

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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SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
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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): **February 17, 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 Operations and Financial Condition

On February 17, 2011, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2010. 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 2.02.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 17, 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.

February 17, 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 February 17 2011



CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Fourth Quarter and Full Year 2010 Financial Results

- AMPYRA[®] (dalfampridine) 2010 Fourth Quarter Net Revenue of \$52.3 Million; AMPYRA Full Year 2010 Net Revenue of \$133.1 Million
- Year-End 2010 Cash, Cash Equivalents and Short-Term Investments of \$240 Million
- Full Year 2011 AMPYRA Net Revenue Guidance of \$205-\$230 Million

HAWTHORNE, N.Y., February 17, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the fourth quarter and full year ended December 31, 2010.

“In just its first ten months since launch, approximately 40,000 people, or 10% of the MS population in the United States, received a prescription for AMPYRA. This reflects the enormous medical need for a medication to improve walking in people with MS, one of the most pervasive and worrying disabilities associated with this condition,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “AMPYRA’s success in 2010 provides us with a solid base to continue to build this business in 2011.”

Financial Results

AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg net revenue - For the quarter ended December 31, 2010, the Company reported AMPYRA net revenue of \$52.3 million. For the full year ended December 31, 2010, the Company reported net revenue of \$133.1 million. Acorda began shipping AMPYRA to specialty pharmacies on March 1, 2010. AMPYRA revenue is recognized following shipment of the product from the Company’s distribution facility to its network of specialty pharmacies.

ZANAFLEX CAPSULES[®] (tizanidine hydrochloride) and ZANAFLEX[®] (tizanidine hydrochloride) tablets net revenue - For the quarter ended December 31, 2010, the Company reported combined net revenue of ZANAFLEX CAPSULES and ZANAFLEX tablets of \$12.1 million, compared to combined net revenue of \$12.1 million for the same quarter in 2009. For the full year ended December 31, 2010, the Company reported combined net revenue of ZANAFLEX CAPSULES and ZANAFLEX tablets of \$48.5 million, compared to combined net revenue of \$50.0 million in 2009.

ZANAFLEX revenue is recognized using a deferred revenue recognition model, meaning ZANAFLEX CAPSULES and ZANAFLEX tablets shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of ZANAFLEX CAPSULES and ZANAFLEX tablets are reported.

ZANAFLEX CAPSULES and ZANAFLEX tablets shipments - Total ZANAFLEX CAPSULES and ZANAFLEX tablets shipments for the quarter ended December 31, 2010 were \$15.8 million, compared to total shipments of \$18.4 million for the same quarter in 2009. For the full year ended December 31, 2010, total ZANAFLEX CAPSULES and ZANAFLEX tablet shipments were \$57.3 million, compared to total shipments of \$66.7 million in 2009.

Research and development expenses for the quarter ended December 31, 2010 were \$8.0 million, including \$1.6 million of share-based compensation, compared to \$10.6 million including \$1.1 million of share-based compensation for the same quarter in 2009. Research and development expenses for the full year ended December 31, 2010 were \$30.6 million, including \$5.3 million of share-based compensation, compared to \$34.6 million including \$3.7 million of share-based compensation in 2009. Research and development expenses for the full year ended December 31, 2010 included costs related to AMPYRA post-marketing studies, clinical costs associated with the close-out of the Company's MS extension study sites, launch stock inventory received prior to regulatory approval and the development of the Company's pipeline products, including the initiation of a Phase 1 clinical trial for Glial Growth Factor 2 (GGF2).

Sales, general and administrative expenses for the quarter ended December 31, 2010 were \$41.8 million, including \$3.6 million of share-based compensation, compared to \$22.9 million including \$2.3 million of share-based compensation for the same quarter in 2009. Sales, general and administrative expenses for the full year ended December 31, 2010 were \$133.3 million, including \$12.5 million of share-based compensation, compared to \$90.3 million including \$8.6 million of share-based compensation in 2009. The increase in expenses was primarily due to increases in AMPYRA launch activities.

The Company reported net income of \$3.7 million for the quarter ended December 31, 2010, or \$0.10 per basic EPS and \$0.09 per diluted EPS, compared to a net loss of \$22.5 million, or \$0.59 per basic and diluted EPS for the same quarter in 2009. The Company reported a net loss of \$11.8 million for the full year ended December 31, 2010, or \$0.31 per basic and diluted EPS, compared to a net loss of \$83.9 million, or \$2.22 per basic and diluted EPS, in 2009.

As of December 31, 2010, Acorda held cash, cash equivalents and short-term investments of \$240.0 million.

AMPYRA Update

- As of December 31, 2010, approximately 40,000 people with MS have filled a prescription for AMPYRA, representing approximately 10% of all MS patients in the United States.
- Approximately 7,000 healthcare professionals had written at least one prescription for AMPYRA as of December 31, 2010.
- As part of its post-marketing commitment to the U.S. Food and Drug Administration (FDA), the Company has initiated a clinical trial of a 5 mg tablet, as well as a renal impairment trial.
- The Company is currently working with external formulation companies to develop a once-daily formulation of AMPYRA.
- New clinical data analyses on AMPYRA will be presented at the upcoming American Academy of Neurology (AAN) meeting in April 2011.
- On January 21, 2011 Biogen Idec announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) decided against approval of FAMPYRA[®] (prolonged-release fampridine 10 mg tablets) to improve walking ability in adult patients with multiple sclerosis (MS). Biogen Idec is appealing for a re-examination of the decision by the CHMP.

