ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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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): **March 7, 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 March 7, 2013, Acorda Therapeutics, Inc. ("Acorda") and its collaborator Vanderbilt University Medical Center issued a press release announcing data from a Phase 1 clinical trial of Glial Growth Factor 2 (GGF2) designed to study safety, tolerability and exploratory measures of efficacy in people with heart failure who were already on optimized regimens of currently available therapies. The study evaluated the effects of a range of doses, with each participant receiving a single dose. Data from this trial, which enrolled patients at Vanderbilt and St. Joseph's Hospital in Atlanta, GA, are being presented on Sunday, March 10 at the American College of Cardiology 62 nd Annual Scientific Session in San Francisco, CA. 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 March 7, 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.

March 7, 2013

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated March 7, 2013

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FOR IMMEDIATE RELEASE

Data from First Clinical Trial of GGF2 in Heart Failure Presented at the American College of Cardiology 62 nd Annual Scientific Session

- Study Identifies a Maximum Tolerated Dose of GGF2
- Preliminary Efficacy Measures Show GGF2 Improves Heart Function

ARDSLEY, NY and NASHVILLE, TN – March 7, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) and collaborator Vanderbilt University Medical Center today announced data from a Phase 1 clinical trial of Glial Growth Factor 2 (GGF2) designed to study safety, tolerability and exploratory measures of efficacy in people with heart failure who were already on optimized regimens of currently available therapies. The study evaluated the effects of a range of doses, with each participant receiving a single dose. Data from this trial, which enrolled patients at Vanderbilt and St. Joseph's Hospital in Atlanta, GA, are being presented on Sunday, March 10 at the American College of Cardiology 62 nd Annual Scientific Session in San Francisco, CA.

"We have completed the first in human trial with GGF2 in patients with heart failure, and especially want to thank our patients who volunteered for this important study. We are very encouraged by the results," said Daniel Lenihan, M.D., Professor of Medicine and Director, Clinical Research at the Vanderbilt University Medical Center, Division of Cardiovascular Medicine. "It is notable that trends of long-lasting and dose-related improvement in cardiac function were seen following a single dose in patients who were already optimized on standard therapies. GGF2 warrants further investigation as a treatment for heart failure."

"Preclinical studies have suggested that GGF2 may improve heart function through direct repair of cardiac muscle, a novel mechanism of action. This first clinical trial in patients with heart failure identified a maximally tolerated GGF2 dose and key safety parameters to be monitored in future studies. This information supports continued development of the compound as a potential treatment for heart failure," said Anthony Caggiano, M.D., Ph.D., Vice President of Research and Development at Acorda.

This was a double-blind, placebo controlled, escalating single dose clinical trial that included 40 patients with advanced heart failure. Safety and exploratory efficacy were monitored for 90 days in patients randomized to receive various doses of GGF2 or placebo.

Safety Findings
In this study, a single dose of GGF2 in patients with heart failure was generally well tolerated up to 0.75 mg/kg. Among participants receiving GGF2, the most commonly observed adverse events were headache, site injection reaction and gastrointestinal symptoms. There were no notable effects of treatment on hematology or electrocardiogram, and no adverse events led to withdrawal from the study.

A dose-limiting adverse event of hepatotoxicity (liver injury) meeting Hy's Law criteria (elevated ALT, AST and bilirubin) occurred in the highest-dose cohort. The patient's liver function tests and bilirubin had returned to normal by two weeks after dosing . There was also one reported case of uroepithelial carcinoma, a form of cancer in the cells that line the bladder, which was diagnosed three months after dosing in the highest-dose cohort. The patient's baseline urinalysis showed the presence of red blood cells, indicating that the tumor was likely present prior to dosing.

Ejection Fraction Findings
A left ventricle ejection fraction of 55% or higher is considered normal; all participants in the Phase 1 GGF2 trial had left ventricle ejection fraction of less than 40%. Trial participants receiving GGF2 showed a consistent and dose-responsive trend towards improving left ventricular ejection fraction over 28 and 90 days compared to placebo.

Mean ejection fractions at screening in the treatment and placebo groups were 27% and 29%, respectively. For the cohort receiving the maximally tolerated dose (0.75 mg/kg) of GGF2, the mean ejection fraction at screening was 28% and the absolute mean changes in ejection fraction at day 8, day 14, day 28, and day 90 were 5%, 12%, 12.0% and 9.0%, compared to absolute mean changes of -1%, -1%, 0% and 2% for the placebo group; thus, the mean ejection fraction for this GGF2 group at day 28 was 40%, versus 29% for placebo.

Acorda has discussed the findings from this initial study with the U.S. Food and Drug Administration (FDA) and has reached agreement on the next clinical study of GGF2 in heart failure. This study will primarily investigate further the safety profile of GGF2 across a range of doses, and will continue to explore efficacy outcomes.

The FDA has granted Fast Track designation for GGF2 for the treatment of heart failure.

About GGF2
GGF2 is the leading development candidate from Acorda's neuregulin program. Neuregulins are a class of naturally occurring protein growth factors that have multiple effects on the nervous and cardiovascular systems.

Preclinical studies demonstrate that GGF2 acts directly to repair cardiac muscle and improve its contractile function. No currently available therapies do this, and GGF2 may therefore offer an important new treatment option for people with heart failure.

In addition to its clinical program in heart failure, the Company also has preclinical development programs for GGF2 in a number of neurological indications, including peripheral nerve injury and stroke.

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 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.

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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