ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 02/24/09 for the Period Ending 02/24/09

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): **February 24, 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 February 24, 2009, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and the full year ended December 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 February 24, 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.

February 24, 2009

By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

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 Fourth Quarter and Full Year 2008 Financial Results

- Filed New Drug Application (NDA) for Lead Clinical Product, Fampridine-SR on January 30, 2009
- Announced Positive Results of Second Phase 3 Trial for Fampridine-SR in June 2008
- Ended 2008 with $246 Million in Cash, Cash Equivalents and Short-term Investments; Sufficient to Fund Operations Through 2010

HAWTHORNE, N.Y., February 24, 2009 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the fourth quarter and full year ended December 31, 2008.

“2008 was a year of exceptional achievement for Acorda. Our recent NDA filing for Fampridine-SR in MS follows the success of our second Phase 3 clinical trial, which was conducted under a special protocol assessment from the FDA. We have initiated pre-launch educational programs in the U.S., and are in discussions with potential marketing partners regarding the commercialization of Fampridine-SR in non-U.S. markets,” said Ron Cohen, M.D., President and CEO of Acorda Therapeutics. “In addition, by the end of this year we plan to file an initial Investigational New Drug application, or IND, for the lead clinical candidate in our neuregulins program, GGF2, in congestive heart failure. Having completed two successful financings in 2008, we had a cash balance of $246.0 million as of December 31, and are well capitalized to execute on our plans through 2010.”

Financial Results and Product Update

Zanaflex Capsules ® (tizanidine hydrochloride) and Zanaflex ® (tizanidine hydrochloride) tablets gross sales - For the fourth quarter ended December 31, 2008, the Company reported combined gross sales of Zanaflex Capsules and Zanaflex tablets of $14.0 million, compared to combined gross sales of $12.8 million for the same quarter in 2007. For the full year ended December 31, 2008, the Company reported combined gross sales of Zanaflex Capsules and Zanaflex tablets of $53.4 million, compared to combined gross sales of $43.6 million 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 December 31, 2008 were $16.5 million, compared to total shipments of $15.4 million for the same quarter in 2007. For the full year ended December 31, 2008, total Zanaflex Capsules and Zanaflex tablet shipments were $62.9 million, compared to total shipments of $48.6 million in 2007.

Research and development expenses for the quarter ended December 31, 2008 were $10.8 million, including $0.7 million of share-based compensation, compared to $9.6 million including $0.3 million of share-based compensation for the same quarter in 2007. Research and development expenses for the full year ended December 31, 2008 were $36.6 million, including $2.3 million of share-based compensation, compared to $22.4 million including $1.2 million of share-based compensation in 2007. Research and development expense increases for the full year ended December 31, 2008 included costs related to our Fampridine-SR Phase 3 and long-term extension studies, preparation for the NDA filing for Fampridine-SR and development of our preclinical pipeline products.

Sales, general and administrative expenses for the quarter ended December 31, 2008 were $19.6 million, including $2.0 million of share-based compensation, compared to $13.6 million including $1.6 million of share-based compensation for the same quarter in 2007. Sales, general and administrative expenses for the full year ended December 31, 2008 were $73.3 million, including $7.5 million of share-based compensation, compared to $48.2 million including $6.6 million of share-based compensation in 2007. This increase in expenses was primarily due to increases in Fampridine-SR pre-launch activities and Zanaflex Capsules promotional activities. Sales, general and administrative expenses are expected to continue to increase in 2009 primarily due to an increase in our expected pre-launch costs.

Other income (expense) for the quarter ended December 31, 2008 was $0.6 million compared to $0.8 million for the same quarter in 2007. Other income (expense) for the full year ended December 31, 2008 was $(0.9) million compared to $1.5 million in 2007.

The Company reported a net loss of $20.2 million for the quarter ended December 31, 2008, or $0.54 per diluted common share, compared to a net loss of $13.7 million, or $0.48 per diluted common share, for the same quarter in 2007. The Company reported a net loss of $74.3 million for the full year ended December 31, 2008, or $2.19 per diluted common share, compared to a net loss of $38.0 million, or $1.45 per diluted common share, in 2007.

As of December 31, 2008, Acorda held cash, cash equivalents and short-term investments of $246.0 million, compared to $95.1 million at December 31, 2007, which is expected to be sufficient to fund the Company's operations through 2010.

Significant Events for 2008 and 2009 to Date

Zanaflex Capsules and Zanaflex tablets Franchise

- Gross sales of Zanaflex Capsules and tablets increased 22.5% to $53.4 million in 2008 from $43.6 million in 2007.
- Zanaflex franchise operations were cash flow positive on an operating basis for 2008.
- The Company projects that Zanaflex revenue will grow modestly and the Zanaflex franchise will continue to be cash flow positive on an operating basis in 2009.

Fampridine-SR

- Acorda filed an NDA for Fampridine-SR on January 30, 2009. The Company expects the submission, if accepted, will be subject to standard review, which would provide a target for the FDA to complete its review within ten months from receipt of the submission.

