ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 05/06/09 for the Period Ending 05/06/09

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): **May 6, 2009**

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 6, 2009, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2009. 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

99.1 Press Release dated May 6, 2009.

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 6, 2009

By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated May 6, 2009

Exhibit 99.1

CONTACT:

Tierney Saccavino
Acorda Therapeutics
(914) 347-4300 ext. 104
tsaccavino@acorda.com

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

FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports First Quarter 2009 Financial Results

- **Fampridine-SR New Drug Application (NDA) Accepted for Filing by FDA on May 5, 2009**
    - **Priority Review Granted; October 22, 2009 PDUFA Date**

HAWTHORNE, N.Y., May 6, 2008 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the first quarter of 2009.

"I am pleased that we were able to work quickly to address the comments from the FDA and resubmit our NDA, approximately three weeks from having received the Refuse to File letter on our initial NDA submission, and that the FDA accepted the filing two weeks later," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "We are also encouraged that the FDA has elected to assign Priority Review status to the Fampridine-SR NDA. Our focus in the coming months is to work with the FDA during the regulatory review of Fampridine-SR, to prepare for its launch in the U.S., if approved, and to continue discussions with potential Fampridine-SR commercialization partners for ex-U.S. markets."

Financial Results and Product Update
Zanaflex Capsules ® (tizanidine hydrochloride) and Zanaflex ® (tizanidine hydrochloride) Tablets gross sales - For the quarter ended March 31, 2009, the Company reported combined gross sales of Zanaflex Capsules and Zanaflex tablets of $14.6 million, compared to combined gross sales of $12.7 million for the same quarter in 2008. 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.

Zanaflex Capsules and Zanaflex Tablets shipments - Total Zanaflex Capsules and Zanaflex tablet shipments for the quarter ended March 31, 2009 were $16.3 million, compared to total shipments of $14.8 million for the same quarter in 2008.

Research and development expenses for the quarter ended March 31, 2009 were $7.9 million, including $0.8 million of share-based compensation, compared to $9.6 million including $0.4 million of share-based compensation for the same quarter in 2008. Research and development expense increases for the quarter ended March 31, 2009 included costs related to our Fampridine-SR long-term extension studies, costs related to our NDA preparation and filing for Fampridine-SR and development of our preclinical pipeline products. The decrease in R&D costs in the first quarter of 2009 compared to the first quarter of 2008 is primarily due to the Company's

acquisition of certain in-process research and development assets from NRI, which resulted in a non-cash expense of approximately $2.7 million during the quarter ended March 31, 2008.

Sales, general and administrative expenses for the quarter ended March 31, 2009 were $20.0 million, including $1.9 million of share-based compensation, compared to $15.3 million including $1.5 million of share-based compensation for the same quarter in 2008. This increase in expenses was primarily due to increases in Fampridine-SR pre-launch activities and SG&A staff and compensation. Sales, general and administrative expenses are expected to increase in 2009 compared to 2008, primarily due to an increase in our expected pre-launch costs.

Other expense for the quarter ended March 31, 2009 was $0.7 million compared to $0.1 million for the same quarter in 2008.

The Company reported a net loss of $18.7 million for the quarter ended March 31, 2009, or $0.50 per diluted common share, compared to a net loss of $16.4 million, or $0.54 per diluted common share, for the same quarter in 2008.

As of March 31, 2009, Acorda held cash, cash equivalents and short-term investments of $226.0 million, which are expected to be sufficient to fund the Company's operations through 2010.

Fampridine-SR Update

- Acorda submitted the Fampridine-SR NDA to the FDA on January 30, 2009. On March 30, the Company received a Refuse to File (RTF) letter from the FDA, which cited the need to correct "format issues" and requested additional supporting information before the NDA could be accepted for review. Based on subsequent discussions with the FDA, Acorda resubmitted the Fampridine-SR NDA on April 22, 2009. On May 5, 2009, the FDA accepted the Fampridine-SR NDA for filing and assigned it Priority Review with a Prescription Drug User Fee Act (PDUFA) date of October 22, 2009.

- The Company is continuing discussions with potential Fampridine-SR commercialization partners for ex-U.S. markets. As Acorda determines the commercialization path in these markets, the Company is preparing for a centralized MAA filing in the EU and an NDS filing to Health Canada.

- In February 2009, the results of the first Phase 3 study of Fampridine-SR in MS, MS-F203, were published in the prestigious medical journal *The Lancet* .

Corporate Update

- Acorda supported the National Multiple Sclerosis Society's Walk MS program as National Sponsor in 2009. This sponsorship ties into Acorda's *I Walk Because* campaign, the Company's flagship outreach initiative to the MS community. The campaign is built around Acorda's IWalkBecause.org web site and the *I Walk Because* booth, which is featured at 14 Walk MS events across the country. The Company estimates that more than 25,000 individuals have visited the booth this year.

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 2009 results.

To participate in the conference call, please dial 800-659-2056 (domestic) or 617-614-2714 (international) and reference the access code 39750877. The presentation will be available via a live webcast at:
http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2195534

A replay of the call will be available from 10:30 a.m. ET on May 6, 2009 until midnight on June 3, 2009. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 55087603. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at http://www.acorda.com.

About Fampridine-SR
Fampridine-SR is a sustained-release tablet formulation of the investigational drug fampridine (4-aminopyridine or 4-AP). In laboratory studies, fampridine has been found to improve impulse conduction in nerve fibers in which the insulating layer, called myelin, has been damaged.

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company developing therapies for spinal cord injury, multiple sclerosis and related nervous system disorders. The Company's marketed products include 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 delays in obtaining or failure to obtain FDA approval of Fampridine-SR, the risk of unfavorable results from future studies of Fampridine-SR, Acorda Therapeutics' ability to successfully market and sell Fampridine-SR, if approved, and Zanaflex Capsules, competition, failure to protect its 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 its 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, 2009	December 31, 2008
Assets		
Cash, cash equivalents and short-term investments	$ 225,952	$ 246,049
Trade receivable, net	4,743	4,762
Other current assets	6,381	5,094
Finished goods inventory	5,064	6,144
Property and equipment, net	2,780	2,348
Intangible assets, net	16,245	16,565
Other assets	501	539
Total assets	$ 261,666	$ 281,501
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 18,340	$ 24,119
Deferred product revenue	25,368	24,304
Current portion of revenue interest liability	6,921	6,181
Long term notes payable	6,957	6,905
Non-current portion of revenue interest liability	12,588	12,835
Stockholders' equity	191,492	207,157
Total liabilities and stockholders' equity	$ 261,666	$ 281,501

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

	Three Months Ended March 31,	
	2009	2008
Gross sales - Zanaflex	$ 14,618	$ 12,676
Less: discounts and allowances	(2,149)	(1,189)
Net sales	12,469	11,487
Grant revenue	—	26
Total net revenue	12,469	11,513
Cost of sales	(2,559)	(2,986)
Gross profit	9,910	8,527
Operating expenses:		
Research and development	7,917	9,592
Sales and marketing	12,874	10,197
General and administrative	7,147	5,063
Total operating expenses	27,938	24,852
Operating loss	$ (18,028)	$ (16,325)
Other expense, net	(680)	(106)
Net loss	$ (18,708)	$ (16,431)
Net loss per common share - basic and diluted	$ (0.50)	$ (0.54)
Weighted average per common share - basic and diluted	37,643	30,344