ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Telephone	914-347-4300
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Symbol	ACOR
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
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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): **November 4, 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 November 4, 2008, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 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 November 4, 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.

November 4, 2008

By: */s/ David Lawrence*

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated November 4, 2008

Exhibit 99.1

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Third Quarter 2008 Financial Results

HAWTHORNE, N.Y., November 4, 2008 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the third quarter of 2008.

"We made significant progress this quarter in preparing a New Drug Application for Fampridine-SR, which we expect to submit electronically to the U.S. Food and Drug Administration in the first quarter of 2009. We also concluded a series of meetings with four European regulatory agencies, and as a result are planning to file a Marketing Authorization Application for Fampridine-SR in Europe in 2009," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "In addition, we completed a $127 million net equity financing in August, finishing the third quarter in a strong financial position with a cash balance of over $260 million."

Financial Results and Product Update

Zanaflex Capsules ® (tizanidine hydrochloride) and Zanaflex ® (tizanidine hydrochloride) Tablets Gross Sales - For the quarter ended September 30, 2008, the Company reported combined gross sales of Zanaflex Capsules and Zanaflex tablets of $13.7 million, compared to combined gross sales of $11.5 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 Zanaflex tablets are reported.

Zanaflex Capsules and Zanaflex Tablets Shipments - Total Zanaflex Capsules and Zanaflex tablet shipments for the quarter ended September 30, 2008 were $15.7 million, compared to total shipments of $13.2 million for the same quarter in 2007.

Research and development expenses for the quarter ended September 30, 2008 were $8.7 million, including $0.6 million of share-based compensation, compared to $5.6 million including $0.3 million of share-based compensation for the same quarter in 2007. Research and development expense increases for the quarter ended September 30, 2008 included costs related to our Fampridine-SR long-term extension studies, preparation for a New Drug Application (NDA) filing for Fampridine-SR and development of two of our preclinical pipeline products for potential Investigational New Drug (IND) filings in late 2009.

Sales, general and administrative expenses for the quarter ended September 30, 2008 were $20.3 million, including $2.1 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 was 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 September 30, 2008 was $0.9 million compared to $1.0 million for the same quarter in 2007.

The Company reported a net loss of $18.9 million for the quarter ended September 30, 2008, or $0.53 per diluted common share, compared to a net loss of $8.5 million, or $0.30 per diluted common share, for the same quarter in 2007.

As of September 30, 2008, Acorda held cash, cash equivalents and short-term investments of $263.2 million, compared to $105.1 million on September 30, 2007, which are expected to be sufficient to fund the Company's operations through 2010.

Fampridine-SR Scientific Update

On September 20, additional data from our second Phase 3 clinical trial of Fampridine-SR (MS-F204) on walking ability in people with multiple sclerosis (MS) was presented at the late breaking news session of the World Congress on Treatment and Research in Multiple Sclerosis. The key findings highlighted in the poster included:

- The response rate for Fampridine-SR treated patients was higher than placebo across all MS subtypes. Response rates for the four major MS subtypes in the study were: relapsing-remitting, 37.2%; secondary-progressive, 45.9%; primary-progressive, 50.0%; and progressive-remitting, 40.0%.
- Response rates were similar between study participants who were being treated with immunomodulators and those who were not.

Data from the Phase 2 Fampridine-SR multiple sclerosis trial (MS-F202) was published in the October edition of *Neurology* , the peer-reviewed journal of the American Academy of Neurology.

Fampridine-SR Regulatory Update

Acorda has completed scientific advice meetings with four European national regulatory agencies to discuss the development program completed for Fampridine-SR. As a result of these meetings, the Company plans to submit a Marketing Authorization Application (MAA) with the European Medicines Agency (EMEA) in 2009, under the centralized procedure, after the NDA is filed in the U.S. The Company is evaluating options to maximize the value of the product outside the U.S., including meeting with potential marketing and distribution partners.

Acorda is on track to file the NDA in the U.S. in the first quarter of 2009. The Company may also request Priority Review of the NDA.

Corporate Update

The Company completed a successful public offering of 4.6 million shares of its common stock in August 2008, raising net proceeds of approximately $127 million. This will be used to conduct activities related to the filing of an NDA and an MAA for Fampridine-SR, for pre-launch activities associated with the commercialization of Fampridine-SR, if approved, for research and development, including in connection with preclinical studies related to our neuregulin, remyelinating antibodies and chrondroitinase programs, and for general corporate purposes, including the funding of working capital and capital expenditures.

Acorda also announced its preclinical pipeline was selected by Windhover Information, a leader in providing analysis of the healthcare industry, as one of the top 10 most interesting neuroscience projects in development available for strategic partnering. Acorda plans to file IND applications in late 2009 for two preclinical compounds, a remyelinating monoclonal antibody (rhIgM22) and a

neuregulin protein with potential neurological and cardiac applications (GGF2), pending results of toxicology studies.

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 third quarter 2008 results.

To participate in the conference call, please dial 866-713-8310 (domestic) or 617-597-5308 (international) and reference the access code 13930885. The presentation will be available via a live webcast at http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2000115

A replay of the call will be available from 10:30 a.m. ET on November 4, 2008 until midnight on December 3, 2008. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 98421748. 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. In June 2008, Fampridine-SR 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 has completed two Phase 3 clinical trials to evaluate the safety and efficacy of Fampridine-SR 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)

	September 30, 2008	December 31, 2007
Assets		
Cash, cash equivalents and short-term investments	$ 263,245	$ 95,121
Trade receivable, net	4,016	4,265
Other current assets	3,695	3,923
Finished goods inventory	7,454	7,724
Property and equipment, net	1,869	1,652
Intangible assets, net	17,155	13,944
Other assets	545	677
Total assets	$ 297,979	$ 127,306
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 23,752	$ 15,453
Deferred product revenue	23,375	21,837
Current liabilities	1,338	1,973
Long term notes payable	6,854	6,703
Non-current portion of revenue interest liability	18,315	17,907
Stockholders' equity	224,345	63,433
Total liabilities and stockholders' equity	$ 297,979	$ 127,306

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Gross sales - Zanaflex	$ 13,667	$ 11,507	$ 39,442	$ 30,810
Less: discounts and allowances	(1,224)	(1,068)	(4,153)	(2,576)
Net sales	12,443	10,439	35,289	28,234
Grant revenue	23	20	76	36
Total net revenue	12,466	10,459	35,365	28,270
Cost of sales	(2,701)	(2,182)	(8,517)	(5,746)
Gross profit	9,765	8,278	26,848	22,524
Operating expenses:				
Research and development	8,651	5,603	25,758	12,854
Sales and marketing	14,420	7,918	36,349	22,006
General and administrative	5,948	3,720	17,392	12,550
Total operating expenses	29,019	17,241	79,499	47,410
Operating loss	$ (19,254)	$ (8,963)	$ (52,651)	$ (24,886)
Other income (expense), net	398	431	(1,458)	641
Net loss	$ (18,856)	$ (8,532)	$ (54,109)	$ (24,245)
Net loss per common share - basic and diluted	$ (0.53)	$ (0.30)	$ (1.65)	$ (0.95)
Weighted average per common share - basic and diluted	35,265	28,209	32,724	25,468