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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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): **April 30, 2010**

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 April 30, 2010, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 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

99.1 Press Release dated April 30, 2010.

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.

April 30, 2010

By: */s/ David Lawrence*

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated April 30, 2010

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports First Quarter 2010 Financial Results

- **AMPYRA™ (dalfampridine) Extended Release Tablets, 10 mg Approved January 22, 2010; Launched March 1, 2010**
- **Filed Investigational New Drug Application on March 19 for Lead Preclinical Product, GGF2, in Heart Failure**

HAWTHORNE, N.Y., April 30, 2010 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the first quarter of 2010.

"We are very pleased by the performance of AMPYRA since it became commercially available on March 1. As of April 29, more than 2,000 physicians have written at least one prescription and we have already received many reports about the positive impact AMPYRA is having on people with MS," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "We are also excited to have filed an Investigational New Drug Application for our lead preclinical product, GGF2, and expect to start a Phase 1 clinical trial in patients with heart failure in mid-2010."

Financial Results and Product Update
AMPYRA gross sales - For the quarter ended March 31, 2010, the Company reported gross sales of AMPYRA of $3.4 million compared to no gross sales for the same quarter in 2009. Gross sales of AMPYRA are recognized following shipment of the product from the Company's distribution facility to its network of specialty pharmacies. Acorda began shipping AMPYRA to specialty pharmacies on March 1, 2010.

ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and ZANAFLEX ® (tizanidine hydrochloride) Tablets gross sales - For the quarter ended March 31, 2010, the Company reported combined gross sales of ZANAFLEX CAPSULES and ZANAFLEX tablets of $13.8 million compared to combined gross sales of $14.6 million for the same quarter in 2009. ZANAFLEX gross sales are recognized using a deferred revenue recognition model, meaning ZANAFLEX CAPSULES and ZANAFLEX tablet 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. The Company expects sales of ZANAFLEX CAPSULES will decline in 2010.

ZANAFLEX CAPSULES and ZANAFLEX Tablets shipments - Total ZANAFLEX CAPSULES and ZANAFLEX tablet shipments for the quarter ended March 31, 2010 were $13.4 million, compared to total shipments of $16.3 million for the same quarter in 2009.

Research and development expenses for the quarter ended March 31, 2010 were $8.1 million, including $0.8 million of share-based compensation, compared to $7.9 million including $0.8 million of share-based compensation for the same quarter in 2009. Research and development expense increases for the quarter ended March 31, 2010 included costs related to AMPYRA long-term extension studies, expensed AMPYRA inventory received prior to regulatory approval and development of the Company's preclinical pipeline products.

Sales, general and administrative expenses for the quarter ended March 31, 2010 were $26.7 million, including $2.4 million of share-based compensation, compared to $20.0 million including $1.9 million of share-based compensation for the same quarter in 2009. The increase in expenses was primarily due to increases in AMPYRA pre-launch and launch activities. Acorda expects that launch expenses will continue to increase significantly throughout the course of the year.

The Company reported a net loss of $21.1 million for the quarter ended March 31, 2010, or $0.56 per diluted common share, compared to a net loss of $18.7 million, or $0.50 per diluted common share, for the same quarter in 2009.

During the first quarter of 2010, the Company received approximately $19 million in shipments of AMPYRA inventory from Elan Pharma International Limited for product and safety stock requirements.

As of March 31, 2010, Acorda held cash, cash equivalents and short-term investments of $243.6 million.

