ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 03/31/06 for the Period Ending 03/31/06

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): **March 31, 2006**

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) 347-7400**

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 March 31, 2006, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2005. 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 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

99.1 Press Release dated March 31, 2006

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.

March 31, 2006

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated March 31, 2006

Exhibit 99.1

CONTACTS:

Erica Wishner
Acorda Therapeutics
(914) 347-4300 ext. 162
ewishner@acorda.com

FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Fourth Quarter and Full Year 2005 Financial Results

HAWTHORNE, NY, March 31, 2006 — Acorda Therapeutics (Nasdaq:ACOR) today announced its financial results for the fourth quarter and full year ended December 31, 2005.

"The launch of Zanaflex Capsules in April 2005 transformed Acorda into a fully-integrated biotechnology company. In 2005, we also received an SPA from the FDA for our Fampridine-SR Phase 3 study in MS, which we initiated. We now have a commercial sales and marketing operation, complementing our strong pipeline and clinical and pre-clinical capabilities," stated Ron Cohen, M.D., President and CEO. "These accomplishments provided the foundation for the successful completion of our initial public offering in February 2006."

Financial Results

For the quarter ended December 31, 2005, gross sales of Zanaflex Capsules were $1.4 million and gross sales of Zanaflex tablets were $1.3 million providing combined gross sales of $2.7 million, compared to $0 for the same quarter in 2004. For the year ended December 31, 2005, gross sales of Zanaflex Capsules were $2.5 million and gross sales of Zanaflex tablets were $3.4 million providing combined gross sales of $5.9 million, compared to $0 for the prior year. 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 Capsule shipments to wholesalers for the quarter ended December 31, 2005 were $1.7 million and Zanaflex tablet shipments were $2.3 million providing total shipments of $4.0 million, compared to $3.9 million in Zanaflex tablet shipments for the same quarter in 2004. For the year ended December 31, 2005, Zanaflex Capsule shipments were $7.8 million and Zanaflex tablet shipments were $10.3 million providing total shipments to wholesalers of $18.1 million, compared to $6.7 million in Zanaflex tablet shipments for the prior year. Deferred product revenue as of December 31, 2005 was $16.7 million compared to $6.7 million as of December 31, 2004.

For the quarter ended December 31, 2005, cost of sales increased by $2.3 million over the quarter ended December 31, 2004. This increase was primarily due to a $1.8 million reserve for excess inventory with expiration dating of less than 24 months at the time of purchase that, if not sold, will be written off in 2006.

For the year ended December 2005, cost of sales increased by $4.2 million compared to the year ended 2004. This increase was primarily due to a $1.8 million reserve for excess inventory with expiration dating of 24 months at the time of purchase that, if not sold, will be written off in 2006.

Net loss for the fourth quarter ended December 31, 2005 was $15.8 million or $75.59 per share, compared to a net loss of $18.5 million or $93.73 per share for the quarter ended December 31, 2004. For the year ended December 31, 2005, net loss was $60.4 million or $295.97 per share, compared to a net loss of $69.5 million or $351.76 per share for the year ended 2004. For the periods reported, our earnings per share calculations were based on the Company's pre-IPO outstanding common shares.

As of December 31, 2005, the Company held cash, cash equivalents and short term investments of $13.8 million.

For the quarter ended December 31, 2005, total operating expenses increased by $1.3 million over the quarter ended December 31, 2004. This increase was primarily attributable to increased expenses related to the marketing,

distribution and sales administration expenses for sales of Zanaflex Capsules.

For the year ended December 31, 2005, operating expenses decreased by $5.5 million compared to the year ended December 31, 2004. This decrease was primarily due to the completion of two Phase 3 clinical trials of Fampridine-SR in spinal cord injury (SCI), and one Phase 2 clinical trial of Fampridine-SR in multiple sclerosis (MS) during the first quarter of 2004. The Company also realized a reduction in its non-cash share based compensation cost and salary expense during 2005 due to the Company's repricing of certain of its stock options during 2004 that resulted in a charge to earnings in 2004. The Company also reduced its staff in early 2005 resulting in a lower salary expense, which was partially offset by increases in marketing, distribution and sales administration expenses related to the launch of Zanaflex Capsules, distribution expenses for Zanaflex tablets and an increase in salaries and benefits related to the Company's Zanaflex Capsules specialty sales force.

Zanaflex Capsules Highlights

- In April 2005, Acorda launched its first marketed product, Zanaflex Capsules. Zanaflex Capsules is a new formulation of tizanidine, one of the two leading treatments approved for the management of spasticity. The Company initially launched the product with a 14-person, in-house specialist sales force.
- On March 3, 2006, the Company reported the expansion of its in-house sales force from 14 to 32 sales professionals.
- In March 2006, the Company initiated a primary care pilot program with Innovex, using 6 part-time representatives making exclusive calls for Zanaflex Capsules. Also, on March 30, 2006, the Company gave notice of termination to Cardinal Health of its syndicated sales force agreement.

