

ACORDA THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 04/22/15 for the Period Ending 04/22/15

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): **April 22, 2015**

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.)

**420 Saw Mill River Road,
Ardsley, NY**
(Address of principal executive offices)

10502
(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))
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Item 8.01 **Other Events**

On April 22, 2015, Acorda Therapeutics, Inc.(the “Company”) issued a press release announcing that the Company presented data from a Phase 1 clinical trial of rHIgM22, a remyelinating antibody being studied for the treatment of multiple sclerosis (MS). Safety data showed rHIgM22 was well-tolerated in each of the five tested doses, supporting additional clinical development. In addition, testing detected rHIgM22 in cerebrospinal fluid (CSF), indicating the drug’s access to the central nervous system. These data were presented at the 67th American Academy of Neurology Annual Meeting in Washington, DC. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated April 22, 2015

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.

April 22, 2015

By: /s/ Michael Rogers
Name: Michael Rogers
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.

Description

99.1

Press Release dated April 22, 2015

**CONTACT:**

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FOR IMMEDIATE RELEASE

Acorda Presents Data on First Clinical Study of Remyelinating Antibody for Multiple Sclerosis at American Academy of Neurology Annual Meeting

rHIgM22 well-tolerated at all tested doses
Antibody detected in cerebrospinal fluid
Beginning second Phase 1 clinical trial in 2Q15

Ardsley, N.Y. (April 22, 2015) -- Acorda Therapeutics, Inc. (Nasdaq:ACOR) today presented data from a Phase 1 clinical trial of rHIgM22, a remyelinating antibody being studied for the treatment of multiple sclerosis (MS). Safety data showed rHIgM22 was well-tolerated in each of the five tested doses, supporting additional clinical development. In addition, testing detected rHIgM22 in cerebrospinal fluid (CSF), indicating the drug's access to the central nervous system. These data were presented at the 67th American Academy of Neurology Annual Meeting in Washington, DC.

“In this study, rHIgM22 was well-tolerated over the full range of dose levels tested. Furthermore, we were able to verify that rHIgM22 is present in the CSF, showing that the antibody is available to the brain,” said Anthony Caggiano, M.D., Ph.D., Acorda's Senior Vice President of Research and Development. “We plan to advance our clinical program based on these data; the next study will include patients experiencing acute relapses. The combined results of these two studies will inform subsequent trials, which we anticipate will enroll both stable patients and those experiencing active relapses.”

This was a placebo-controlled, single-dose, escalating study in 72 patients with clinically stable MS to explore dose tolerability for six months after treatment. rHIgM22 was well-tolerated at all doses tested, with no safety signals identified. There were no dose-limiting toxicities and no serious adverse events in any of the five rHIgM22 dose levels in the study. The data presented included the concentration of rHIgM22 in the CSF at two days and four weeks after IV infusion. The antibody was measured at levels expected for antibodies of this class. There were no significant changes from baseline in clinical measures including MRI, magnetic resonance spectroscopy, Expanded Disability Status Scale, Timed 25-Foot Walk, and low contrast visual acuity.

The most commonly observed adverse events (>5% in the combined rHIgM22 treatment groups) reported in the study were: headache, contact dermatitis, multiple sclerosis relapse, infusion site hematoma, fatigue, arthralgia, back pain, muscular weakness, neck pain, pain in an extremity, pruritus, contusion, and flushing. No participants withdrew due to adverse events. No safety signals were identified by standard clinical MRI evaluations, or standard clinical, laboratory or ECG assessments.

The data were presented in a poster, “Safety and Tolerability of the Remyelinating Therapeutic Antibody rHIgM22 in Patients with Stable Multiple Sclerosis” (poster presentation number P4.339). Top-line safety and tolerability data were previously announced by the Company in February 2015.

About MS and rHIgM22

Multiple sclerosis (MS) is a chronic, usually progressive disease in which the immune system attacks and degrades the function of nerve fibers in the brain and spinal cord by destroying myelin (a process known as demyelination) and eventually the nerve fibers themselves. Myelin is a fatty layer of membranes that insulates nerves, facilitating the transmission of electrical impulses through nerve pathways that control all neurological functions. In people with MS, disruption in neurological function often leads to impairments in movement, bowel/bladder function, vision and sexual function.

The cells that make myelin, called oligodendrocytes, can initially repair myelin damage. As MS progresses, the ability of oligodendrocytes to repair areas of demyelination is not sufficient to prevent permanent neurological injury. Currently, there are no therapies that repair or restore myelin in demyelinating diseases such as MS. If myelin is able to be repaired, it may restore electrical conduction and may serve to protect the exposed nerve fiber from further damage.

rHIgM22 is a recombinant human monoclonal antibody identified in the laboratory of Moses Rodriguez, M.D. at Mayo Clinic. In preclinical studies, rHIgM22 has been found to protect oligodendrocytes and stimulate them to repair areas of demyelination. rHIgM22 treatment also resulted in sustained improvements in motor activity in preclinical models.

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 disorders.

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), as demonstrated by an increase in walking speed. The Company has one of the leading pipelines in the industry of novel neurological therapies. Acorda is currently developing a number of clinical and preclinical stage therapies. This pipeline addresses a range of disorders including

post-stroke walking deficits, Parkinson's disease, epilepsy, neuropathic pain, heart failure, MS and spinal cord injury.

For more information, please visit the Company's website at: www.acorda.com.

AMPYRA (dalfampridine) Important Safety Information

Do not take AMPYRA if you

- have ever had a seizure,

- have certain types of kidney problems, or

- are allergic to dalfampridine (4-aminopyridine), the active ingredient in AMPYRA.

Take AMPYRA exactly as prescribed by your doctor.

Before taking AMPYRA, tell your doctor if you

- have kidney problems or any other medical conditions

- are taking compounded 4-aminopyridine

- are pregnant or plan to become pregnant. It is not known if AMPYRA will harm your unborn baby.

- are breast-feeding or plan to breast-feed. It is not known if AMPYRA passes into your breast milk. You and your doctor should decide if you will take AMPYRA or breast-feed. You should not do both.

- are taking any other medicines

Stop taking AMPYRA and call your doctor right away if you have a seizure while taking AMPYRA. You could have a seizure even if you never had a seizure before. Your chance of having a seizure is higher if you take too much AMPYRA or if your kidneys have a mild decrease of function, which is common after age 50. Your doctor may do a blood test to check how well your kidneys are working before you start AMPYRA.

AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

AMPYRA may cause serious side effects, including

- severe allergic reactions. Stop taking AMPYRA and call your doctor right away or get emergency medical help if you have shortness of breath or trouble breathing, swelling of your throat or tongue, or hives;

- kidney or bladder infections.

The most common adverse events for AMPYRA in MS patients were urinary tract infection, trouble sleeping, dizziness, headache, nausea, weakness, back pain, problems with balance, multiple sclerosis relapse, burning, tingling, or itching of your skin, irritation in your nose and throat, constipation, indigestion, and pain in your throat.

Please see the Patient Medication Guide at <https://ampyra.com/medication-guide.pdf>.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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 the ability to realize the benefits anticipated from the Civitas transaction and to successfully integrate Civitas' operations into our operations; 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 CVT-301, Plumiaz, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, Plumiaz, or any other products under development; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; 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 in connection therewith; competition; 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; and, failure to comply with regulatory requirements could result in adverse action by regulatory agencies.

These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities and 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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