ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	420 SAW MILL RIVER ROAD
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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): **November 3, 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 November 3, 2009, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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

99.1 Press Release dated November 3, 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.

November 3, 2009

By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated November 3, 2009

Exhibit 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Third Quarter 2009 Financial Results

- *Positive Vote by U.S. Food and Drug Administration (FDA) Advisory Committee for Fampridine-SR on October 14*
- *FDA Extends Fampridine-SR PDUFA Goal Date to January 22, 2010*

HAWTHORNE, N.Y., November 3, 2009 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the third quarter of 2009.

"The positive vote from the FDA Advisory Committee was an important step toward making Fampridine-SR available to people with multiple sclerosis who may benefit from this novel therapy, if approved," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "We look forward to continuing to work with the FDA as it completes its review of the Fampridine-SR submission."

Financial Results and Product Update

Zanaflex Capsules ® (tizanidine hydrochloride) and Zanaflex ® (tizanidine hydrochloride) Tablets gross sales - For the quarter ended September 30, 2009, the Company reported combined gross sales of Zanaflex Capsules and Zanaflex tablets of $14.5 million, compared to combined gross sales of $13.7 million for the same quarter 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. There has been a slight downward trend in prescriptions over the first three quarters of 2009.

Zanaflex Capsules and Zanaflex Tablets shipments - Total Zanaflex Capsules and Zanaflex tablet shipments for the quarter ended September 30, 2009 were $15.3 million, compared to total shipments of $15.7 million for the same quarter in 2008.

License Revenue - For the quarter ended September 30, 2009, the Company reported license revenue of $2.4 million, a portion of the $110 million received from Biogen Idec for the collaboration agreement entered into on June 30, 2009. The balance of this payment will be recognized as revenue ratably over the remainder of the estimated term of the collaboration agreement. The Company currently estimates the revenue recognition period to be approximately 12 years.

Cost of License Revenue - For the quarter ended September 30, 2009, the Company recorded cost of license revenue of $0.2 million 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 12 year term of the collaboration agreement as the related revenue is recognized.

Research and development expenses for the quarter ended September 30, 2009 were $8.2 million, including $0.9 million of share-based compensation, compared to $8.7 million including $0.6 million of share-based compensation for the same quarter in 2008. The decrease in research and development expenses for the quarter ended September 30, 2009 was primarily due to a decrease in regulatory and clinical development program expenses relating to Fampridine-SR partially offset by increased expenses related to the development of the Company's preclinical pipeline products.

Sales, general and administrative expenses for the quarter ended September 30, 2009 were $23.3 million, including $2.3 million of share-based compensation, compared to $20.4 million including $2.1 million of share-based compensation for the same quarter in 2008. This increase in expenses was primarily due to increases in Fampridine-SR pre-launch activities, medical affairs educational programs and SG&A staff and compensation. Sales, general and administrative expenses will continue to increase in 2009 compared to 2008, primarily due to an increase in the Company's expected pre-launch costs.

The Company reported a net loss of $19.4 million for the quarter ended September 30, 2009, or $0.51 per diluted common share, compared to a net loss of $18.9 million, or $0.53 per diluted common share, for the same quarter in 2008.

As of September 30, 2009 Acorda held cash, cash equivalents, and short-term investments of $292.4 million. The Company expects this balance will provide a year-end 2009 cash, cash equivalents and short-term investment balance in excess of $250 million.

Fampridine-SR Update

- On October 14, the Peripheral and Central Nervous System Drugs Advisory Committee appointed by the FDA voted 12 to 1 that clinical data on Fampridine-SR 10 mg twice daily demonstrated substantial evidence of effectiveness as a treatment to improve walking in people with multiple sclerosis (MS) and voted 10 to 2 (1 abstention) that it is clinically meaningful and can be safe for use.
- The Advisory Committee voted that lower doses of Fampridine-SR be studied as part of a post-marketing commitment. In addition, the Committee recommended against mandatory electroencephalography (EEG) screenings for prospective Fampridine-SR patients.
- On October 22, the FDA notified the Company that the October 22 Prescription Drug User Fee Act (PDUFA) goal date for the Fampridine-SR New Drug Application (NDA) was being extended to January 22, 2010. The Company had submitted additional information on its proposed Risk Evaluation and Mitigation Strategy (REMS) program following the Advisory Committee meeting and evolution of its commercial distribution plan, which the FDA accepted as a solicited major amendment.
- In September, data on safety, efficacy and retention rates from up to two years of participation in the Fampridine-SR extension studies were presented at the 25 th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) and the 13 th Congress of the European Federation of Neurological Societies (EFNS).

Corporate Update

- Acorda and the FDA held a pre-IND meeting regarding the development plan for GGF2 in congestive heart failure. Based on feedback from the FDA, the Company expects to file an IND in early 2010.
- Ruhi Khan was promoted to Vice President, Business Development.

- Anthony Caggiano, M.D., Ph.D., was promoted to Vice President, Preclinical Development.
- CEO Ron Cohen was named one of the 100 Most Inspiring People in the Life Sciences Industry in the July/August edition of *PharmaVOICE* .

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 third quarter 2009 results.

To participate in the conference call, please dial 800-561-2718 (domestic) or 617-614-3525 (international) and reference the access code 47843550. The presentation will be available via a live webcast at:

http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2517249

A replay of the call will be available from 12:00 p.m. ET on November 3, 2009 until midnight on December 3, 2009. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 54903294. 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.

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. 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)

	September 30, 2009	December 31, 2008
Assets		
Cash, cash equivalents and short-term investments	$ 292,414	$ 246,049
Trade receivable, net	4,386	4,762
Other current assets	8,745	5,094
Finished goods inventory	5,775	6,144
Property and equipment, net	3,344	2,348
Intangible assets, net	15,603	16,565
Other assets	7,330	539
Total assets	$ 337,597	$ 281,501
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 21,932	$ 24,119
Deferred product revenue	27,126	24,304
Current portion of deferred license revenue	9,429	—
Current portion of revenue interest liability	6,402	6,181
Long term notes payable	7,060	6,905
Non-current portion of revenue interest liability	11,157	12,835
Non-current portion of deferred license revenue	98,214	—
Stockholders' equity	156,277	207,157
Total liabilities and stockholders' equity	$ 337,597	$ 281,501

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Gross sales - Zanaflex	$ 14,463	$ 13,667	$ 43,835	$ 39,442
Less: discounts and allowances	(1,606)	(1,224)	(5,959)	(4,153)
Net sales	12,857	12,443	37,876	35,289
License revenue	2,357	—	2,357	—
Grant revenue	—	23	—	76
Total net revenue	15,214	12,466	40,233	35,365
Cost of sales	(2,602)	(2,701)	(8,112)	(8,517)
Cost of license revenue	(165)	—	(165)	—
Gross profit	12,447	9,765	31,956	26,848
Operating expenses:				
Research and development	8,198	8,651	23,982	25,758
Sales and marketing	15,551	14,420	44,107	36,349
General and administrative	7,699	5,948	23,091	17,392
Total operating expenses	31,448	29,019	91,180	79,499
Operating loss	$ (19,001)	$ (19,254)	$ (59,224)	$ (52,651)
Other income (expense), net	(429)	398	(2,243)	(1,458)
Net loss	$ (19,430)	$ (18,856)	$ (61,467)	$ (54,109)
Net loss per common share - basic and diluted	$ (0.51)	$ (0.53)	$ (1.63)	$ (1.65)
Weighted average per common share - basic and diluted	37,750	35,265	37,701	32,724