ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 09/25/13 for the Period Ending 09/25/13

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
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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): **September 25, 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	**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 September 25, 2013, Acorda Therapeutics, Inc. issued a press release announcing that the first patient has been enrolled in a trial of AC105 , its proprietary magnesium formulation for the treatment of spinal cord injury (SCI). This Phase 2 trial will evaluate the safety and tolerability of the drug in people with traumatic SCI, and also incorporates several exploratory efficacy measures. 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 September 25, 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.

September 25, 2013

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated September 25, 2013

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Initiation of Phase 2 Trial of Treatment for Spinal Cord Injury

AC105 improved motor function after spinal cord injury in preclinical studies

ARDSLEY, N.Y. -- September 25, 2013 -- Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the first patient has been enrolled in a trial of AC105, its proprietary magnesium formulation for the treatment of spinal cord injury (SCI). This Phase 2 trial will evaluate the safety and tolerability of the drug in people with traumatic SCI, and also incorporates several exploratory efficacy measures.

“In preclinical studies, AC105 improved motor function in SCI when therapy was initiated within a few hours after injury,” said Andrew R. Blight, Ph.D., Acorda Therapeutics’ Chief Scientific Officer. “Spinal cord injuries often result in severe, lifelong disability, so we’re excited to explore the potential to improve outcomes for people who suffer these very serious injuries.”

Magnesium’s neuroprotective properties are well established in the laboratory; however, the tolerable dosage range in the clinic is relatively narrow, which has made it a challenge to develop a practical therapy. Preclinical research shows that AC105’s formulation helps deliver magnesium to the injury site within the CNS, thereby providing a protective effect, but without requiring higher levels in the blood, which might result in significant side effects.

The primary objective of this double-blind, randomized and placebo controlled study is to evaluate the safety and tolerability of AC105 in people who have suffered an SCI. The study also includes several exploratory efficacy measures, including standard scales used to assess motor function. Participants in the trial will receive six intravenous doses of AC105 or placebo over 30 hours; the first dose to be administered within 12 hours of the injury.

The U.S. Food and Drug Administration (FDA) granted Fast Track designation for AC105 to improve functional recovery following acute SCI. The Company received a

$2.67 million research contract from the U.S. Army Medical Research and Material Command to support the study. Acorda may potentially expand its AC105 program into other neurological injury indications.

Additional details on this clinical study, including enrollment criteria, can be found at: http://www.clinicaltrials.gov/ct2/show/NCT01750684

About Spinal Cord Injury

Spinal cord injury (SCI) is usually caused by trauma, such as a motor vehicle accident, fall or sports injury. According to the National Spinal Cord Injury Statistical Center (NSCISC), there are between 183,000 and 230,000 people in the United States, and approximately 2 million people worldwide living with a spinal cord injury. Each year, there are approximately 11,000 new injuries reported in the United States. Males account for the majority of spinal cord injury patients with 50-70% of those occurring in those aged 15-35.

The costs of living with SCI can be considerable and can vary greatly due to the severity of injury. Long-term complications from SCI can include neurologic impairments resulting in paralysis, loss of sensation and disruption of any body system controlled by nerves originating at or below the area of the injury. Average annual medical cost for an SCI patient is $15,000-30,000 per year and the annual direct and indirect costs of SCI are estimated at $9.7 billion in the U.S. alone. There are currently no FDA-approved therapies indicated to treat, mitigate, or reverse SCI.

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, cerebral palsy, 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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