

**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 7, 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 October 7, 2015, Acorda Therapeutics, Inc. issued a press release announcing that it will present new analyses of pharmacokinetic data from a Phase 1 clinical trial of rHIgM22, a remyelinating antibody being studied for the treatment of multiple sclerosis (MS), and five-year post-marketing safety data on AMPYRA<sup>®</sup> (dalfampridine) Extended Release Tablets, 10 mg at the 31<sup>st</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). The meeting is being held in Barcelona, Spain, October 7 - 10. 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 October 7, 2015

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## 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.

October 7, 2015

**Acorda Therapeutics, Inc.**

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

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**EXHIBIT INDEX**

Exhibit No.

Description

99.1

Press Release dated October 7, 2015

**CONTACT:**

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Acorda Therapeutics  
(914) 326-5232  
jmacdonald@acorda.com

FOR IMMEDIATE RELEASE

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## Acorda to Present New rHIgM22 and AMPYRA<sup>®</sup> (dalfampridine) Data at the 31<sup>st</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS)

Ardsley, N.Y. – October 7, 2015 -- Acorda Therapeutics, Inc. (Nasdaq: ACOR) will present new analyses of pharmacokinetic data from a Phase 1 clinical trial of rHIgM22, a remyelinating antibody being studied for the treatment of multiple sclerosis (MS), and five-year post-marketing safety data on AMPYRA<sup>®</sup> (dalfampridine) Extended Release Tablets, 10 mg at the 31<sup>st</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). The meeting is being held in Barcelona, Spain, October 7 - 10.

“Acorda is committed to researching novel therapies that can improve the lives of people with multiple sclerosis. The scientific data being presented at ECTRIMS feature new information about our investigational and marketed MS therapies” said Enrique Carrazana, M.D., Chief Medical Officer of Acorda. “Our investigational compound rHIgM22 potentially represents a completely new approach to the treatment of MS. An analysis of pharmacokinetic data of rHIgM22 showed the drug is present in the cerebrospinal fluid, and thus readily available to the brain. This is one of the most promising areas of MS research.”

AMPYRA is the first and only medication approved to improve walking in people with MS. This was demonstrated by an increase in walking speed. Ampyra has been used by more than 100,000 people since its approval in 2010. Long-term safety data being presented at ECTRIMS demonstrate that the clinical profile of AMPYRA is consistent with the product label and findings in Phase 3 studies.

“Safety Profile of Dalfampridine Extended Release in Multiple Sclerosis: 5-Year Post-Marketing Experience in the United States,” (Poster #EP1461) will be exhibited on Friday, October 9, from 3:30 – 5:00pm. Michele Jara, PhD, study author and Senior Director, Drug Safety and Risk Management for Acorda, will present the poster.

“Pharmacokinetics of a CNS-Penetrating, Putative Remyelinating Human Monoclonal Antibody, rHIgM22, in a Phase 1 Clinical Trial in Patients with Stable Multiple

Sclerosis (MS),” (Poster #661) will be exhibited on Thursday, October 8, from 3:45 – 5:00pm. Andrew Eisen, MD, PhD, study author and Senior Director, Translational Medicine for Acorda, will present the poster.

More detailed information on the meeting can be found on the conference website: <http://www.ectrims-congress.eu/2015/ectrims-2015.html>.

Other data from the rHlgM22 study were first presented at the 67<sup>th</sup> American Academy of Neurology Annual Meeting.