Fampridine-SR Highlights

- In May 2005, the Company announced that it had received a Special Protocol Assessment (SPA) on the protocol design of its Phase 3 trial of Fampridine-SR. The FDA agreed that the trial, if successful, could qualify as one of the pivotal efficacy studies required for drug approval.
- In June 2005, Acorda reported the initiation of the Phase 3 trial. The study is evaluating the safety and efficacy of Fampridine-SR in improving walking ability in people with MS.
- On March 3, 2006, the Company reported that it had completed enrollment in its Phase 3 clinical trial of Fampridine-SR. The Company expects to report data from this trial in the third quarter of 2006.

Corporate Highlights

- In December 2005 we entered an agreement with Paul Royalty Fund to receive $15 million in funding in exchange for a portion of net revenues (as defined in the agreement, which is different from our net revenues determined in accordance with GAAP) on Zanaflex Capsules, Zanaflex tablets, and other formulations. The agreement allows for additional funding based on the achievement of milestones.
- On February 10, 2006 the Company announced the completion of its Initial Public Offering of its common stock, raising net proceeds of $31.8 million after deducting the underwriting discount and offering expenses. This amount included the sale of shares from the underwriters' over allotment option.
- On March 10, 2006, the Company announced that Lorin J. Randall, Senior Vice President and Chief Financial Officer for Eximias Pharmaceutical Corporation, joined the Acorda Board of Directors and will serve as the Chairman of Acorda's Audit Committee.

Conference Call and Webcast

Ron Cohen, President and Chief Executive Officer, David Lawrence, Chief Financial Officer, and Mary Fisher, Chief Operating Officer will host a conference call today at 8:30 am ET to review the Company's fourth quarter and year-end 2005 results. To access the call, please dial 866-383-8003 (domestic) or 617-597-5330 (international) five minutes prior to the start time, and provide the access code 81810986. A replay of the call will be available from 10:30 a.m. Eastern Time on March 31 until 11:59 p.m. Eastern Time on April 29, 2006. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international), and provide the access code 98316449. A live audio

webcast of the call can also be accessed from the Company's website, at http://www.acorda.com.

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 the Phase 3 clinical trial of Fampridine SR, delays in obtaining or failure to obtain FDA approval of Fampridine SR, competition, the ability to obtain additional financing to support Acorda Therapeutics' operations, unfavorable results from its preclinical programs, and failure to protect its intellectual property or to defend against the intellectual property claims of others. 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 Acorda Therapeutics

Acorda Therapeutics is a biotechnology company developing therapies for SCI, MS and related nervous system disorders. The Company's marketed products include Zanaflex Capsules™ (tizanidine hydrochloride), a short-acting drug indicated for the management of spasticity. For full prescribing information, please go to www.zanaflexcapsules.com. Acorda's lead clinical-stage product is Fampridine-SR, which is in a Phase 3 clinical trial for 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
Consolidated Statements of Operations
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2005	2004	2005	2004
Gross sales - Zanaflex	$ 2,684	$ —	$ 5,923	$ —
Less: discounts and allowances	(122)	(4,272)	(1,114)	(4,417)
Net sales	2,562	(4,272)	4,809	(4,417)
Grant revenue	152	35	336	479
Total net revenue	2,714	(4,237)	5,145	(3,938)
Less: cost of sales	(2,858)	(523)	(5,132)	(885)
Gross profit	(144)	(4,760)	13	(4,823)
Operating expenses:				
Research and development	3,237	3,378	12,890	21,999
Sales and marketing	3,441	1,869	13,098	4,662
General and administrative	2,096	2,250	8,435	13,283
Total operating expenses	8,774	7,497	34,423	39,944
Operating loss	(8,918)	(12,257)	(34,410)	(44,767)
Other income (expense):				
Interest and amortization of debt discount expense	(702)	(88)	(1,526)	(385)
Interest income	54	80	402	409
Other income	—	—	1	2
	(648)	(8)	(1,123)	26
Cumulative effect of change in accounting principle	—	—	3	—
Net loss	(9,566)	(12,265)	(35,530)	(44,741)
Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders	(6,212)	(6,250)	(24,849)	(24,746)
Net loss allocable to common shareholders	$ (15,778)	$ (18,515)	$ (60,379)	$ (69,487)
Net loss per share allocable to common stockholders - basic and diluted	$ (75.59)	$ (93.73)	$ (295.27)	$ (351.76)
Weighted average common shares outstanding used in computing net loss per share allocable to common stockholders - basic and diluted	208,734	197,541	204,485	197,541

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

	2005	2004
Assets		
Cash and cash equivalents	$ 11,761	$ 11,729
Short-term investments	2,001	9,397
Finished goods inventory held by the Company, net	5,587	192
Property and equipment, net	1,707	2,547
Intangible assets, net	5,952	3,386
Total assets	$ 33,912	$ 30,982
Liabilities and stockholders' equity (deficit)		
Accounts payable, accrued expenses and other liabilities	$ 14,060	$ 4,820
Deferred product revenue	16,736	6,668
Total current liabilities	35,858	15,872
Long term liabilities	23,377	9,317
Stockholders deficit	(116,536)	(60,571)
Total Liabilities and Stockholders deficit	$ 33,912	$ 30,982