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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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): **February 11, 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 February 11, 2008, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and the full year ended December 31, 2007. 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.

The information in this Item 2.02 of Form 8-K shall be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") and otherwise subject to the liabilities of that section, and it shall be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

Item 9.01 Financial Statements and Exhibits
99.1 Press Release dated February 11, 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.

February 11, 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 February 11, 2008

Exhibit 99.1

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Fourth Quarter and Full Year 2007 Financial Results

- Lead clinical product, Fampridine-SR, entered and completed enrollment for second Phase 3 clinical trial in multiple sclerosis (MS); data expected in the latter part of Q2 08
- Zanaflex Capsules ® gross sales grew 114.6% to $38.8 million for the full year

HAWTHORNE, N.Y. February 11, 2008—Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the fourth quarter and full year ended December 31, 2007.

Financial Results

Zanaflex Gross Sales

For the fourth quarter ended December 31, 2007, the Company reported gross sales of Zanaflex Capsules (tizanidine hydrochloride) of $11.8 million and gross sales of Zanaflex ® (tizanidine hydrochloride) tablets of $1.0 million, providing combined gross sales of $12.8 million, compared to gross sales of Zanaflex Capsules of $6.9 million and gross sales of Zanaflex tablets of $1.3 million providing combined gross sales of $8.2 million for the same quarter in 2006. For the full year ended December 31, 2007, the Company reported gross sales of Zanaflex Capsules of $38.8 million and gross sales of Zanaflex tablets of $4.8 million, providing combined gross sales of $43.6 million, compared to gross sales of Zanaflex Capsules of $18.1 million and gross sales of Zanaflex tablets of $8.4 million providing combined gross sales of $26.5 million for the same period in 2006. 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 December 31, 2007 were $14.1 million and Zanaflex tablet shipments were $1.3 million, providing total shipments of $15.4 million compared to $10.6 million of Zanaflex Capsules shipments and $2.0 million of tablet shipments for total shipments of $12.6 million for the same quarter in 2006. For the year ended December 31, 2007, Zanaflex Capsules shipments were $44.1 million and Zanaflex tablets shipments were $4.5 million, providing total shipments of $48.6 million compared to $24.2 million of Zanaflex Capsules shipments and $6.7 million of tablet shipments for total shipments of $30.9 million for the prior year. The decrease in tablet shipments in 2007 is primarily attributable to the Company's strategy of converting prescriptions from Zanaflex tablets to Zanaflex Capsules.

Corporate

Research and development expenses for the quarter ended December 31, 2007 were $9.6 million, including $0.3 million of share-based compensation, compared to $3.2 million including $0.2 million of share-based compensation for the same quarter in 2006. Research and development expenses were $22.4 million including $1.2 million of share-based compensation for the year ended December 31, 2007, compared to $12.1 million including $0.6 million of share-based compensation for the year ended December 31, 2006. Research and development expenses are expected to increase in 2008 as the Company continues to execute its strategy of completing the clinical development of, and working to obtain regulatory approval for, Fampridine-SR in MS, and advancing its preclinical programs towards clinical trials.

Sales, general and administrative expenses for the quarter ended December 31, 2007 were $13.6 million, including $1.6 million of share-based compensation, compared to $8.2 million including $0.8 million of share-based compensation for the same quarter in 2006. Sales, general and administrative expenses were $48.2 million including $6.6 million of share-based compensation for the year ended December 31, 2007, compared to $31.6 million including $3.2 million of share-based compensation for the year ended December 31, 2006. Sales, general and administrative expenses are expected to increase in 2008 primarily due to an increase in our expected pre-marketing expenses associated with the possible launch of Fampridine-SR.

The Company reported a net loss of $13.7 million for the quarter ended December 31, 2007, or $0.48 per share, compared to a net loss of $7.0 million, or $0.30 per share, for the same period in 2006. The Company reported a net loss of $38.0 million for the full year ended December 31, 2007, or $1.45 per share, compared to a net loss of $60.0 million, or $3.27 per share, in 2006.

As of December 31, 2007, Acorda held cash, cash equivalents and short-term investments of $95.1 million, compared to $53.8 million at December 31, 2006. This $95.1 million is expected to be sufficient to fund the Company's operations into the first quarter of 2009, with spending weighted to the second half of 2008, pending the results of the Fampridine-SR Phase 3 trial.

Significant Events for 2007 and for 2008 to Date:

"2007 was a year of solid achievement for Acorda. We exceeded our target of doubling Zanaflex Capsules sales over 2006, and we began and completed enrollment in our second Phase 3 clinical trial of Fampridine-SR in MS, under an SPA. We also initiated investments for the commercialization of Fampridine-SR, if approved," said Ron Cohen, M.D., President and Chief Executive Officer of Acorda Therapeutics. "As a result of this groundwork, we are well-positioned to achieve key milestones in 2008. These include completing our second Phase 3 clinical trial of Fampridine-SR in MS, and, if this trial is successful, preparing for an NDA filing and accelerating our pre-launch activities for Fampridine-SR, as well as scaling up manufacturing of our remyelinating antibody and neuregulin preclinical programs under GMP, a key step for advancing these programs to clinical trials."

