ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 12/09/10 for the Period Ending 12/09/10

Address	420 SAW MILL RIVER ROAD
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Telephone	914-347-4300
CIK	0001008848
Symbol	ACOR
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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): **December 9, 2010**

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.)

15 Skyline Drive, Hawthorne, NY	**10532**
(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 December 9, 2010, Acorda Therapeutics, Inc. issued a press release announcing that the first patient has been enrolled in the first clinical trial of Glial Growth Factor 2 (GGF2). Acorda is collaborating with the Vanderbilt University Heart and Vascular Institute to conduct this Phase 1 single-dose trial in patients with heart failure . 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 December 9, 2010

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.

December 9, 2010

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated December 9, 2010

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

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

HAWTHORNE, NY, December 9, 2010 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the first patient has been enrolled in the first clinical trial of Glial Growth Factor 2 (GGF2). Acorda is collaborating with the Vanderbilt University Heart and Vascular Institute to conduct this Phase 1 single-dose trial in patients with heart failure.

“In preclinical models, GGF2 restored the integrity of heart muscle and improved function, which represents a novel approach to treat heart failure,” said Anthony Caggiano, M.D. Ph.D., Vice President of Research and Development at Acorda. “This first clinical trial in patients with heart failure is an important step to assess the safety of GGF2 in humans and will inform the design of potential future trials.”

The primary objective of this double-blind, randomized study is to evaluate the safety and tolerability of GGF2 in patients with heart failure. In this trial, participants will receive either placebo or a low dose of GGF2 administered as a single intravenous infusion. If GGF2 is well tolerated, subsequent groups will receive single infusions of higher doses.

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. It is believed to improve the heart's ability to contract by promoting the repair of tissue damage that results from heart disease or injury. GGF2 may offer a unique treatment strategy as preclinical studies demonstrate that GGF2 acts directly to repair cardiac muscle and improve its contractile function.

About Heart Failure
Heart failure is a chronic, progressive condition in which the heart muscle is unable to pump enough blood through the heart to meet the body's need for blood and oxygen. Heart failure results from damage to heart, caused by trauma such as heart attack or 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).

Existing medications for heart failure aim to compensate for the heart's diminished blood pumping ability. There is evidence that such medications, together with dietary changes, may have a modest indirect impact on the heart muscle itself, but do not directly repair the heart muscle.

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company developing therapies for multiple sclerosis, spinal cord injury and related nervous system disorders. The Company is commercializing and marketing AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, in the Unites States. AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS); this was demonstrated by an improvement in walking speed. AMPYRA was developed using Elan's Matrix Drug Absorption System (MXDAS ®) technology and is manufactured by Elan based on a supply agreement with Acorda.

Acorda also markets ZANAFLEX CAPSULES ® (tizanidine hydrochloride) , a short-acting drug for the management of spasticity. The Company's pipeline includes a number of products in development for the treatment, regeneration and repair of the spinal cord and brain.

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 Acorda Therapeutics' ability to successfully market and sell Ampyra in the United States and to successfully market Zanaflex Capsules; third party payors (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; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of Ampyra outside of the United States and our dependence on our collaboration partner Biogen Idec in connection therewith; competition; failure to protect Acorda Therapeutics' intellectual property or to defend against the intellectual property claims of others; the ability to obtain additional financing to support Acorda Therapeutics' operations; and, unfavorable results from our preclinical programs. 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 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.