

ACORDA THERAPEUTICS INC
Form 8-K
October 19, 2010

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 19, 2010

Acorda Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-50513
(Commission
File Number)

13-3831168
(I.R.S. Employer
Identification No.)

15 Skyline Drive, Hawthorne, NY
(Address of principal executive offices)

10532
(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 19, 2010, Acorda Therapeutics, Inc. (the “registrant”) issued a press release announcing that data from preclinical studies show that Glial Growth Factor 2 (GGF2) promoted functional recovery following a permanent focal ischemic stroke. A copy of the press release is attached hereto as Exhibit 99.1 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 19, 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.

October 19, 2010

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated October 19, 2010.

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Preclinical Studies Show GGF2 Promotes Functional Recovery from Stroke with Treatment Initiated Up to Seven Days After Event

Hawthorne, N.Y., October 19, 2010 – Acorda Therapeutics, Inc. (NASDAQ: ACOR) today announced that data from preclinical studies show that Glial Growth Factor 2 (GGF2) promoted functional recovery following a permanent focal ischemic stroke. In a series of studies, GGF2 was administered starting up to seven days after the event to explore the neurorestorative properties of this novel growth factor. These studies were recently published online in *Neuropharmacology*, and the paper is scheduled to appear in a future print edition of the journal. An accompanying editorial discussed the need for new approaches in stroke intervention, and the potential role that GGF2 may play in improving function after stroke, pending further preclinical and clinical studies.

In one study, GGF2 was administered one hour following a permanent middle cerebral artery occlusion (MCAO) preclinical stroke model. In a second study, GGF2 was administered starting at 1, 3 or 7 days following MCAO. Daily intravenous administration continued for 10 days in both studies, and recovery of neurological function was assessed using a series of sensory and motor tests performed one day before MCAO, and at 1, 3, 7, 14 and 21 days after MCAO. The data showed that GGF2 was effective in improving recovery of neurological function both when delivered acutely and when delivered starting up to seven days after the onset of MCAO.

“Currently, FDA-approved stroke interventions need to be administered within a few hours of the event, which limits therapy to a very small minority of people who suffer a stroke. A therapy that could promote functional recovery from stroke with a longer time window to initiate treatment would represent an important advance in care,” said Anthony Caggiano, Acorda’s Vice President of Preclinical Development. “GGF2 is a neurorestorative agent that is thought to work through a novel mechanism involving repair of tissue damage in both the nervous and cardiovascular systems. This approach differs significantly from neuroprotective agents that have been explored in the past as potential treatments for stroke. These data show that GGF2 can be administered effectively in preclinical models of stroke up to a week following the event. Acorda is conducting further preclinical stroke studies with GGF2, and if the data

continue to show promise, we plan to advance the compound to human clinical trials in stroke, in addition to the currently planned trials in heart failure.”

Acorda plans to initiate Phase 1 studies in patients with heart failure based on an Investigational New Drug (IND) application filed with the U.S. Food and Drug Administration (FDA) in March 2010. The company is also pursuing preclinical studies in other cardiac and neurological applications for GGF2 and other neuregulin growth factors.

About GGF2

GGF2, a 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 central nervous system conditions.

Acorda submitted an IND for GGF2 as a therapy for heart failure in March 2010, based on extensive research by the Company and both independent and collaborative academic centers. 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 resulting from heart disease or injury. Existing medications for heart failure primarily aim to modify the workload of the heart, rather than promote ventricular repair.

Acorda is also continuing preclinical studies of potential cardiac and neurology indications for GGF2 and other neuregulin growth factors.

About Stroke

Stroke is a disease that affects blood flow to and within the brain. A stroke occurs when a blood vessel that carries oxygen and nutrients to the brain is either blocked by a clot (ischemic stroke) or bursts (hemorrhagic stroke). When blood flow is interrupted, part of the brain is deprived of the oxygen it needs, and rapidly starts to die. Ischemic stroke accounts for about 87 percent of all stroke cases.

In the United States, stroke affects approximately 800,000 people each year and is the third leading cause of death. It is the main cause of disability in the western world. Eighty percent of people who have a stroke survive and often have permanent neurological deficits and significant disability leading to an enormous healthcare burden. The American Stroke Association estimates Americans will pay about \$73.7 billion in 2010 for stroke-related medical costs and disability.

The current pharmacologic strategy for treating ischemic stroke is to eliminate the blood clot which is blocking blood flow to the brain. This approach must be implemented within several hours of symptom onset. This treatment restores blood flow to the brain and therefore limits the extent of lost brain tissue, but only 3-5% of individuals who suffer a stroke are eligible for this acute treatment. There is no pharmacologic stroke therapeutic approved for use beyond several hours post-stroke.

About Acorda Therapeutics

Acorda Therapeutics is a biotechnology company developing therapies for multiple sclerosis, spinal cord injury and related nervous system disorders. The Company's marketed products include AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg, 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; and 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, 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

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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. 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.
