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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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, 2008**

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, 2008, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2008. 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 5, 2008.

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, 2008

By: /s/ David Lawrence
Name: David Lawrence, M.B.A.
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated May 5, 2008

Exhibit 99.1

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports First Quarter 2008 Financial Results

HAWTHORNE, N.Y., May 5, 2008 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the first quarter 2008.

"Acorda made impressive progress in all areas of our business in the first quarter of 2008. We reported favorable results of our Fampridine-SR Thorough QT study, continued to deliver solid Zanaflex Capsules sales performance, and entered into a manufacturing agreement for our preclinical neuregulins program. In addition, we were successful in raising approximately $75 million in additional capital to fund our programs," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "As a result, we are well-positioned to address the important milestones ahead, particularly completion of our Phase 3 trial of Fampridine-SR which, if successful, will be followed by the filing of a new drug application, or NDA, in the first quarter of 2009. We are also executing on pre-launch activities and the preparation of our preclinical pipeline for two potential investigational new drug, or IND, filings in late 2009."

Financial Results and Product Update

Zanaflex ® (tizanidine hydrochloride) Gross Sales - For the quarter ended March 31, 2008, the Company reported gross sales of Zanaflex Capsules ® (tizanidine hydrochloride) of $11.8 million and gross sales of Zanaflex tablets of $0.9 million, providing combined gross sales of $12.7 million, compared to gross sales of Zanaflex Capsules of $7.6 million and gross sales of Zanaflex tablets of $1.2 million providing combined gross sales of $8.8 million for the same quarter in 2007. Gross sales are recognized using a deferred revenue recognition model, meaning Zanaflex product shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of Zanaflex Capsules and tablets are reported.

Zanaflex Shipments - Zanaflex Capsules shipments for the quarter ended March 31, 2008 were $13.6 million and Zanaflex tablet shipments were $1.2 million, providing total shipments of $14.8 million compared to $7.1 million of Zanaflex Capsules shipments and $0.8 million of tablet shipments for total shipments of $7.9 million for the same quarter in 2007.

"Zanaflex Capsules have played a vital role in allowing Acorda to transition into a fully-integrated pharmaceutical company. The commercial expertise we have developed from launching this product and growing the business has prepared us for the launch of Fampridine-SR, if approved," said John Librie, Senior Vice President, Sales and Marketing. "We anticipate continued sales growth in 2008, although at a more moderate pace as the Zanaflex franchise matures. We also expect our Zanaflex commercial operations to produce a positive net cash flow this year."

Research and development expenses for the quarter ended March 31, 2008 were $9.6 million, including a $2.7 million non-cash charge for the acquisition of certain assets from Neurorecovery, Inc. (NRI), and $0.4 million of share-based compensation, compared to $3.2 million, including $0.3 million of share-based compensation, for the same quarter in 2007. Other research and development expense increases for the quarter ended March 31, 2008 include clinical trial costs related to our Fampridine-SR Phase 3 trial, costs related to the preparation for a potential NDA filing and development of two of our preclinical pipeline products for potential IND filings in late 2009.

Sales, general and administrative expenses for the quarter ended March 31, 2008 were $15.3 million, including $1.5 million of share-based compensation, compared to $11.3 million including $1.9 million of share-based compensation for the same quarter in 2007. This increase in expenses was primarily due to increases in Zanaflex promotional activities and Fampridine-SR pre-launch activities. Sales, general and administrative expenses are expected to continue to increase in 2008 primarily due to an increase in our expected pre-launch activities.

The Company reported a net loss of $16.4 million for the quarter ended March 31, 2008, or $0.54 per diluted common share, compared to a net loss of $7.5 million, or $0.32 per diluted common share, for the same quarter in 2007.

