ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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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 23, 2013**

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 April 23, 2013, Mayo Clinic and Acorda Therapeutics, Inc. issued a press release announcing that the first patient has been enrolled in the first clinical trial of rHIgM22, a remyelinating antibody being studied for the treatment of multiple sclerosis (MS). This is a Phase 1 clinical trial enrolling people with MS to assess the safety and tolerability of rHIgM22. The study also includes several exploratory efficacy measures. 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 April 23, 2013

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 23, 2013

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated April 23, 2013

CONTACT:

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FOR IMMEDIATE RELEASE

Mayo Clinic and Acorda Therapeutics Announce Initiation of Phase 1 Trial of Remyelinating Antibody in People with Multiple Sclerosis

- Discovered at Mayo Clinic, rHIgM22 Represents Potential New Approach to MS Treatment

ROCHESTER, MN and ARDSLEY, NY – April 23, 2013 – Mayo Clinic and Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the first patient has been enrolled in the first clinical trial of rHIgM22, a remyelinating antibody being studied for the treatment of multiple sclerosis (MS). This is a Phase 1 clinical trial enrolling people with MS to assess the safety and tolerability of rHIgM22. The study also includes several exploratory efficacy measures.

In MS, a person's own immune system destroys myelin, a substance that insulates nerves and facilitates conduction of nerve impulses that control neurological function such as movement and vision. Progressive damage to myelin causes functional impairment in people with MS. Currently there are no approved therapies that stimulate the repair or regrowth of myelin once it has been damaged.

"This remyelinating antibody, if successful in clinical trials and approved, would be a novel approach to treating people with chronic neurologic deficits from multiple sclerosis or other similar conditions," said Moses Rodriguez, M.D., a neurologist specializing in MS at the Mayo Clinic, whose team initially identified rHIgM22. "We are excited that this Mayo discovery is now being evaluated in people with MS to determine its therapeutic potential."

"The current standard of MS care does not address the underlying issue of the loss of myelin that leads to progressive functional impairment in people with MS," said Anthony Caggiano, M.D., Ph.D., Acorda's Vice President of Research and Development .

“Stimulation of remyelination represents a novel and potentially significant advance in the treatment of people with MS, and one which could be complementary to existing therapies. In preclinical studies, rHIgM22 has shown the ability to stimulate production of new myelin and improve function.”

The primary objective of this double-blind, randomized single ascending dose study is to evaluate the safety and tolerability of rHIgM22 in people with MS. The study also includes several exploratory efficacy measures, including magnetic resonance imaging and standard clinical measures used to assess people with MS, such as walking ability. Participants in the trial will receive either placebo or rHIgM22 administered as a single intravenous dose. If rHIgM22 is well tolerated in study groups receiving a low dose of rHIgM22, subsequent groups will receive single infusions of higher doses. Participants in this study will continue receiving their standard MS treatments.

Additional details on this clinical study, including enrollment criteria and contact information for study sites, can be found at:

http://www.clinicaltrials.gov/ct2/show/NCT01803867?term=acorda&rank=12

The remyelinating antibody program is the result of a research collaboration between Acorda and the Mayo Foundation for Medical Education and Research. Acorda licensed worldwide rights to patents and other intellectual property for these antibodies related to nervous system disorders under an exclusive license agreement with the Mayo Clinic in September 2000. Dr. Rodriguez is an employee of Mayo Foundation.

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 neurological functions such as movement, bowel/bladder function, vision and sexual function.

The cells that make myelin, called oligodendrocytes, can initially repair myelin, but as MS progresses, there is little spontaneous repair. 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.

Preclinical studies in animal models and laboratory studies have demonstrated rHIgM22 can protect oligodendrocytes (the myelin producing cells) and stimulate them to repair areas of demyelination. rHIgM22 treatment of these animals also resulted in sustained improvements in motor activity.

About Mayo Clinic
Mayo Clinic is a nonprofit worldwide leader in medical care, research and education for people from all walks of life. For more information, visit MayoClinic.com or MayoClinic.org/news .

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 Actavis, Inc. under its agreement with Acorda.

Acorda has one of the leading pipelines in the industry of novel neurological therapies. The Company is developing Diazepam Nasal Spray for treatment of certain epileptic seizures. It is also studying AMPYRA to improve a range of functional impairments caused by MS, as well as its potential for use in other neurological conditions, including cerebral palsy and post-stroke deficits. In addition, Acorda is developing clinical stage compounds AC105 for acute treatment of spinal cord injury, GGF2 for treatment of heart failure and rHIgM22, a remyelinating monoclonal antibody, for the treatment of MS. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and spinal cord injury. Chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury, is in preclinical development.

Acorda 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 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 Diazepam Nasal Spray or any other acquired or in-licensed programs; we may not be able to complete

development of, obtain regulatory approval for, or successfully market Diazepam Nasal Spray or other products under development; 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; failure 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 & 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 develop ments occurring after the date of this release.