AMPYRA Update

- On January 22, 2010 AMPYRA™ (dalfampridine) Extended Release Tablets, 10 mg was approved by the U.S. Food and Drug Administration (FDA) as an oral treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed. AMPYRA demonstrated efficacy in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). AMPYRA can be used alone or with existing MS therapies, including immunomodulator drugs.
- On March 1, 2010 AMPYRA became commercially available. AMPYRA is being distributed exclusively through a network of specialty pharmacies, coordinated by AMPYRA Patient Support Services (APSS). This distribution process is well established within the MS community, and physicians and patients are familiar with this model. The process begins when a prescription is submitted by a physician to APSS. APSS then conducts a benefits investigation for the patient, and communicates with the patient about insurance coverage for AMPYRA. APSS also provides information on co-pay and patient assistance programs. Once this process is completed, the prescription is sent to a specialty pharmacy, which confirms the benefits and mails the prescription directly to the patient.
- As of April 29, 2010 more than 2,000 physicians had written at least one prescription for AMPYRA.
- Due to initial pent-up demand, currently it is taking up to 30 days to complete the process and deliver AMPYRA to the patient. In response, resources have been added at AMPYRA Patient Support Services. Consequently, waiting time for initial prescriptions has begun to decrease and is expected to continue to decrease over time. The Company believes it has adequate drug stock to meet demand.
- Acorda completed the expansion of its sales force in March, with 100 sales representatives calling on approximately 5,500 target physicians. The Company also has teams of Regional Scientific Managers and Managed Markets representatives providing information on AMPYRA to physicians and payors.

- Four new analyses of long-term clinical trial data were presented at the 62nd American Academy of Neurology (AAN) Annual meeting in April 2010. The Company has also submitted data for the upcoming CMSC meeting in June 2010.
- Acorda's partner Biogen Idec, which is responsible for commercialization outside the U.S., has filed regulatory applications for Fampridine prolonged-release tablets in regions including Europe, Canada, Switzerland, Australia and New Zealand.

GGF2

- In March, Acorda submitted an Investigational New Drug (IND) application for GGF2 as a therapy for heart failure. The Company plans to initiate a Phase 1 single ascending dose clinical trial in patients with heart failure in mid-2010.

Corporate Update

- Lauren Sabella joined the Company as Executive Vice President of Commercial Development, and Adrian L. Rabinowicz, M.D., FAAN, joined as Senior Vice President and Head, Medical Affairs.

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 2010 results.

To participate in the conference call, please dial 866-804-6920 (domestic) or 857-350-1666 (international) and reference the access code 95216244. The presentation will be available via a live webcast at:

http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2652906

A replay of the call will be available from 12:30 p.m. ET on April 30, 2010 until midnight on May 30, 2010. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 12059307. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at http://www.acorda.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's marketed products include AMPYRA™ (dalfampridine), 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; and 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, 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. 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, 2010	December 31, 2009
Assets		
Cash, cash equivalents and short-term investments	$ 243,589	$ 272,092
Trade receivable, net	8,083	5,879
Other current assets	10,709	8,417
Finished goods inventory	23,612	6,893
Property and equipment, net	2,087	1,891
Intangible assets, net	23,180	17,149
Other assets	6,956	7,150
Total assets	$ 318,216	$ 319,471
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 42,133	$ 26,589
Deferred product revenue	29,707	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	6,749	6,179
Long term notes payable	6,025	7,112
Non-current portion of revenue interest liability	6,082	6,268
Non-current portion of deferred license revenue	93,500	95,857
Stockholders' equity	123,447	137,333
Total liabilities and stockholders' equity	$ 318,216	$ 319,471

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

	Three Months Ended March 31,	
	2010	**2009**
Revenues:		
Gross product sales	$ 17,254	$ 14,618
Less: discounts and allowances	(1,863)	(2,149)
Net sales	15,391	12,469
License revenue	2,357	—
Total revenues	17,748	12,469
Costs and expenses:		
Cost of sales	3,076	2,559
Research and development	8,062	7,917
Selling, general and administrative	26,714	20,021
Total operating expenses	37,852	30,497
Operating loss	$ (20,104)	$ (18,028)
Other expense, net	(1,010)	(680)
Net loss	$ (21,114)	$ (18,708)
Net loss per common share - basic and diluted	$ (0.56)	$ (0.50)
Weighted average per common share - basic and diluted	38,021	37,643