

ACORDA THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 02/02/15 for the Period Ending 02/02/15

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
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): **February 2, 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))
-

Item 8.01 Other Events

On February 2, 2015, Acorda Therapeutics, Inc. (the “Company”) issued a press release announcing that safety and tolerability data from a Phase 1 clinical trial of rHIgM22, a remyelinating antibody being studied for the treatment of multiple sclerosis (MS). The trial, which followed participants for up to six months after receiving a single dose of rHIgM22, found no dose-limiting toxicities at any of the five dose levels studied. Based on these data, the Company intends to advance clinical development of rHIgM22. 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 February 2, 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.

February 2, 2015

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

EXHIBIT INDEX

Exhibit No.

99.1

Description

Press Release dated February 2, 2015



CONTACTS

Media:
 Jeff Macdonald
 Acorda Therapeutics
 (914) 326-5232
 jmacdonald@acorda.com

Investors:
 Felicia Vonella
 Acorda Therapeutics
 (914) 326-5146
 fvonella@acorda.com

FOR IMMEDIATE RELEASE

Acorda Announces Safety and Tolerability Data from First Clinical Trial of Remyelinating Antibody in Multiple Sclerosis

Phase 1 trial results support advancing development of rHIgM22

ARDSLEY, N.Y. – February 2, 2015 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced safety and tolerability data from a Phase 1 clinical trial of rHIgM22, a remyelinating antibody being studied for the treatment of multiple sclerosis (MS). The trial, which followed participants for up to six months after receiving a single dose of rHIgM22, found no dose-limiting toxicities at any of the five dose levels studied. Based on these data, the Company intends to advance clinical development of rHIgM22.

“We’re encouraged by the outcome of this trial, which showed that rHIgM22 was well-tolerated at all of the dose levels we studied,” said Anthony Caggiano, M.D., Ph.D., Acorda’s Senior Vice President of Research and Development. “We are currently developing the protocol for our next Phase 1 clinical trial of rHIgM22. The data from this study will help inform the design of the next trial, which will enroll people with MS who are experiencing an active relapse.”

This was a multi-center, double-blind, randomized, placebo-controlled study designed to evaluate safety, tolerability, pharmacokinetics, and immunogenicity of a single dose of rHIgM22 in participants with any type of MS who were clinically stable for at least three months. All participants remained on their existing MS treatment regimens, including disease-modifying therapies.

The first part of the study included five cohorts, with each cohort receiving a higher dose of rHIgM22 than the previous one. Each cohort consisted of 10 participants (eight receiving drug, two receiving placebo), who were followed for three months after receiving a single dose of study medication. In the second part of the study, 21 treatment-naïve participants were randomized to receive placebo or one of the two highest doses of rHIgM22 from the first part of the study. These participants were followed for six months to assess safety and tolerability. The second part of the study also included several exploratory clinical, imaging and biomarker measures, which

are still being analyzed. The study was not powered to determine statistical significance on these measures.

Additional details from the trial will be presented at future medical meetings.

Safety Findings

Across all of the study groups, 55 participants received one of the five doses of rHIgM22 and 17 received placebo (no sample size power calculation was used to determine the number of participants in each group). There were no dose-limiting toxicities and no serious adverse events (SAE) in any of the five rHIgM22 dose levels in the study. There was one SAE of squamous cell carcinoma in a placebo-treated participant.

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.

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 could 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.

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 Idec 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.

