ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 08/28/12 for the Period Ending 08/28/12

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): **August 28, 2012**

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 August 28, 2012, Acorda Therapeutics, Inc. issued a press release announcing that data from a preclinical study showed that treatment with Glial Growth Factor 2 (GGF2) improved erectile function in an animal model following a cavernous nerve (CN) injury, a common complication of prostate surgery. These data were featured in a platform presentation at the ISSM/SMSNA World Meeting on Sexual Medicine in Chicago, IL. 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 August 28, 2012

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.

August 28, 2012

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated August 28, 2012

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces GGF2 Preclinical Data on Treatment of Erectile Dysfunction

ARDSLEY, N.Y. – August 28, 2012 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) announced data from a preclinical study showed that treatment with Glial Growth Factor 2 (GGF2) improved erectile function in an animal model following a cavernous nerve (CN) injury, a common complication of prostate surgery. These data were featured in a platform presentation at the ISSM/SMSNA World Meeting on Sexual Medicine in Chicago, IL.

Approximately 270,000 prostate surgeries are performed in the United States annually. The vast majority of those surgeries are to treat prostate cancer and prostate enlargement (benign prostatic hyperplasia, or BPH). The National Cancer Institute estimates that approximately 120,000 men in the U.S. diagnosed with prostate cancer in 2012 will have surgery to remove the prostate. The American Urological Association estimates that more than 150,000 men annually in the U.S. have surgery to address BPH.

“One of the most common complications of prostate surgery is erectile dysfunction, caused by inadvertent damage to the cavernous nerve during surgery. There is currently no effective therapy for preventing these complications,” said Andrew R. Blight, Ph.D., Acorda Therapeutics’ Chief Scientific Officer. “The data from this study are consistent with previous preclinical work, indicating that GGF2 can improve erectile function after cavernous nerve damage, either through neuroprotection or stimulation of nerve regeneration. Based on the existing data, we believe that GGF2 may have the potential to also address other peripheral nerve injuries.”

The platform presentation, “GGF2 Is Neuroprotective In A Rat Model Of Cavernous Nerve Injury-Induced Erectile Dysfunction,” given by Arthur Burnett, M.D., included data from a study conducted by the Departments of Urology and Neurology at the Johns Hopkins University School of Medicine. It is the second collaborative effort between Acorda and independent academic institutions exploring the use of GGF2 to improve erectile function. Results from a previous preclinical study, conducted by Ottawa

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Hospital Research Institute at the University of Ottawa and presented by principal investigator Anthony Bella, M.D. at the American Urology Association 2011 annual meeting, also showed GGF2 improved erectile function following CN injury. The current study extended previous observations over a wider dose range and used electron microscopy to assess the injured nerves.

The study evaluated erectile function in five treatment groups of rats: two groups that did not have CN injury, one of which received an inactive control solution and the other received 15 mg/kg of GGF2, and three groups with a crush injury of the CN that received the inactive control, the 15 mg/kg dose of GGF2 or a lower dose of GGF2 (5 mg/kg). Treatments were administered subcutaneously 24 hours before the injury, 24 hours after and then once weekly for five weeks.

Nerve function was assessed using electrical stimulation of the nerve and recording intracavernous pressure, a standard measure of erectile function. During low-level stimulation, pressure was increased more in the lower dose GGF2 group than in the higher dose group or the inactive control group. During higher-level stimulation, pressure was improved in both lower and higher dose GGF2 groups compared to the control group, and was similar to the two groups that did not receive nerve injury. Electron microscopic evaluation of the cavernous nerve showed a greater number of nerve fibers in the GGF2 treated groups at 5 weeks following the injury.

GGF2 is Acorda's leading development candidate from the Company's neuregulin program. Neuregulins are a class of naturally occurring protein growth factors that have multiple effects on the nervous and cardiovascular systems. Acorda has ongoing studies of GGF2 in a number of cardiac and neurological indications, including heart failure, peripheral nerve injury and stroke. Results from Acorda's Phase 1 clinical study in heart failure are expected by the end of 2012.

The World Meeting on Sexual Medicine is jointly organized by the International Society for Sexual Medicine (ISSM) and the Sexual Medicine Society of North America (SMSNA). It is the 18 th Scientific Meeting of the SMSNA and the 15 th World Meeting of the ISSM.

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 is developing an industry-leading pipeline of novel neurological therapies. The Company is studying AMPYRA to improve a range of functional impairments caused by MS, as well as its use in other neurological conditions, including cerebral palsy and chronic stroke. In addition, Acorda is developing clinical stage compounds AC105 for acute treatment of spinal cord injury and GGF2 for treatment of heart failure. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and spinal cord injury. Additional preclinical programs include rHIgM22, a remyelinating monoclonal antibody for the treatment of MS, and chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury.

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 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 any acquired or in-licensed programs; 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; f ailure 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 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 press 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.

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