The impact of the NRI acquisition discussed above and the differences between non-GAAP and GAAP net loss and net loss per diluted share are reconciled in the table below. The Company believes it is appropriate to present this supplemental information as it will allow investors to better understand the Company's operating results for the first quarter of 2008 and its ongoing performance in a manner similar to how the Company analyzes its operating results. Adjustments and other factors make it more difficult to make meaningful period to period comparisons. These non-GAAP financial measures should not be construed as being more important than comparable GAAP measures.

Reconciliation of GAAP Net Loss to Adjusted Net Loss

The following table reconciles the Company's net loss and net loss per diluted share as determined in accordance with U.S. generally accepted accounting principles (GAAP) to its adjusted net loss and net loss per diluted share for the three months ended March 31, 2008:

	Three Months Ended (in thousands, except per-share amounts)	
	March 31, 2008	
	Net loss	Net loss per diluted share
GAAP net loss	$ (16,431)	$ (0.54)
Net adjustments to GAAP:		
— NRI acquisition (1)	$ 2,686	$ 0.09
Adjusted net loss	$ (13,745)	$ (0.45)

(1) The Company's adjusted financial results for the first quarter of 2008 exclude the acquisition of certain assets from NRI. The Company issued 100,000 shares of its Common Stock as the purchase price for these assets. The transaction was accounted for as an acquisition of in-process research and development assets and, as such, resulted in a non-cash expense in the first quarter of 2008 of approximately $2.7 million. The per-share effect of this adjustment was derived by subtracting the computation of diluted earnings per share on the adjusted net loss from the GAAP net loss per share.

As of March 31, 2008, Acorda held cash, cash equivalents and short-term investments of $160.3 million. This is expected to be sufficient to fund the Company's operations into the third quarter of 2009, with spending weighted to the second half of 2008 and into 2009, pending the results of the Fampridine-SR Phase 3 trial.

Fampridine-SR Update

The Company announced results from a Thorough QT study, which evaluated the potential to cause an increase in the electrocardiographic QT interval. Fampridine-SR, at both therapeutic and supratherapeutic doses, was found to be no different than placebo.

The Company has requested meetings with regulatory authorities in key member states in the European Union with the goal of determining Acorda's EU regulatory strategy for Fampridine-SR. The Company expects to have an update on this strategy later in the year.

Data from the second Phase 3 study of Fampridine-SR are expected in the second half of the second quarter of 2008.

Pre-launch Activities Update

The Company implemented pre-launch community outreach activities, including a national sponsorship of the Walk MS Program in conjunction with the National MS Society (NMSS) with a booth presence at 10 of the largest walks across the country and launch of a companion website, www.iwalkbecause.org. The Company also launched an MS education program at the American Academy of Neurology (AAN) meeting this April in Chicago. This program aims to educate physicians and other caregivers treating patients with MS about walking issues.

Preclinical Update

On April 14, 2008, the Company hosted an analyst and investor event in Chicago to provide an overview of its two most advanced preclinical candidates, the remyelinating antibody and neuregulin programs. Dr. Moses Rodriguez, Professor of Neurology and Immunology at Mayo Clinic College of Medicine, and Dr. Douglas E. Vaughan, C. Sidney Burwell Professor of Medicine and Professor of Pharmacology and Chief, Division of Cardiovascular Medicine at Vanderbilt University, gave presentations highlighting efficacy in preclinical models of MS and cardiac damage, respectively, and anticipated clinical programs.

In published studies, the remyelinating antibodies have demonstrated the ability to stimulate repair of the myelin sheath in three different animal models of MS. In particular, these antibodies were found to react with molecules on the surface of cells that make the myelin sheath and stimulate them in a number of ways, leading to increased myelin activity. In preclinical studies, neuregulins have demonstrated potential for neurological protection in a number of indications, including models of MS and stroke. Neuregulins have also shown the potential to reduce and even reverse dysfunction in preclinical models of congestive heart failure by directly strengthening and protecting heart muscle cells.

