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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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): **November 2, 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) 347-4300**

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 2, 2006, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2006. 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 November 2, 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.

November 2, 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 November 2, 2006

Exhibit 99.1

CONTACTS:

Tierney Saccavino
Acorda Therapeutics
(914) 347-4300 ext. 104
tsaccavino@acorda.com

FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Third Quarter 2006 Financial Results

HAWTHORNE, N.Y. November 2, 2006—Acorda Therapeutics (Nasdaq: ACOR) today announced its financial results for the third quarter ended September 30, 2006.

Financial Results

For the quarter ended September 30, 2006, gross sales of Zanaflex Capsules™ (tizanidine hydrochloride) were $5.0 million and gross sales of Zanaflex ® tablets were $1.5 million providing combined gross sales of $6.5 million. For the same quarter in 2005 gross sales of Zanaflex Capsules were $0.9 million and gross sales of Zanaflex tablets were $1.9 million for total gross sales of $2.8 million. Gross sales are recognized using a deferred revenue recognition model, where Zanaflex product shipments to wholesalers are recorded as deferred revenue and only recognized as revenue or gross sales when end-user prescriptions of Zanaflex Capsules and tablets are reported. Shipments to wholesalers for the quarter ended September 30, 2006 of $8.7 million consisted of $6.9 million for Zanaflex Capsules and $1.8 million for Zanaflex tablets. For the same quarter in 2005, we recorded $2.5 million in shipments consisting of $0.4 million in Zanaflex Capsules and $2.1 million in Zanaflex tablets.

Net loss for the third quarter ended September 30, 2006 was $7.2 million or $.37 per share, compared to a net loss of $13.9 million or $66.62 per share for the same quarter in 2005.

As of September 30, 2006, the Company held cash, cash equivalents and short-term investments of $18.4 million. The Company believes that its current financial resources, including the net proceeds of $29.8 million from the recently completed October 2006 financing, should be sufficient to fund its operations and meet its financial obligations into the first quarter of 2008 based on the Company's current projected revenue and spending levels.

"I was pleased to report in September that the Company achieved positive results from its Phase 3 clinical trial of Fampridine-SR on walking ability in people with multiple sclerosis," stated Ron Cohen, M.D., President and CEO. "We believe that Fampridine-SR, if approved, could be a first-in-class product, as no existing therapies are indicated to improve walking or other function for people with MS. We also have had continued growth in our Zanaflex Capsules franchise, and recently announced the expansion of our commercial sales force from 32 to 65. This sales organization will provide the commercial foundation for the launch of Fampridine-SR, if approved."

Fampridine-SR Highlights

- The Company reported positive data from the Phase 3 clinical trial of Fampridine-SR on September 25, 2006. Following are the top-line results from that trial:
    - Statistical significance was achieved on all three efficacy criteria defined in the Special Protocol Assessment (SPA) by the Food and Drug Administration (FDA). A significantly greater proportion of Fampridine-SR responders had a consistent improvement in walking speed, the study's primary outcome, compared to people taking placebo (34.8 percent vs. 8.3 percent) as measured by the Timed 25-Foot Walk ($p<0.001$). In addition, the effect was maintained in this study throughout the 14-week treatment period ($p<0.001$) and there was a statistically significant improvement in the 12-Item MS Walking Scale (MSWS-12) for walking responders vs. non-responders ($p<0.001$).

- The average increase in walking speed over the treatment period for this Phase 3 study compared to baseline was 25.2 percent for the drug responder group vs. 4.7 percent for the placebo group.

- Additionally, increased response rate on the Timed 25-Foot Walk was seen across all four major types of MS.

- The Company has requested a meeting with the FDA to discuss next steps for the Fampridine-SR program, and expects that meeting to occur before year end.

- The Company intends to present comprehensive data from this trial at an upcoming medical meeting.

- As of October 31, 2006, over 1,150 people had been exposed to Fampridine-SR in clinical trials, including over 300 individuals with MS who have been exposed for greater than six months, over 140 for greater than a year, and over 125 for greater than two years.

Zanaflex Capsules Highlights

- The Company recently announced that it will expand its Zanaflex Capsules sales force to 65 people, including 52 area business managers who will call on specialists as well as primary care physicians who are high-volume prescribers. The current sales force of 32 people, including 25 area business managers, has an average of 15 years experience in sales and sales management in the biotechnology and pharmaceutical industries. This team currently reaches approximately 3,200 specialists. The expanded sales force will be able to reach approximately 7,400 specialists and primary care physicians.

Conference Call and Webcast

Ron Cohen, President and Chief Executive Officer, David Lawrence, Chief Financial Officer, Mary Fisher, Chief Operating Officer and Andrew Blight, Chief Scientific Officer will host a conference call today at 8:30 am ET to review the Company's third quarter 2006 results. To access the call, please dial 866-543-6407 (domestic) or 617-213-8898 (international) and reference the access code 94915046. A replay of the call will be available from 10:30 a.m. Eastern Time on November 2, 2006 until December 2, 2006 at midnight. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 39211037. A live audio webcast of the call can also be accessed from the Company's website, at http://www.acorda.com, for the next 30 days.

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, 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(TM) (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, Fampridine-SR, recently completed a Phase 3 study 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
Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	September 30, 2006	December 31, 2005
Assets		
Cash and cash equivalents	$ 11,921	$ 11,761
Short-term investments	6,440	2,001
Finished goods inventory held by the Company	5,861	5,587
Property and equipment, net	1,277	1,707
Intangible assets, net	5,398	5,952
Total assets	$ 40,317	$ 33,912
Liabilities and stockholders' equity (deficit)		
Accounts payable, accrued expenses and other liabilities	$ 6,922	$ 14,060
Deferred product revenue	16,307	16,736
Total current liabilities	27,443	35,858
Long term liabilities	21,268	23,377
Stockholders deficit	(8,393)	(116,536)
Total Liabilities and Stockholders deficit	$ 40,317	$ 33,912

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Gross sales—Zanaflex	$ 6,538	$ 2,761	$ 18,304	$ 3,239
Less: discounts and allowances	(381)	(147)	955	(992)
Net sales	6,157	2,614	19,259	2,247
Grant revenue	70	30	371	184
Total net revenue	6,227	2,644	19,630	2,431
Less: cost of sales	(1,652)	(707)	(4,037)	(2,274)
Gross profit	4,575	1,937	15,593	157
Operating expenses:				
Research and development	2,595	2,510	8,892	9,652
Sales and marketing	5,297	4,288	14,142	9,657
General and administrative	3,435	2,406	9,273	6,339
Total operating expenses	11,327	9,204	32,307	25,648
Operating loss	$ (6,752)	$ (7,267)	$ (16,714)	$ (25,491)
Other income (expense):				
Interest and amortization of debt discount expense	(767)	(304)	(1,674)	(824)
Interest income	281	89	853	347
Other income	68	—	71	1
	(418)	(215)	(750)	(476)
Cumulative effect of change in accounting principle	—	3	454	3
Net loss	(7,170)	(7,479)	(17,010)	(25,964)
Beneficial conversion feature, accretion of issuance costs and preferred dividends	—	(6,427)	(36,007)	(18,636)
Net loss allocable to common shareholders	$ (7,170)	$ (13,906)	$ (53,017)	$ (44,600)
Net loss per share allocable to common stockholders—basic and diluted	$ (0.37)	$ (66.62)	$ (3.17)	$ (221.17)
Weighted average common shares outstanding used in computing net loss per share allocable to common stockholders—basic and diluted	19,633	209	16,746	202