ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 10/08/13 for the Period Ending 10/08/13

Address	420 SAW MILL RIVER ROAD
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Telephone	914-347-4300
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Industry	Biotechnology & Drugs
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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 8, 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 October 8, 2013, Acorda Therapeutics, Inc. issued a press release announcing that the first patient has been enrolled in the second clinical trial of Glial Growth Factor 2 (GGF2). This Phase 1b single-infusion trial in people with heart failure will assess tolerability of three dose levels of GGF2, and also includes several explorative measures of efficacy. 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 8, 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.

October 8, 2013

By: /s/ David Lawrence
Name: David Lawrence
Title: Chief of Business Operations

EXHIBIT INDEX

Exhibit No .	*Description*
99.1	Press Release dated October 8, 2013

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Initiation of Second Phase 1 GGF2 Clinical Trial in Heart Failure

ARDSLEY, N.Y. – October 8, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the first patient has been enrolled in the second clinical trial of Glial Growth Factor 2 (GGF2). This Phase 1b single-infusion trial in people with heart failure will assess tolerability of three dose levels of GGF2, and also includes several explorative measures of efficacy.

"The first clinical trial with GGF2 in people with heart failure provided initial data on tolerability and activity of a single infusion over a wide range of doses. That study also supported observations in preclinical models that GGF2 improved heart function as measured by ejection fraction," said Anthony Caggiano, M.D. Ph.D., Vice President of Research and Development at Acorda. "This second trial will employ a narrower range of single infusion doses to assess safety, various measures of efficacy, including changes in ejection fraction and cardiovascular endurance, and whether there is evidence of interaction with other medications commonly used in heart failure."

Additional details on the study design and site locations can be found at: http://clinicaltrials.gov/ct2/show/NCT01944683?term=ggf2&rank=1.

Results of the first Phase 1 GGF2 clinical trial were presented earlier this year at the American College of Cardiology 62 nd Annual Scientific Session. The trial design included seven cohorts of six participants each, four of whom received GGF2 and two of whom received placebo at each dose. In the study, a single infusion of GGF2 in patients with heart failure was generally well tolerated up to dose levels of 0.75 mg/kg. Among trial participants who received GGF2, the most commonly observed adverse events were headache, site injection reaction and gastrointestinal symptoms. A dose limiting toxicity (DLT) was identified in a single subject receiving the highest planned dose level of 1.5 mg/kg. This DLT was characterized by transient elevations in liver enzymes and bilirubin which met the Hy's Law definition for drug induced liver injury. No liver enzyme elevations were seen below the 1.5 mg/kg dose in this study. Trial participants who received a single GGF2 infusion showed a consistent dose-dependent improvement in left ventricular ejection fraction at 28 and 90 days after the infusion as compared to participants who received a placebo infusion. These cardiodynamic results and the safety findings were reviewed

with the U.S. Food and Drug Administration (FDA), and the current trial was designed to further define safe dose level ranges while exploring efficacy measures and potential drug interactions.

GGF2, which is part of a family of proteins known as neuregulins, has been shown to be pharmacologically active in a number of preclinical models of cardiovascular and neurological conditions. GGF2 acts directly on heart muscle cells, or cardiomyocytes. GGF2 may offer a unique treatment strategy as it is believed to improve the heart's ability to contract by promoting the repair of damaged heart muscle and improving its contractile function.

About Heart Failure
Heart failure is a chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body's need for oxygen. Heart failure is most commonly the result of damage to the heart caused by coronary artery disease or from added stress to the heart from other health conditions, such as diabetes or high blood pressure.

The United States Centers for Disease Control and Prevention (CDC) estimates that approximately 5.8 million Americans have heart failure, and roughly 670,000 are newly diagnosed each year.

Common symptoms of heart failure include shortness of breath (dyspnea), persistent coughing or wheezing, build up of excessive fluid in body tissue that may cause swelling of the feet, ankles, legs and abdomen (edema), and fatigue. Healthcare professionals typically classify heart failure based on the severity of symptoms and how those symptoms limit physical activity. Heart failure can range from no symptoms and no limitations on ordinary physical activity (Class 1) through severe physical limitations with patients experiencing symptoms even while at rest (Class 4).

About GGF2
GGF2 may offer a unique heart failure therapeutic option, as existing medications aim to compensate for the heart's diminished blood pumping ability, but do not directly restore heart muscle function. GGF2 acts at the level of the muscle cells, or cardiomyocytes, and is believed to improve the heart's ability to contract by restoring cardiomyocyte functions that are impaired in heart failure. In preclinical studies, GGF2 improved contractile function. It may also protect the heart structure from acute and chronic stressors.

GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and peripheral nerve damage.

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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