ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
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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 10, 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 10, 2012, Acorda Therapeutics, Inc. issued a press release announcing safety data from more than 62,400 people with multiple sclerosis (MS) taking AMPYRA (dalfampridine) Extended Release Tablets, 10 mg during the first two years of availability in the United States. The data showed that the safety profile of AMPYRA is similar to that observed in clinical trials. This analysis was presented at the 28 th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), being held in Lyon, France from October 10-13. AMPYRA is known as prolonged-, modified, or sustained-release fampridine (FAMPYRA ®) in some countries outside the United States. 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 10, 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 10, 2012

By: David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated October 10, 2012

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

AMPYRA ® Two-Year Safety Data Presented at 28 th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS)

- Two-year data from more than 62,400 people with multiple sclerosis highlight AMPYRA safety profile

ARDSLEY, N.Y. – October 10, 2012 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced safety data from more than 62,400 people with multiple sclerosis (MS) taking AMPYRA (dalfampridine) Extended Release Tablets, 10 mg during the first two years of availability in the United States. The data showed that the safety profile of AMPYRA is similar to that observed in clinical trials.

This analysis was presented at the 28 th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), being held in Lyon, France from October 10-13. AMPYRA is known as prolonged-, modified, or sustained-release fampridine (FAMPYRA ®) in some countries outside the United States.

The analysis examined all post-marketing adverse events (AEs) that were reported to Acorda and the U.S. Food and Drug Administration (FDA) from March 2010 through March 2012. As is typical in post-marking data collection, there is a potential for underreporting of AEs. Key findings included:

- Among the 62,400 patients who were prescribed AMPYRA during the first two years following FDA approval, 160 seizures were reported, or approximately 4.6 per 1000 patient-years of use. This rate is comparable to the rate of seizure seen in the overall MS population. Length of treatment prior to a seizure ranged from first dose to two years, with 20% of the seizures occurring within a week of starting treatment. Because of their disease, people with MS are at a higher risk of seizure than people who do not have MS.

- The most frequently reported AEs from March 2010 through March 2012 were dizziness, insomnia, balance disorder, headache, nausea, urinary tract infection,

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back pain, and asthenia. These are similar to the AEs most frequently reported during AMPYRA clinical trials.

“AMPYRA has been available for over two years in the United States, providing us with safety data from real-world use by people with MS. These data showed that the safety profile of AMPYRA in clinical practice is consistent with what was observed in clinical trials,” said Enrique Carrazana, M.D., Acorda Therapeutics’ Chief Medical Officer. “The data also indicate the rate of seizure has remained consistent over time, and is within the range that is expected in the overall MS population.”

This poster presentation was sponsored by Acorda Therapeutics, Inc. In markets outside of the United States, AMPYRA is available as FAMPYRA. FAMPYRA is being developed and commercialized by Biogen Idec in these markets based on a licensing agreement with Acorda.

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 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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