ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
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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): **May 5, 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 2.02 Results of Operations and Financial Condition

On May 5, 2011, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2011. 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

Exhibit No.	Description
99.1	Press Release dated May 5, 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.

May 5, 2011

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated May 5, 2011

EXHIBIT 99.1

CONTACT:

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

FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports First Quarter 2011 Financial Results

- *AMPYRA ® (dalfampridine) Net Revenue of $46.8 Million; Maintain Current Year Guidance of $205-$230 Million AMPYRA Net Revenue*
- *AMPYRA Patent Application Allowed in U.S.; Patent Set to Expire February 2026*

HAWTHORNE, N.Y., May 5, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the first quarter ended March 31, 2011.

"We were delighted that the U.S. Patent and Trademark Office allowed our patent application related to the use of sustained release 4-aminopyridine to improve walking in people with MS. This provides patent coverage into 2026 and significant additional runway for AMPYRA's life cycle management," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "We also recently launched several initiatives highlighting the broad range of MS patients who can potentially benefit from AMPRYA, including those at earlier stages of their walking disability. We expect these programs will drive an increase in new patients being prescribed AMPYRA."

FINANCIAL RESULTS

The Company reported GAAP net loss of $0.7 million for the quarter ended March 31, 2011, or $0.02 per basic and diluted EPS, including share-based compensation charges totaling $3.8 million. The GAAP net loss for the first quarter of 2010 was $21.1 million, or $0.56 per basic and diluted EPS including share-based compensation charges of $3.2 million.

Non-GAAP net income, before share-based compensation charges, for the quarter ended March 31, 2011 was $3.1 million or $0.08 per share, compared to a non-GAAP net loss of $17.9 million, or $0.47 per share for the same quarter in 2010.

AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg net revenue - For the quarter ended March 31, 2011, the Company reported AMPYRA net revenue of $46.8 million, compared to $3.1 million in net revenue for the same quarter in 2010. 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 March 31, 2011, the Company reported combined net revenue of ZANAFLEX CAPSULES and ZANAFLEX tablets of $12.2 million, compared to combined net revenue of $12.3 million for the

same quarter in 2010.

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 March 31, 2011 were $16.9 million, compared to total shipments of $13.4 million for the same quarter in 2010.

Research and development expenses for the quarter ended March 31, 2011 were $10.7 million, including $1.1 million of share-based compensation, compared to $8.1 million including $0.8 million of share-based compensation for the same quarter in 2010. Research and development expenses for the quarter included costs related to AMPYRA post-marketing studies and life cycle management programs, clinical costs associated with the close-out of the Company's AMPYRA multiple sclerosis (MS) extension study sites and the development of the Company's pipeline products, including Phase 1 clinical trial expenses for Glial Growth Factor 2 (GGF2).

The Company reaffirms its full year 2011 research and development expense guidance of $40-$45 million excluding share-based compensation charges.

Sales, general and administrative expenses for the quarter ended March 31, 2011 were $38.1 million, including $2.7 million of share-based compensation, compared to $26.7 million including $2.4 million of share-based compensation for the same quarter in 2010. The increase in expenses was primarily due to increases in AMPYRA sales and marketing activities and expenses related to ZANAFLEX CAPSULES patent infringement litigation.

The Company reaffirms its full year 2011 sales, general and administrative expense guidance of $130-$140 million excluding share-based compensation charges.

As of March 31, 2011, Acorda held cash, cash equivalents and short-term investments of $225.3 million.

This press release includes financial results prepared in accordance with accounting principles generally accepted in the United States (GAAP), and also certain historical and forward-looking non-GAAP financial measures. In particular, Acorda has provided its first quarter 2011 and 2010 income (loss), adjusted to exclude share-based compensation charges, and has also provided projected amounts of research and development (R&D) and sales, general, and administrative (SG&A) expenses excluding share-based compensation charges. These non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, we believe the presentation of income (loss) and projected R&D and SG&A expenses excluding share-based compensation charges, when viewed in conjunction with our GAAP results, provide investors with a more meaningful understanding of our ongoing and projected operating performance because they exclude non-cash charges that are substantially dependent on changes in the market price of our common stock. We believe these non-GAAP financial measures help indicate underlying trends in the company's business, and are important in comparing current results with prior period results and understanding projected operating performance. Also, management uses these non-GAAP financial measures to establish budgets and operational goals, and to manage the company's business and to evaluate its performance. A reconciliation of the historical non-GAAP financial results presented in this release to our GAAP financial results is included in the attached financial statements.

AMPYRA UPDATE

- On April 19, the Company announced that the United States Patent and Trademark Office (USPTO) allowed U.S. Patent Application No. 11/010,828 entitled "Sustained Release Aminopyridine Composition." The claims of the patent application relate to methods to improve walking in patients with multiple sclerosis (MS) by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. The patent that issues from this application, which will be eligible for listing in the U.S. Food and Drug Administration (FDA) Orange Book, is set to expire in early February 2026, based on the USPTO's calculated patent term adjustment of 413 days, which the Company is currently evaluating.