Zanaflex Capsules and Zanaflex tablets franchise

- Gross sales of Zanaflex Capsules increased 114.6% to $38.8 million in 2007 from $18.1 million in 2006.
- Zanaflex Capsules and tablets operations were cash flow neutral in 2007.
- In the first quarter of 2007, the Company completed the doubling of its sales force to 65 professionals.
- In October, Acorda filed a lawsuit against Apotex Corp. and Apotex Inc. in response to Apotex Inc.'s submission of an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) seeking marketing approval for generic versions of the Company's three Zanaflex Capsules dosage strengths.

Fampridine-SR

- In January 2008, the Company announced the results of its successful Thorough QT study. The study evaluated the potential of Fampridine-SR to cause an increase in the electrocardiographic QT interval. Fampridine-SR, at both therapeutic (10mg twice a day) and supratherapeutic doses (30mg twice a day), was found to be no different than placebo. The FDA requires thorough QT studies for all new drugs seeking regulatory approval.
- In June 2007, Acorda initiated a second Phase 3 clinical trial in MS; enrollment was completed in November. This trial is being conducted under a special protocol assessment (SPA), which states that, if the trial is successful, efficacy requirements for filing an NDA will have been met. The Company expects data from this trial in the latter part of the second quarter of 2008. The NDA filing remains targeted for the first quarter of 2009.
- The Company initiated pre-marketing activities in the U.S., including plans to approximately double its existing sales force before a potential Fampridine-SR launch. These activities will accelerate in 2008 if the second Phase 3 trial is successful.

Corporate

- In February 2008, the Company acquired intellectual property, clinical data and other assets related to uses of aminopyridine in peripheral neuropathies and to two early stage development candidates from Neurorecovery, Inc.
- In June 2007, Acorda sold 4, 189 ,460 shares of common stock at $18.50 per share, for net proceeds of $72.2 million, including the exercise of the underwriters' option.
- Acorda welcomed two new Board of Directors members: Ian F. Smith, Executive Vice President & Chief Financial Officer of Vertex Pharmaceuticals, and Barry Greene, President and Chief Operating Officer of Alnylam Pharmaceuticals.
- Acorda joined the Russell 3000 and the NASDAQ NeuroInsights Neurotech indices.
- Ron Cohen, M.D., Acorda's President and CEO, was named the Ernst and Young Entrepreneur of the Year for the Metro New York Area and also was inducted into the Spinal Cord Injury Hall of Fame.

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 Acorda Therapeutics' ability to successfully market and sell Zanaflex Capsules ®, the risk of unfavorable results from future studies of Fampridine-SR, delays in obtaining or failure to obtain FDA approval of Fampridine-SR, 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.

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 multiple sclerosis (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.

Financial Statements

Acorda Therapeutics, Inc
Condensed Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	December 31, 2007	December 31, 2006
Assets		
Cash, cash equivalents and short-term investments	$ 95,121	$ 53,756
Trade and grant receivable, net	4,330	4,389
Other current assets	3,858	7,867
Finished goods inventory	7,724	6,221
Property and equipment, net	1,652	1,223
Intangible assets, net	13,944	10,178
Other assets	677	734
Total assets	$ 127,306	$ 84,368
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 15,453	$ 14,033
Deferred product revenue	21,837	20,441
Current liabilities	1,973	4,436
Long term notes payable	6,703	6,695
Non-current portion of revenue interest liability	17,907	20,094
Stockholders' equity	63,433	18,669
Total liabilities and stockholders' equity	$ 127,306	$ 84,368

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	2006	2007	2006
Gross sales - Zanaflex	$ 12,776	$ 8,245	$ 43,586	$ 26,548
Less: discounts and allowances	(1,584)	(560)	(4,160)	396
Net sales	11,192	7,685	39,426	26,944
Grant revenue	23	35	60	407
Total net revenue	11,215	7,720	39,486	27,351
Cost of sales	(2,609)	(3,085)	(8,356)	(7,123)
Gross profit	8,606	4,635	31,130	20,228
Operating expenses:				
Research and development	9,556	3,162	22,410	12,055
Sales and marketing	8,731	4,937	30,737	19,079
General and administrative	4,880	3,288	17,430	12,561
Total operating expenses	23,167	11,387	70,577	43,695
Operating loss	$ (14,561)	$ (6,752)	$ (39,447)	$ (23,467)
Other income (expense), net	832	(257)	1,473	(1,007)
Cumulative effect of change in accounting principle	—	—	—	454
Net loss	(13,729)	(7,009)	(37,974)	(24,020)
Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders	—	—	—	(36,007)
Net loss	$ (13,729)	$ (7,009)	$ (37,974)	$ (60,027)
Net loss per common share - basic and diluted	$ (0.48)	$ (0.30)	$ (1.45)	$ (3.27)
Weighted average per common share - basic and diluted	28,519	23,093	26,237	18,346