

ACORDA THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 01/10/11 for the Period Ending 01/10/11

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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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): **January 10, 2011**

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.)

15 Skyline Drive, Hawthorne, NY
(Address of principal executive offices)

10532
(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 2.02 Results of Operation and Financial Condition

On January 10, 2011, Acorda Therapeutics, Inc. issued a press release announcing certain financial information regarding the fourth fiscal quarter of 2010 as well as for the full 2010 fiscal year, including that AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg gross sales in the fourth quarter of 2010 were \$55.7 million, and \$141.4 million for the full year 2010. The Company also announced that it is providing a business update today at the J.P. Morgan Healthcare Conference. 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 January 10, 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.

January 10, 2011

Acorda Therapeutics, Inc.

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

Exhibit Index

Exhibit
No.

Description

99.1 Press Release dated January 10, 2011

**CONTACT:**

Jeff Macdonald
 Acorda Therapeutics
 (914) 347-4300 ext. 232
 jmacdonald@acorda.com

FOR IMMEDIATE RELEASE

Acorda Therapeutics To Provide Business Update Today at J.P. Morgan Healthcare Conference

- *AMPYRA 2010 Fourth Quarter Gross Sales of \$55.7 Million; Full Year 2010 Gross Sales of \$141.4 Million*
- *Zanaflex Capsules and tablets 2010 Fourth Quarter Shipments of \$15.8 Million; Full Year 2010 Shipments of \$57.3 Million*
- *Expected Year-End Cash, Cash Equivalents and Short-Term Investments in Excess of \$235 Million*

HAWTHORNE, N.Y., January 10, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg gross sales in the fourth quarter of 2010 were \$55.7 million, and \$141.4 million for the full year 2010. In addition, fourth quarter shipments of Zanaflex Capsules[®] (tizanidine hydrochloride) and tablets were \$15.8 million in the fourth quarter of 2010 and full year shipments were \$57.3 million. Zanaflex gross sales are recognized using a deferred revenue recognition model, and are not yet final. As of December 31, 2010, Acorda expects that cash, cash equivalents and short-term investments will be in excess of \$235 million. The final year-end balance will be available in the company's fourth quarter earnings report.

President and CEO Ron Cohen, M.D. will provide a business update on AMPYRA, the company's pipeline products and business development strategy at the 29th Annual J.P. Morgan Healthcare Conference today at 2:00 p.m. Pacific Time in San Francisco, CA. The presentation will be available via webcast at www.acorda.com.

"AMPYRA is the first medication indicated to improve walking in people with multiple sclerosis, a critical need in this disease. More than 31,000 patients received a prescription in the first seven months of commercial availability, underscoring AMPYRA's utility in addressing this previously unmet need," said Dr. Cohen. "The successful launch of AMPYRA provides a solid base on which to continue building value in our company, through increased trial of AMPYRA by appropriate patients, advancing our product pipeline and acquiring clinical stage compounds to complement our existing assets."

AMPYRA was approved by the U.S. Food and Drug Administration (FDA) on January 22, 2010 as a treatment to improve walking in people with MS. This was demonstrated by an increase in walking speed.

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 \leq 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 $\geq 2\%$ 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.

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 now 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 United 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 and to successfully market Zanaflex Capsules; 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; failure to protect Acorda Therapeutics' intellectual property or to defend against the intellectual property claims of others; the ability to obtain additional financing to support Acorda Therapeutics' operations; and, unfavorable results from our preclinical 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.