ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	420 SAW MILL RIVER ROAD
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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): **February 23, 2010**

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 23, 2010, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter ended December 31, 2009. 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

(d) Exhibits

99.1 Press Release dated February 23, 2010.

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 23, 2010

By: */s/ David Lawrence*

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated February 23, 2010

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Fourth Quarter and Full Year 2009 Financial Results

- Announced FDA Approval of AMPYRA™ (dalfampridine) Extended Release Tablets, 10 mg on January 22, 2010 to Improve Walking in People with Multiple Sclerosis (MS); Demonstrated by Increase in Walking Speed
- AMPYRA Commercial Launch Expected March 2010
- IND Filing for GGF2 in Heart Failure Expected Early 2010

HAWTHORNE, N.Y., February 23, 2010 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the fourth quarter and full year ended December 31, 2009.

"The FDA approval of AMPYRA represents an important advance in the treatment of MS. It is also a significant step for Acorda toward our goal of becoming a leading innovator in neurology," said Ron Cohen, M.D., President and CEO of Acorda Therapeutics. "We expect commercial supply of AMPYRA to be available beginning in March. As we launch AMPYRA, we also are focusing on advancing our preclinical pipeline to the clinic. We believe GGF2 may have important applications in both cardiac and neurological conditions, and will look to demonstrate proof of concept initially in heart failure. We expect to file an IND for this indication in early 2010."

Financial Results and Product Update

ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and ZANAFLEX ® (tizanidine hydrochloride) tablets gross sales - For the fourth quarter ended December 31, 2009, the Company reported combined gross sales of ZANAFLEX CAPSULES and ZANAFLEX tablets of $14.4 million, compared to combined gross sales of $14.0 million for the same quarter in 2008. For the full year ended December 31, 2009, the Company reported combined gross sales of ZANAFLEX CAPSULES and ZANAFLEX tablets of $58.3 million, compared to combined gross sales of $53.4 million in 2008.

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 franchise operations were cash flow positive on an operating basis for 2009.

ZANAFLEX CAPSULES and ZANAFLEX tablets shipments - Total ZANAFLEX CAPSULES and ZANAFLEX tablet shipments for the quarter ended December 31, 2009 were $18.4 million, compared to total shipments of $16.5 million for the same quarter in 2008. For the full year ended December 31, 2009, total ZANAFLEX CAPSULES and ZANAFLEX tablet shipments were $66.7million, compared to total shipments of $62.9 million in 2008.

License Revenue - For the quarter ended December 31, 2009, the Company reported license revenue of $2.4 million, a portion of the $110 million received from Biogen Idec International GmbH (Biogen Idec), a subsidiary of Biogen Idec Inc., for the collaboration agreement entered

into on June 30, 2009. For the full year ended December 31, 2009, the Company reported license revenue of $4.7 million. The balance of this payment will be recognized as revenue ratably over the remainder of the estimated term of the collaboration agreement.

Cost of License Revenue - For the quarter ended December 31, 2009, the Company recorded cost of license revenue of $0.2 million and for the full year ended December 31, 2009, the Company recorded cost of license revenue of $0.3 million. This cost is related to the $7.7 million payment made to Elan as a result of the collaboration agreement the Company entered into with Biogen Idec. This payment will be recognized as expense ratably over the estimated term of the collaboration agreement as the related revenue is recognized.

Research and development expenses for the quarter ended December 31, 2009 were $10.6 million, including $1.1 million of share-based compensation, compared to $10.8 million including $0.7 million of share-based compensation for the same quarter in 2008. Research and development expenses for the full year ended December 31, 2009 were $34.6 million, including $3.7 million of share-based compensation, compared to $36.6 million including $2.3 million of share-based compensation in 2008. Research and development expense for the full year ended December 31, 2009 included costs related to our AMPYRA Phase 3 and long-term extension studies, preparation for the AMPYRA NDA filing and FDA Advisory Committee meeting for AMPYRA and development of our preclinical pipeline products.

