposition Division is open to appeal.

"We are pleased that the Opposition Division has recognized the validity of our patent claims for FAMPYRA," said Ron Cohen, M.D., Acorda's President and CEO.

This European patent (EP-1 732 548 B) is set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. In addition, FAMPYRA received 10-year market exclusivity upon approval by the European Commission that is set to expire in 2021.

FAMPYRA is exclusively developed and commercialized outside the United States by Biogen Idec under a collaboration and licensing agreement with Acorda. FAMPYRA is indicated in the European Union for the improvement of walking in adult patients with multiple sclerosis (MS) with walking disability (EDSS 4-7).

FAMPYRA is the ex-U.S. trade name for AMPYRA ® (dalfampridine) Extended Release Tablets, 10mg, which is being developed and marketed in the United States by Acorda. AMPYRA is an oral medication approved by the U.S. Food and Drug Administration as a treatment to improve walking in patients with MS. This was demonstrated by an increase in walking speed.

In the United States, AMPYRA is covered by multiple patents providing coverage through 2027. In addition, AMPYRA has Orphan drug status providing market exclusivity through January 22, 2017.

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. 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 FAMPYRA
FAMPYRA ® is a prolonged-release (sustained release) tablet formulation of the drug fampridine (4-aminopyridine, 4-AP or dalfampridine). FAMPYRA is indicated in the European Union for the improvement of walking in adult patients with multiple sclerosis (MS) with walking disability (EDSS 4-7). In clinical trials the highest incidence of adverse reactions identified with FAMPYRA given at the recommended dose was urinary tract infection, although infection was often not proven by culture. Other adverse drug reactions identified were mainly divided between neurological disorders, such as insomnia, balance disorder, dizziness, paraesthesia, headache and gastrointestinal disorders including nausea, dyspepsia and constipation. In post-marketing experience, there have been reports of seizure. Confounding factors may have contributed to the occurrence of seizure in some patients.

For more information about FAMPYRA, please visit www.biogenidec.com

About Acorda Therapeutics
Founded in 1995, Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with neurological conditions.

Acorda markets three FDA-approved therapies including: AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in patients with multiple sclerosis (MS); ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity; and Qutenza ® (capsaicin) 8% Patch, for the management of neuropathic pain associated with postherpetic neuralgia. AMPYRA is marketed outside the

United States as FAMPYRA ® (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda.

Acorda has one of the leading pipelines in the industry of novel neurological therapies. The Company is currently developing six clinical-stage therapies and one preclinical stage therapy that address a range of disorders including post-stroke deficits, epilepsy, stroke, peripheral nerve damage, spinal cord injury, neuropathic pain, and heart failure. For more information, please visit the Company's website at: www.acorda.com.

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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