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): **August 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 August 5, 2008, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 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 August 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.

August 5, 2008

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

Exhibit Index

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

Exhibit 99.1

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Second Quarter 2008 Financial Results

HAWTHORNE, N.Y., August 5, 2008 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the second quarter of 2008.

"Acorda continued to achieve important milestones in this quarter," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "In June, we announced positive results of our second Phase 3 clinical trial of Fampridine-SR in multiple sclerosis, which were consistent with the results of our successful first Phase 3 trial. We are now focused on completing our New Drug Application, or NDA, which we expect to file in the first quarter of 2009. In addition, our Zanaflex franchise continued to deliver solid performance in the face of a genericized market. This performance is a credit to the effectiveness of our commercial team, which will also provide the foundation for our commercial launch of Fampridine-SR, if approved."

Financial Results and Product Update

Zanaflex Capsules ® (tizanidine hydrochloride) and Zanaflex ® (tizanidine hydrochloride) Tablets Gross Sales - For the quarter ended June 30, 2008, the Company reported combined gross sales of Zanaflex Capsules and Zanaflex tablets of $13.1 million, compared to combined gross sales of $10.5 million for the same quarter in 2007. 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 tablets are reported.

Zanaflex Capsules and Zanaflex Tablets Shipments - Total Zanaflex Capsules and Zanaflex tablet shipments for the quarter ended June 30, 2008 were $ 16.0 million, compared to total shipments of $12.1 million for the same quarter in 2007.

Research and development expenses for the quarter ended June 30, 2008 were $8.1 million, including $0.6 million of share-based compensation, compared to $4.0 million including $0.3 million of share-based compensation for the same quarter in 2007. Research and development expense increases for the quarter ended June 30, 2008 include clinical trial costs related to our Fampridine-SR Phase 3 trial, costs related to the preparation for an 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 June 30, 2008 were $17.6 million, including $1.8 million of share-based compensation, compared to $11.6 million including $1.6 million of share-based compensation for the same quarter in 2007. This increase in expenses is primarily due to increases in Zanaflex Capsules promotional activities and Fampridine-SR pre-launch activities. Sales, general and administrative expenses are expected to continue to increase in 2008 and in 2009 primarily due to an increase in our expected pre-launch costs.

Interest expense for the quarter ended June 30, 2008 was $2.8 million compared to $0.8 million for the same quarter in 2007. The increase in interest expense is primarily due to a $1.4 million non-cash adjustment to the effective interest expense recognition related to the November 2006 amended revenue interests assignment agreement with an affiliate of Paul Capital Healthcare (formerly Paul Royalty Fund).

The Company reported a net loss of $18.8 million for the quarter ended June 30, 2008, or $0.58 per diluted common share, compared to a net loss of $8.2 million, or $0.33 per diluted common share, for the same quarter in 2007.

As of June 30, 2008, Acorda held cash, cash equivalents and short-term investments of $149.0 million, compared to $ 104.7 million on June 30, 2007. This $149.0 million is expected to be sufficient to fund the Company's operations into the fourth quarter of 2009.

Fampridine-SR Update

On June 2, the Company announced positive results from its second Phase 3 clinical trial of Fampridine-SR (MS-F204) on walking ability in people with multiple sclerosis (MS). A significantly greater proportion of people taking Fampridine-SR in the trial had a consistent improvement in walking speed compared to people taking placebo (42.9% vs. 9.3%), as measured by the Timed 25-Foot Walk ($p < 0.001$). Consistent improvement in walking speed was the primary endpoint of the study as agreed upon in the Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA). The study's only prospectively defined secondary outcome measure, leg strength, showed a statistically significant increase in the Fampridine-SR Timed Walk responders compared to placebo ($p = 0.028$). There was a small improvement in leg strength for Fampridine-SR Timed Walk non-responders compared to placebo that was not statistically significant.

The Company intends to present additional clinical results from this trial in September at the World Congress on Treatment and Research in Multiple Sclerosis.

As of July 18, 2008, 177 subjects from MS-F202 had been enrolled in an extension trial and 101, or approximately 57 percent, remained active in the trial, with duration of treatment ranging from 3.8 to 4.4 years. As of the same date, 269 patients from MS-F203 had been enrolled in a separate extension study and 203 of these, or approximately 75 percent, remained active, with duration of treatment ranging from 1.8 to 2.6 years. Also, as of this same date, 214 patients from MS-F204 had been enrolled in a third extension study and 194, or approximately 89 percent, remained active, with a duration of treatment ranging from one to 11 months. The total exposure to Fampridine-SR in our MS studies to date, including both double-blind and open label studies, is over 1,200 patient-years.

Corporate Update

Ron Cohen was appointed to the Executive Committee of the Biotechnology Industry Organization (BIO). Dr. Cohen was also named Vice Chair of the Emerging Companies Section of BIO. BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,200 members worldwide.

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 second quarter 2008 results.

To participate in the conference call, please dial 866-356-3377 (domestic) or 617-597-5392 (international) and reference the access code 76531596. The presentation will be available via a live webcast at http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=1907680.

A replay of the call will be available from 10:30 a.m. ET on August 5, 2008 until midnight on September 5, 2008. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 36885479. 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. Fampridine-SR recently completed a second 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, recently completed a second 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 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)

	June 30, 2008	December 31, 2007
Assets		
Cash, cash equivalents and short-term investments	$ 149,010	$ 95,121
Trade receivable, net	4,957	4,265
Other current assets	3,760	3,923
Finished goods inventory	6,475	7,724
Property and equipment, net	1,826	1,652
Intangible assets, net	17,751	13,944
Other assets	619	677
Total assets	$ 184,398	$ 127,306
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 19,761	$ 15,453
Deferred product revenue	24,696	21,837
Current liabilities	1,880	1,973
Long term notes payable	6,804	6,703
Non-current portion of revenue interest liability	18,845	17,907
Stockholders' equity	112,412	63,433
Total liabilities and stockholders' equity	$ 184,398	$ 127,306

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Gross sales - Zanaflex	$ 13,099	$ 10,499	$ 25,775	$ 19,304
Less: discounts and allowances	(1,740)	(1,014)	(2,929)	(1,509)
Net sales	11,359	9,484	22,846	17,795
Grant revenue	27	10	53	16
Total net revenue	11,386	9,494	22,899	17,811
Cost of sales	(2,830)	(2,011)	(5,816)	(3,565)
Gross profit	8,556	7,484	17,083	14,246
Operating expenses:				
Research and development	8,058	4,008	17,650	7,251
Sales and marketing	11,732	7,118	21,929	14,088
General and administrative	5,838	4,476	10,901	8,830
Total operating expenses	25,628	15,602	50,480	30,169
Operating loss	$ (17,072)	$ (8,118)	$ (33,397)	$ (15,923)
Other income (expense), net	(1,750)	(46)	(1,856)	211
Net loss	(18,822)	(8,164)	(35,253)	(15,712)
Net loss per common share - basic and diluted	$ (0.58)	$ (0.33)	$ (1.12)	$ (0.65)
Weighted average per common share - basic and diluted	32,557	24,450	31,451	24,074