Sales, general and administrative expenses for the quarter ended December 31, 2009 were $22.7 million, including $2.3 million of share-based compensation, compared to $19.6 million including $2.0 million of share-based compensation for the same quarter in 2008. Sales, general and administrative expenses for the full year ended December 31, 2009 were $89.9 million, including $8.6 million of share-based compensation, compared to $73.3 million including $7.5 million of share-based compensation in 2008. This increase in expenses was primarily due to increases in AMPYRA pre-launch activities and ZANAFLEX CAPSULES promotional activities.

Other income (expense), net for the quarter ended December 31, 2009 was $(0.4) million compared to $0.6 million for the same quarter in 2008. Other income (expense) for the full year ended December 31, 2009 was $(2.7) million compared to $(0.9) million in 2008.

The Company reported a net loss of $22.5 million for the quarter ended December 31, 2009, or $0.59 per diluted common share, compared to a net loss of $20.2 million, or $0.54 per diluted common share, for the same quarter in 2008. The Company reported a net loss of $83.9 million for the full year ended December 31, 2009, or $2.22 per diluted common share, compared to a net loss of $74.3 million, or $2.19 per diluted common share, in 2008.

As of December 31, 2009, Acorda held cash, cash equivalents and short-term investments of $272.1 million, compared to $246.0 million at December 31, 2008.

Significant Events for 2009 and 2010 to Date

AMPYRA

- Two platform and two poster presentations on AMPYRA have been accepted for the American Academy of Neurology annual meeting in April 2010.
- On February 3, 2010 the Company announced a Wholesale Acquisition Cost (WAC) of $1,056 for a 30-day supply of AMPRYA (one 60-count bottle). Acorda also provided details on its patient assistance and co-pay programs.
- On January 29, 2010, Acorda received written confirmation from the FDA that the Company has received seven years of orphan drug exclusive approval for the use of AMPYRA for treatment to improve walking in patients with MS, beginning January 22, 2010.

- Acorda received FDA marketing approval for AMPYRA on January 22, 2010. AMPYRA is indicated to improve walking in patients with MS. This was demonstrated by an increase in walking speed.
- On October 14, AMPYRA was reviewed by the FDA Peripheral and Central Nervous System Drugs (PCNSD) Advisory Committee. The Committee voted 12 to 1 that clinical data on AMPYRA 10 mg twice daily demonstrated substantial evidence of effectiveness as a treatment to improve walking in people with MS and voted 10 to 2 (1 abstention) that it is clinically meaningful and can be safe for use. The Committee also recommended by a vote of 12 to 1 that Acorda be required to evaluate the effects of doses lower than 10 mg twice daily, but by a 10 to 2 vote (1 abstention) that these studies not be required prior to approval.
- In June, Acorda and Biogen Idec entered into an exclusive collaboration and license agreement to develop and commercialize AMPYRA in markets outside the United States. Outside the U.S., Biogen Idec is referring to the drug as Fampridine Prolonged Release (PR) tablets. The agreement provided for an upfront payment of $110 million to Acorda and additional payments of up to $400 million based on the successful achievement of future regulatory and sales milestones. In addition, Biogen Idec will make double-digit, tiered royalty payments to Acorda on ex-U.S. sales, as well as paying Acorda for all payments due from Acorda to Elan for ex-US sales, including royalties owed.
    - In January 2010, Biogen Idec announced the submission of applications for approval of the drug to European and Canadian health authorities.
- On May 6, Acorda announced the FDA accepted the AMPYRA New Drug Application (NDA) for filing, assigning it Priority Review.
- Phase 3 clinical trial data on AMPYRA in multiple sclerosis (MS) were published in the February 28 issue of *The Lancet* , one of the world's leading medical journals.

Corporate

- Lauren Sabella joined Acorda as Executive Vice President, Commercial Development in January 2010.
- Dr. Adrian Rabinowicz joined Acorda as Senior Vice President, Medical Affairs in February 2010.

ZANAFLEX CAPSULES and ZANAFLEX Tablets Franchise

- Gross sales of ZANAFLEX CAPSULES and tablets increased 9.1% to $58.3 million in 2009 from $53.4 million in 2008.
- ZANAFLEX franchise operations were cash flow positive on an operating basis for 2009.