- As part of the process to determine if AMPYRA is eligible for patent extension of up to five years under provisions in the Hatch-Waxman Act, the FDA issued notice that it had determined the total review period for AMPYRA. This finding is subject to a public comment period, during which a petition can be filed to recalculate the eligible days of review. Following the conclusion of this process, the FDA determination becomes final, and the patent term extension application is returned to the USPTO for review.
- New clinical data analyses on AMPYRA were presented at the American Academy of Neurology (AAN) meeting in April 2011. Data presentations included analyses showing that people with MS who responded to AMPYRA had comparable improvements in their walking regardless of baseline walking speed or overall level of MS-related disability. In addition, AMPYRA responders, regardless of baseline disability, showed clinically meaningful improvement on the 12-Item MS Walking Scale (MSWS-12), a patient-based questionnaire that measures the impact of MS on the patient's reported ability to perform daily activities related to walking.
- Effective March 4, 2011, the Company implemented a 7.5% increase for the wholesale acquisition price (WAC) of AMPYRA. The current WAC is $1,135.37 per 30-day supply (60-count pill bottle).
- Acorda is working closely with its partner Biogen Idec on an appeal of the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) negative opinion recommending against the approval of FAMPYRA (the proposed trade name for AMPYRA in Europe).

ZANAFLEX CAPSULES

- The litigation against Apotex Inc. in connection with its application for approval of a generic version of ZANAFLEX CAPSULES is proceeding. The trial date, initially set for April 25, has been moved to May 9, 2011.

PIPELINE

- The Phase 1 GGF2 clinical trial in heart failure patients, being conducted in collaboration with the Vanderbilt University Heart and Vascular Institute, is ongoing.

CORPORATE UPDATES

- Peder Jensen, M.D. was elected to the Board of Directors effective April 19, 2011. Dr. Jensen has more than 24 years of global drug development experience in both pharmaceutical and biotechnology companies, across therapeutic areas including neurology, cardiovascular, anti-infective, oncology and immunology. Most recently, he served as Corporate Senior Vice President, and General Manager, R&D for Japan and Asia/Pacific at Schering-Plough Corporation.
- Wise Young, Ph.D., M.D., resigned from the Board of Directors effective April 19, 2011. Dr. Young served on Acorda's Board of Directors since the Company's founding in 1995, and will continue to advise the Company in a consulting role as Special Scientific Advisor.

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 first quarter 2011 results.

To participate in the conference call, please dial 866-783-2143 (domestic) or 857-350-1602 (international) and reference the access code 70090382. The presentation will be available via a live webcast at:

http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=3958469

A replay of the call will be available from 11:30 a.m. ET on May 5, 2011 until midnight on June 5, 2011. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 59728324. 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 (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 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 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 STATEMENT

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.

Financial Statements

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

	March 31, 2011	December 31, 2010
Assets		
Cash, cash equivalents and short-term investments	$ 225,347	$ 240,029
Trade receivable, net	23,795	22,272
Other current assets	11,743	10,449
Finished goods inventory	44,795	38,418
Property and equipment, net	3,594	3,203
Intangible assets, net	20,707	21,336
Other assets	6,226	6,394
Total assets	$ 336,207	$ 342,101
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 44,958	$ 51,082
Deferred product revenue	30,936	31,296
Current portion of deferred license revenue	9,057	9,429
Current portion of notes payable	1,144	1,144
Current portion of revenue interest liability	1,979	1,297
Long term notes payable	5,090	6,186
Non-current portion of revenue interest liability	3,720	3,977
Non-current portion of deferred license revenue	84,535	86,429
Stockholders' equity	154,788	151,261
Total liabilities and stockholders' equity	$ 336,207	$ 342,101

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

	Three Months Ended March 31,	
	2011	**2010**
Revenues:		
Net revenues	$ 58,925	$ 15,391
License and royalty revenue	2,361	2,357
Total revenues	61,286	17,748
Costs and expenses:		
Cost of sales	12,050	3,076
Research and development	10,708	8,062
Selling, general and administrative	38,087	26,714
Total operating expenses	60,845	37,852
Operating income (loss)	$ 441	$ (20,104)
Other expense, net	(996)	(1,010)
Loss before income taxes	(555)	(21,114)
Provision for income taxes	(117)	-
Net loss	$ (672)	$ (21,114)
Net loss per common share - basic	$ (0.02)	$ (0.56)
Net loss per common share - diluted	$ (0.02)	$ (0.56)
Weighted average per common share - basic	38,781	38,021
Weighted average per common share - diluted	38,781	38,021

Acorda Therapeutics, Inc.
Non-GAAP Income (Loss) and Income (Loss) per Common Share Reconciliation
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2011	**2010**
GAAP net loss	$ (672)	$ (21,114)
Pro forma adjustments:		
Share-based compensation expenses included in R&D	1,103	790
Share-based compensation expenses included in SG&A	2,652	2,396
Total pro forma adjustments	3,755	3,186
Non-GAAP net income (loss)	$ 3,083	$ (17,928)
Net income (loss) per common share - basic	$ 0.08	$ (0.47)
Net income (loss) per common share - diluted	$ 0.08	$ (0.47)
Weighted average per common share - basic	38,781	38,021
Weighted average per common share - diluted	39,769	38,021