### **AMPYRA (dalfampridine) Important Safety Information**

- AMPYRA is contraindicated in patients with history of seizures, moderate or severe renal impairment ( $\text{CrCl} \leq 50 \text{ mL/min}$ ), or history of hypersensitivity to AMPYRA or 4-aminopyridine.
- AMPYRA can cause seizures. The risk of seizures increases with increasing doses. Discontinue AMPYRA and do not restart if seizure occurs. In the post-marketing period seizures have been reported. The majority of seizures occurred at the recommended dose, in patients without a history of seizures, and generally within days to weeks of starting therapy.
- AMPYRA has not been evaluated in patients with history of seizures or with epileptiform activity on an EEG, as these patients were excluded from clinical trials. The risk of seizures in patients with epileptiform activity on an EEG is unknown, and could be substantially higher than that observed in clinical studies.
- AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same. Patients should discontinue use of any product containing 4-aminopyridine prior to initiating AMPYRA to reduce the potential for dose-related adverse reactions.
- AMPYRA can cause anaphylaxis and severe allergic reaction. Signs and symptoms included respiratory compromise, urticaria, and angioedema of the throat or tongue. If an anaphylactic or other serious allergic reaction occurs, discontinue AMPYRA and do not restart.
- AMPYRA is cleared predominantly by the kidneys. The risk of seizures in patients with mild renal impairment ( $\text{CrCl} 51\text{--}80 \text{ mL/min}$ ) is unknown, but AMPYRA plasma levels in these patients may approach those seen at a dose of 15 mg twice daily, a dose that may be associated with an increased risk of seizures; estimated  $\text{CrCl}$  should be known before initiating AMPYRA and monitored at least annually during treatment.
- Urinary tract infections (UTIs) were reported more frequently in controlled studies in patients receiving AMPYRA (12%) as compared to placebo (8%). UTIs in AMPYRA-treated patients should be evaluated and treated as clinically indicated.
- The most common adverse events (incidence  $\geq 2\%$  and at a rate greater than the placebo rate) for AMPYRA in MS patients were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain.
- The risk of adverse events, including seizures, increases with increasing AMPYRA doses. No additional benefit was demonstrated at doses greater than 10 mg twice daily.
- There are no adequate and well-controlled studies of AMPYRA in pregnant women. AMPYRA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- It is not known if AMPYRA passes into breast milk. Discontinue AMPYRA or nursing, taking into consideration the importance of AMPYRA to the mother.
- Safety and effectiveness of AMPYRA in patients younger than 18 years have not been established.

Clinical studies of AMPYRA did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Because elderly patients are more likely to have decreased renal function, it is important to know the estimated CrCl before initiating AMPYRA.

Please click [here](http://ampyra.com/prescribing-information.pdf) for the Full Prescribing Information, also available at [ampyra.com/prescribing-information.pdf](http://ampyra.com/prescribing-information.pdf)

### **About AMPYRA (dalfampridine)**

AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed. AMPYRA, which was previously referred to as Fampridine-SR, is an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), and is known as prolonged-, modified, or sustained-release fampridine (FAMPYRA<sup>®</sup>) in some countries outside the United States (U.S).

In preclinical studies, dalfampridine extended release tablets has been found to improve impulse conduction in nerve fibers in which the insulating layer, called myelin, has been damaged. The mechanism by which dalfampridine exerts its therapeutic effect has not been fully elucidated. AMPYRA is being developed and commercialized in the U.S. by Acorda Therapeutics; FAMPYRA is being developed and commercialized by Biogen Idec in markets outside the U.S. based on a licensing agreement with Acorda. AMPYRA and FAMPYRA are manufactured globally by Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, based on a supply agreement with Acorda.

AMPYRA is available by prescription in the United States. For more information about AMPYRA, including patient assistance and co-pay programs, healthcare professionals and people with MS can contact AMPYRA Patient Support Services at 888-881-1918. AMPYRA Patient Support Services is available Monday through Friday, from 8:00 a.m. to 8:00 p.m. Eastern Time.

### **About MS and rHlgM22**

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.

rHlgM22 is a recombinant human monoclonal antibody identified in the laboratory of Moses Rodriguez, M.D. at Mayo Clinic. In preclinical studies, rHlgM22 has been found to protect oligodendrocytes and stimulate them to repair areas of demyelination. rHlgM22 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. 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](http://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 (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 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.

