ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 09/15/11 for the Period Ending 09/15/11

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): **September 15, 2011**

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.)

15 Skyline Drive, Hawthorne, NY	**10532**
(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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

(b) On September 15, 2011, Acorda Therapeutics, Inc. (the "Company") issued a press release announcing that Thomas C. Wessel, M.D., Ph.D., the Company's Chief Medical Officer and one of its named executive officers, has resigned from the Company. Dr. Wessel's resignation will be effective September 30, 2011. Dr. Wessel is expected to continue to advise the Company in a consulting role through the end of 2011. A copy of the press release announcing Dr. Wessel's resignation is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item.

Item 8.01 Other Events

On September 15, 2011, the Company issued a press release announcing that Enrique J. Carrazana, M.D., will join the Company effective October 15, 2011, as Chief Medical Officer. In this role, Dr. Carrazana will be responsible for managing development programs and regulatory filings for the Company's pipeline products, AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg post-marketing studies, and the Company's medical affairs, clinical operations, regulatory affairs, drug safety and biostatistics departments.

Dr. Carrazana is a Board-certified neurologist with over 20 years of experience in the pharmaceutical industry and clinical practice. Most recently, he was Director of the Epilepsy Center of Excellence at the Miami Veterans' Administration (VA) Hospital and Associate Professor of Neurology at the University of Miami Miller School of Medicine. Prior to this, Dr. Carrazana held various medical leadership roles at Novartis Pharmaceuticals. His last role was Vice President, Global Head Established Medicines Development Franchise based in Basel, Switzerland. Dr. Carrazana was a practicing neurologist before working in the pharmaceutical industry, during which time he served as a principal investigator for numerous clinical trials in the areas of epilepsy, neurodegenerative disorders and neuropathic pain. Dr. Carrazana completed his residency in Neurology and fellowship in Neurophysiology at the Harvard Longwood Neurology Program. He graduated from the Harvard Medical School.

A copy of the press release announcing Dr. Carranza's employment as Chief Medical Officer 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 September 15, 2011

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.

September 15, 2011

By: /s/ Jane Wasman
Name: Jane Wasman
Title: Executive Vice President, General Counsel and Corporate Secretary

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated September 15, 2011

EXHIBIT 99.1

CONTACT:

Jeff Macdonald
Acorda Therapeutics
(914) 347-4300 ext. 4232
jmacdonald@acorda.com

FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Enrique Carrazana, M.D. Joins Company as Chief Medical Officer

HAWTHORNE, NY, September 15, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that Enrique J. Carrazana, M.D., has joined the Company as Chief Medical Officer, and will be starting October 15. In this role, Dr. Carrazana will be responsible for managing development programs and regulatory filings for Acorda's pipeline products, AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg post-marketing studies, and the Company's medical affairs, clinical operations, regulatory affairs, drug safety and biostatistics departments. Thomas Wessel, M.D., Ph.D., who previously served as Chief Medical Officer, will be leaving the Company, but will continue to advise it in a consulting role through the end of the year.

"We are delighted to have a physician of Dr. Carrazana's stature and experience joining Acorda. In addition to post-marketing studies of AMPYRA in MS and other neurological diseases, our pipeline includes two compounds in clinical-stage development and two others in preclinical development. Dr. Carrazana's expertise in integrating clinical, regulatory and commercial considerations into development programs will benefit all of those programs," said Ron Cohen, M.D., Acorda's president and CEO. "In addition, his perspective as a practicing neurologist into the needs of patients and physicians is a great addition to Acorda's already deep expertise in identifying and developing novel neurology products."

Dr. Enrique Carrazana is a Board-certified neurologist with over 20 years of experience in the pharmaceutical industry and clinical practice. Most recently, he was Director of the Epilepsy Center of Excellence at the Miami Veterans' Administration (VA) Hospital and Associate Professor of Neurology at the University of Miami Miller School of Medicine. Prior to this, Dr. Carrazana held various medical leadership roles at Novartis Pharmaceuticals. His last role was Vice President, Global Head Established Medicines Development Franchise based in Basel, Switzerland. Dr. Carrazana was a practicing neurologist before working in the pharmaceutical industry, during which time he served as a principal investigator for numerous clinical trials in the areas of epilepsy, neurodegenerative disorders and neuropathic pain.

“I’m excited about Acorda’s innovative pipeline and the opportunity to join an organization that is committed to exploring new approaches to treating neurological diseases,” said Dr. Carrazana. “I look forward to collaborating with my new colleagues to advance these programs, which have the potential to provide novel, much needed benefits for people affected by neurological disease.”

Dr. Carrazana completed his residency in Neurology and fellowship in Neurophysiology at the Harvard Longwood Neurology Program. He graduated from the Harvard Medical School.

Dr. Cohen added, “We are grateful to Dr. Wessel for his contributions to Acorda. In particular, as a member of the team that successfully filed the U.S. regulatory package for AMPYRA, he helped bring a therapy to market that has now benefited tens of thousands of people with multiple sclerosis to improve their walking. Tom’s background in developing commercially viable neurological products has also been an asset in our evaluation of in-licensing opportunities. We look forward to continuing to work with him on a consulting basis, and wish him all the best for the future.”

Important Safety Information
AMPYRA can cause seizures; the risk of seizures increases with increasing AMPYRA doses. AMPYRA is contraindicated in patients with a prior history of seizure. Discontinue AMPYRA use if seizure occurs.

AMPYRA is contraindicated in patients with moderate or severe renal impairment (CrCl≤50 mL/min); the risk of seizures in patients with mild renal impairment (CrCl 51–80 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 CrCl should be known before initiating treatment with AMPYRA.

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

Urinary tract infections were reported more frequently as adverse reactions in patients receiving AMPYRA 10 mg twice daily compared to placebo.

The most common adverse events (incidence ≥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.

For full U.S. Prescribing Information and Medication Guide for AMPYRA, please visit: www.AMPYRA.com .

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), which was previously called fampridine, and remains known by that name outside the US. In laboratory studies, dalfampridine has been found to improve impulse conduction in nerve fibers in which the insulating layer, called myelin, has been damaged. AMPYRA is being developed and commercialized in the United States by Acorda Therapeutics, and by Biogen Idec in markets outside the U.S. based on a licensing agreement with Acorda. AMPYRA is manufactured globally by Elan 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 at 888-881-1918. For full U.S. Prescribing Information and Medication Guide, please visit: www.AMPYRA.com .

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company developing therapies for multiple sclerosis, spinal cord injury and related nervous system disorders. The Company is commercializing and marketing AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg, in the Unites States. AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS); this was demonstrated by an improvement in walking speed. AMPYRA was developed using Elan’s Matrix Drug Absorption System (MXDAS®) technology and is manufactured by Elan based on a supply agreement with Acorda.

Acorda also markets ZANAFLEX CAPSULES® (tizanidine hydrochloride), a short-acting drug for the management of spasticity. The Company's pipeline includes a number of products in development for the treatment, regeneration and repair of the spinal cord and brain.

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 Acorda Therapeutics' ability to successfully market and sell Ampyra in the United States; third party payors (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; the occurrence of adverse safety events with our products; delays in obtaining

or failure to obtain regulatory approval of Ampyra outside of the United States and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of anticipated potential generic competition on Zanaflex Capsules revenues; failure to protect Acorda Therapeutics' 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; the ability to obtain additional financing to support Acorda Therapeutics' operations; and, unfavorable results from our research and development programs. 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 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.