- In June 2008, Acorda 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 ($p < 0.0001$).
- In January 2008, the Company announced the results of its successful Thorough QT study. The FDA requires Thorough QT studies for all new drugs seeking regulatory approval.
- The Company discussed Fampridine-SR with regulatory authorities in four European member states and believes that the current data are sufficient to file a centralized Marketing Authorization Application (MAA) with the European Medicines Agency (EMEA). The Company is preparing for an MAA as it determines the commercialization pathway and timing of MAA submission that maximizes the value of Fampridine-SR outside the U.S.
- In 2008, Acorda conducted initiatives to increase awareness of walking disability among professional and consumer audiences. These activities included a partnership with the National Multiple Sclerosis Society (NMSS) to sponsor 20 Walk MS programs across the country, and sponsorship of a Harris Interactive survey of people with MS and their caregivers to assess the impact of walking disability on daily life.

Corporate

- As of December 31, 2008, Acorda had cash, cash equivalents and short-term investments of $246.0 million, which is sufficient to fund Company activities through 2010.
- Acorda conducted stock offerings in February and August 2008, resulting in the sale of 8.3 million shares of common stock and raising net proceeds of $201.2 million. Proceeds from the financings were and will be used to support continued development of Fampridine-SR and other Company operations.
- The Company added several key staff members in 2008 and early 2009, including Thomas C. Wessel, M.D., Ph.D. as Chief Medical Officer and Ruhi Khan as Executive Director, Business Development. In addition, John Kelley, President and COO of The Medicines Company, joined Acorda's Board of Directors.
- In August, the Company announced that its preclinical pipeline was selected by Windhover Information and an independent neuroscience expert as one of the top 10 most interesting neuroscience programs in development available for strategic partnering.

Outlook

- Assess European/Rest of World partnership opportunities and determine ex-U.S commercialization strategy
- Submit centralized MAA to EMEA and NDS to Health Canada as optimal ex-U.S. commercialization pathway and availability to patients is determined
- Zanaflex franchise expected to be cash flow positive on operating basis in 2009
- Complete pre-IND toxicology studies and planning to submit initial IND for GGF2 in congestive heart failure in late 2009
- Current cash expected to last through 2010

Full Year 2009 Financial Guidance

Acorda ended 2008 with cash, cash equivalents and short-term investments of $246.0 million. The Company expects its year-end 2009 cash, cash equivalents and short-term investments will be in excess of $150 million.

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 fourth quarter and full year 2008 results.

To participate in the conference call, please dial 866-700-6979 (domestic) or 617-213-8836 (international) and reference the access code 27093206 . The presentation will be available via a live webcast at: http://phoenix.corporate-ir.net/phoenix.zhtml?p=iroleventDetails&c=194451&eventID=2097807

A replay of the call will be available from 10:30 a.m. ET on February 24, 2009 until midnight on March 26, 2009. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 11467599 . 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 filed a New Drug Application (NDA) for its lead clinical product, Fampridine-SR, on January 30, 2009. Clinical trials of Fampridine-SR evaluated 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)

	December 31, 2008	December 31, 2007
Assets		
Cash, cash equivalents and short-term investments	$ 246,049	$ 95,121
Trade receivable, net	4,762	4,330
Other current assets	5,094	3,858
Finished goods inventory	6,144	7,724
Property and equipment, net	2,348	1,652
Intangible assets, net	16,565	13,944
Other assets	539	677
Total assets	$ 281,501	$ 127,306
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 24,119	$ 15,453
Deferred product revenue	24,304	21,837
Other liabilities	6,181	1,973
Long term notes payable	6,905	6,703
Non-current portion of revenue interest liability	12,835	17,907
Stockholders' equity	207,157	63,433
Total liabilities and stockholders' equity	$ 281,501	$ 127,306

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
Gross sales - Zanaflex	$ 13,956	$ 12,776	$ 53,398	$ 43,586
Less: discounts and allowances	(1,517)	(1,584)	(5,670)	(4,160)
Net sales	12,439	11,192	47,728	39,426
Grant revenue	23	23	99	60
Total net revenue	12,462	11,215	47,827	39,486
Cost of sales	(2,838)	(2,609)	(11,355)	(8,356)
Gross profit	9,624	8,606	36,472	31,130
Operating expenses:				
Research and development	10,846	9,556	36,604	22,410
Sales and marketing	12,721	8,731	49,070	30,737
General and administrative	6,845	4,880	24,237	17,430
Total operating expenses	30,412	23,167	109,911	70,577
Operating loss	$ (20,788)	$ (14,561)	$ (73,439)	$ (39,447)
Other income (expense), net	557	832	(901)	1,473
Net loss	$ (20,231)	$ (13,729)	$ (74,340)	$ (37,974)
Net loss per common share - basic and diluted	$ (0.54)	$ (0.48)	$ (2.19)	$ (1.45)
Weighted average per common share - basic and diluted	37,558	28,519	33,939	26,237