Dr. Rodriguez was selected to give a plenary address on the remyelinating antibodies at the Frontiers in Clinical Neuroscience at the AAN annual meeting in Chicago.

Acorda has begun work with contract manufacturers for GGF2, its lead neuregulin development candidate and for rhIgM22, its lead remyelinating antibody candidate. These manufacturers will be responsible for process development, manufacturing scale-up and cGMP (current Good Manufacturing Practices) manufacturing of these molecules for toxicology studies and early phase clinical trials. The Company is targeting INDs for both of these programs in late 2009.

Corporate Update

The Company completed a successful public offering of 3.7 million shares of stock in February 2008, raising net proceeds of $74.6 million, which will be used to complete the second Phase 3 Fampridine-SR clinical trial, to conduct other activities related to the potential filing of a NDA and

preparation for a market launch of Fampridine-SR, if approved, for research and development and for general corporate purposes.

The Company acquired certain assets from Neurorecovery, Inc. to explore additional indications for Fampridine-SR, as well as gain access to pre-clinical compounds that may have utility in nervous system disorders.

Acorda collaborated with the NMSS to conduct and publish a Harris Interactive poll which provided new data related to the impact of mobility loss and walking difficulty on different aspects of daily life for people with multiple sclerosis.

John Librie was promoted to Senior Vice President, Sales and Marketing. Mr. Librie will continue to manage the sales and marketing efforts of Zanaflex Capsules, as well as oversee all pre-commercial and commercial initiatives around Fampridine-SR.

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 2008 results.

To participate in the conference call, please dial 800-659-1966 (domestic) or 617-614-2711 (international) and reference the access code 83158063. The presentation will be available via a live webcast at http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=1827800.

A replay of the call will be available from 10:30 a.m. ET on May 5, 2008 until midnight on June 5, 2008. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 39069479. 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). Laboratory studies have shown that fampridine can improve the communication between damaged nerves, which may result in increased neurological function. Fampridine-SR is currently being studied in a Phase 3 clinical trial to evaluate its safety and efficacy in improving walking ability in people with MS.

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. Acorda's lead clinical product, Fampridine-SR, is in a Phase 3 clinical trial to evaluate its safety and efficacy in improving walking ability in people with MS. 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 the risk of unfavorable results from future studies of Fampridine-SR, delays in obtaining or failure to obtain FDA approval of Fampridine-SR, Acorda Therapeutics' ability to successfully market and sell 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, 2008	December 31, 2007
Assets		
Cash, cash equivalents and short-term investments	$ 160,293	$ 95,121
Trade receivable, net	4,120	4,265
Other current assets	4,105	3,923
Finished goods inventory	6,743	7,724
Property and equipment, net	1,867	1,652
Intangible assets, net	18,348	13,944
Other assets	654	677
Total assets	$ 196,130	$ 127,306
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 19,166	$ 15,453
Deferred product revenue	23,492	21,837
Current liabilities	2,537	1,973
Long term notes payable	6,754	6,703
Non-current portion of revenue interest liability	17,479	17,907
Stockholders' equity	126,702	63,433
Total liabilities and stockholders' equity	$ 196,130	$ 127,306

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

	Three Months Ended March 31,	
	2008	**2007**
Gross sales - Zanaflex	$ 12,676	$ 8,805
Less: discounts and allowances	(1,189)	(494)
Net sales	11,487	8,311
Grant revenue	26	6
Total net revenue	11,513	8,317
Cost of sales	(2,986)	(1,554)
Gross profit	8,527	6,763
Operating expenses:		
Research and development	9,592	3,244
Sales and marketing	10,197	6,970
General and administrative	5,063	4,354
Total operating expenses	24,852	14,568
Operating loss	$ (16,325)	$ (7,805)
Other income (expense), net	(106)	256
Net loss	$ (16,431)	$ (7,549)
Net loss per common share - basic and diluted	$ (0.54)	$ (0.32)
Weighted average per common share - basic and diluted	30,344	23,693

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