ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 01/24/13 for the Period Ending 01/24/13

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): **January 24, 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 January 24, 2013, Acorda Therapeutics, Inc. ("Acorda") issued a press release announcing that that the U.S. Army Medical Research and Material Command (USAMRMC) has awarded Acorda a $2.67 million research contract to support development of AC105, a propriety magnesium formulation being studied as a treatment for acute spinal cord injury (SCI). The contract will help support a Phase 2 clinical trial designed primarily to assess the safety and tolerability of AC105 in people with acute SCI. Acorda plans to open enrollment for this study in the first half of 2013. 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 January 24, 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.

January 24, 2013

By: David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated January 24, 2013

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Department of Defense Contract to Support Study of AC105 in Acute Spinal Cord Injury

ARDSLEY, N.Y. – January 24, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the U.S. Army Medical Research and Material Command (USAMRMC) has awarded the Company a $2.67 million research contract to support development of AC105, a propriety magnesium formulation being studied as a treatment for acute spinal cord injury (SCI).

The contract will help support a Phase 2 clinical trial designed primarily to assess the safety and tolerability of AC105 in people with acute SCI. The Company plans to open enrollment for this study in the first half of 2013.

“Spinal cord injuries often result in severe, lifelong disability, and primarily occur in young people. This leads to long-term care and quality of life issues for the person with the injury, as well as for their family and the healthcare system as a whole," said Anthony Caggiano, M.D., Ph.D., Acorda’s Vice President of Research and Development. “We are pleased to be collaborating with the U.S. Army on this project to determine if AC105 can improve outcomes in SCI. It is also a privilege for us to be working on a therapy that may help those who have been injured in the line of duty.”

In preclinical studies, AC105 demonstrated neuroprotective properties and improvement of locomotor function in SCI when therapy was initiated within several hours of injury. The U.S. Food and Drug Administration (FDA) granted Fast Track designation for AC105 to improve functional recovery of acute SCI patients. Acorda expects to apply for FDA orphan drug designation for the acute treatment of SCI and will explore orphan drug designations in Europe and in other parts of the world.

About Spinal Cord Injury (SCI)
Spinal cord injury (SCI) refers to any injury to the spinal cord that is 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 approximately 270,000 people in the United States living with a spinal cord injury. Each year, there are approximately 12,000 new injuries reported in the United States, the majority of which are males. Spinal cord injuries primarily affect young people, with 50-70% occurring in those aged 15-35.

The costs of living with SCI can be considerable and can vary greatly with the severity of injury. Long-term complications from SCI can include neurologic impairments in any body system controlled by the affected nerves. Average annual medical cost for an SCI patient ranges from $40,000-$178,000 depending on the extent of the injury. There are currently no FDA-approved therapies indicated to treat, mitigate, or reverse SCI.

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 has an industry-leading pipeline 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 rHIgM22, 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 spinal cord injury. Chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury, is in preclinical development.

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 (“DZNS”) or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory

approval for, or successfully market DZNS 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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