Outlook for 2010

- The Company is preparing for the commercial launch of AMPYRA in March 2010. Acorda expects its expanded sales force of 100 representatives to be fully trained and deployed in March.
- The Company plans to file for Hatch-Waxman patent term extension for AMPYRA by the deadline of March 22, 2010.
- The Company expects sales of ZANAFLEX CAPSULES will decline in 2010 due to increasing managed care pressure, among other factors.
- Acorda expects to complete pre-IND toxicology studies and submit an IND for GGF2 in heart failure in early 2010. The Company is planning to start a Phase 1 clinical study in heart failure patients in 2010.
- Research and development expenses are expected to increase in 2010 over 2009 due to the continued development of the Company's pre-clinical programs, including expected initiation of a GGF2 Phase 1 study, and implementation of our post-marketing study commitments for AMPYRA.
- Sales, general and administrative expenses are expected to substantially increase in 2010 over 2009 primarily due to launch costs and sales and marketing expenses for

AMPYRA, including increases in sales, managed markets and medical affairs staff and implementation of our post-marketing study commitments for AMPYRA.

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 2009 results.

To participate in the conference call, please dial 866-730-5770 (domestic) or 857-350-1594 (international) and reference the access code 70697577. The presentation will be available via a live webcast at: http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2652904

A replay of the call will be available from 12:30 p.m. ET on February 23, 2010 until midnight on March 24, 2010. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 66648565. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at http://www.acorda.com.

About Acorda Therapeutics

Acorda Therapeutics is a biotechnology company developing therapies for multiple sclerosis, spinal cord injury and related nervous system disorders. The Company's marketed products include AMPYRA™ (dalfampridine), a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS), this was demonstrated by an improvement in walking speed; and ZANAFLEX CAPSULES ® (tizanidine hydrochloride), a short-acting drug for the management of spasticity. 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 Acorda Therapeutics' ability to successfully market and sell Ampyra in the United States and to successfully market Zanaflex Capsules, the risk of unfavorable results from future studies of Ampyra, the occurrence of adverse safety events with our products, delays in obtaining or failure to obtain regulatory approval of Ampyra outside of the United States and our dependence on our collaboration partner Biogen Idec in connection therewith, competition, failure to protect Acorda Therapeutics' 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 our 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, 2009	December 31, 2008
Assets		
Cash, cash equivalents and short-term investments	$ 272,092	$ 246,049
Trade receivable, net	5,879	4,762
Other current assets	8,417	5,094
Finished goods inventory	6,893	6,144
Property and equipment, net	1,891	1,841
Intangible assets, net	17,149	17,072
Other assets	7,150	539
Total assets	$ 319,471	$ 281,501
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 26,589	$ 24,119
Deferred product revenue	30,704	24,304
Current portion of deferred license revenue	9,429	—
Current portion of revenue interest liability	6,179	6,181
Long term notes payable	7,112	6,905
Non-current portion of revenue interest liability	6,268	12,835
Non-current portion of deferred license revenue	95,857	—
Stockholders' equity	137,333	207,157
Total liabilities and stockholders' equity	$ 319,471	$ 281,501

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2009	2008	2009	2008
Gross sales - Zanaflex	$ 14,432	$ 13,956	$ 58,267	$ 53,398
Less: discounts and allowances	(2,349)	(1,517)	(8,308)	(5,670)
Net sales	12,083	12,439	49,959	47,728
License revenue	2,357	—	4,714	—
Grant revenue	—	23	—	99
Total net revenue	14,440	12,462	54,673	47,827
Cost of sales	(2,946)	(2,838)	(11,059)	(11,355)
Cost of license revenue	(165)	—	(330)	—
Gross profit	11,329	9,624	43,284	36,472
Operating expenses:				
Research and development	10,629	10,846	34,611	36,604
Sales and marketing	13,844	12,721	57,951	49,070
General and administrative	8,889	6,845	31,980	24,237
Total operating expenses	33,362	30,412	124,542	109,911
Operating loss	$ (22,033)	$ (20,788)	$ (81,258)	$ (73,439)
Other income (expense), net	(441)	557	(2,683)	(901)
Net loss	$ (22,474)	$ (20,231)	$ (83,941)	$ (74,340)
Net loss per common share - basic and diluted	$ (0.59)	$ (0.54)	$ (2.22)	$ (2.19)
Weighted average per common share - basic and diluted	37,837	37,558	37,735	33,939