ZANAFLEX CAPSULES and ZANAFLEX Tablets Franchise

- Under the terms of the Paul Royalty Fund (PRF) agreement, the Company paid the second of two \$5.0 million payments to PRF in December 2010.
- The litigation against Apotex Inc. in connection with its application for approval of a generic version of ZANAFLEX CAPSULES continues to proceed, and a trial date has been set for April 25, 2011.

Pipeline

- Acorda initiated a single dose Phase 1 clinical trial for Glial Growth Factor 2 (GGF2) in patients with heart failure. Preclinical studies demonstrate that GGF2 acts directly to repair cardiac muscle and improve its contractile function, and may offer a unique therapeutic option for treatment of the disease.
- The Company's remyelinating antibody, rHIgM22, has completed GMP manufacturing and pilot toxicology studies. GLP toxicology studies are ongoing, and if results are acceptable the Company expects to file an Investigational New Drug (IND) application.

Guidance for 2011

- The Company currently expects AMPYRA full year net revenue to increase to \$205-\$230 million.
- Sales, general and administrative (SG&A) expenses for the full year 2011 are currently expected to be \$130-\$140 million excluding share based compensation charges. SG&A will be primarily driven by commercial and administrative costs related to AMPYRA.
- Research and development (R&D) expenses for the full year 2011 are currently expected to be \$40-\$45 million excluding share based compensation charges. R&D expenses in 2011 include post-marketing studies for AMPYRA and continuing development expenses for our pipeline products, including Phase 1 clinical trials for GGF2.

Webcast and Conference Call

Ron Cohen, President and Chief Executive Officer and David Lawrence, Chief Financial Officer will host a conference call today at 8:30 a.m. ET to review the Company's fourth quarter and full year 2010 results.

To participate in the conference call, please dial 866-783-2138 (domestic) or 857-350-1597 (international) and reference the access code 85537670. The presentation will be available via a live webcast at:

<http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2652920>

A replay of the call will be available from 11:30 a.m. ET on February 17, 2011 until midnight on March 17, 2011. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 24273931. The archived webcast will be available for 30 days in the Investor Events section of the Acorda website at <http://www.acorda.com>.

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 ($\text{CrCl} \leq 50$ 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.

Acorda Therapeutics, Inc
Condensed Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	December 31, 2010	December 31, 2009
Assets		
Cash, cash equivalents and short-term investments	\$ 240,029	\$ 272,092
Trade receivable, net	22,411	5,879
Other current assets	10,310	8,417
Finished goods inventory	38,418	6,893
Property and equipment, net	3,203	1,891
Intangible assets, net	21,336	17,149
Other assets	6,394	7,150
Total assets	<u>\$ 342,101</u>	<u>\$ 319,471</u>
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	\$ 51,082	\$ 26,589
Deferred product revenue	31,296	30,704
Current portion of deferred license revenue	9,429	9,429
Current portion of notes payable	1,144	-
Current portion of revenue interest liability	1,297	6,179
Long term notes payable	6,186	7,112
Non-current portion of revenue interest liability	3,977	6,268
Non-current portion of deferred license revenue	86,429	95,857
Stockholders' equity	151,261	137,333
Total liabilities and stockholders' equity	<u>\$ 342,101</u>	<u>\$ 319,471</u>

Acorda Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended			
	Ended	Twelve Months		
		2010	2009	December 31, 2010
Revenues:				
Net revenues	\$ 64,411	\$ 12,083	\$ 181,545	\$ 49,959
License and royalty revenue	2,389	2,357	9,460	4,714
Total revenues	<u>66,800</u>	<u>14,440</u>	<u>191,005</u>	<u>54,673</u>
Costs and expenses:				
Cost of sales	12,944	2,946	35,518	11,059
Research and development	7,972	10,629	30,600	34,611
Selling, general and administrative	41,768	22,898	133,317	90,261
Total operating expenses	<u>62,684</u>	<u>36,473</u>	<u>199,435</u>	<u>135,931</u>
Operating income (loss)	<u>\$ 4,116</u>	<u>\$ (22,033)</u>	<u>\$ (8,430)</u>	<u>\$ (81,258)</u>
Other expense, net	(445)	(441)	(3,339)	(2,683)
Net income (loss)	<u>\$ 3,671</u>	<u>\$ (22,474)</u>	<u>\$ (11,769)</u>	<u>\$ (83,941)</u>
Net income (loss) per common share - basic	\$ 0.10	\$ (0.59)	\$ (0.31)	\$ (2.22)
Net income (loss) per common share - diluted	\$ 0.09	\$ (0.59)	\$ (0.31)	\$ (2.22)
Weighted average per common share - basic	38,636	37,837	38,355	37,735
Weighted average per common share - diluted	38,911	37,837	38,355	37,735