ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	420 SAW MILL RIVER ROAD
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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): **August 4, 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 August 4, 2009, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 4, 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.

August 4, 2009

By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated August 4, 2009

Exhibit 99.1

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Second Quarter 2009 Financial Results

- *Acorda and Biogen Idec Agree to Fampridine-SR Ex-U.S. Collaboration onJune 30, 2009*
    - *Upfront Payment of $110 Million; Potential Deal Value Over $500 Million*
- *Company Notified by U.S. Food and Drug Administration (FDA) that Advisory Committee Meeting Will be Held for Fampridine-SR*

HAWTHORNE, N.Y., August 4, 2009 — Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the second quarter of 2009.

"A very productive second quarter was highlighted by the completion of our ex-U.S. collaboration with Biogen Idec, which we believe could benefit people with MS as well as Acorda shareholders. Biogen Idec has the capabilities and expertise to maximize the value of Fampridine-SR in ex-US markets, if approved, and to make it available to patients around the world who can potentially benefit from it," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "To continue to build shareholder value, in addition to advancing the Fampridine-SR program we are moving two of our preclinical product candidates towards INDs, and working to identify later stage product opportunities for potential acquisition."

Financial Results and Product Update
Zanaflex Capsules ® (tizanidine hydrochloride) and Zanaflex ® (tizanidine hydrochloride) Tablets gross sales - For the quarter ended June 30, 2009, the Company reported combined gross sales of Zanaflex Capsules and Zanaflex tablets of $14.8 million, compared to combined gross sales of $13.1 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. A slight downward trend in prescriptions was observed over the first two quarters of 2009.

Zanaflex Capsules and Zanaflex Tablets shipments - Total Zanaflex Capsules and Zanaflex tablet shipments for the quarter ended June 30, 2009 were $16.6 million, compared to total shipments of $16.0 million for the same quarter in 2008.

Research and development expenses for the quarter ended June 30, 2009 were $7.9 million, including $0.9 million of share-based compensation, compared to $8.1 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 June 30, 2009 was primarily due to the conclusion

of the second Phase 3 Fampridine-SR study in Q2 2008 offset by increased expenses related to the development of the Company's preclinical pipeline products.

Sales, general and administrative expenses for the quarter ended June 30, 2009 were $23.9 million, including $2.1 million of share-based compensation, compared to $17.6 million including $1.8 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 and SG&A staff and compensation. Sales, general and administrative expenses are expected to increase in 2009 compared to 2008, primarily due to an increase in the Company's expected pre-launch costs.

Collaboration accounting - For the quarter ended June 30, 2009, the Company recorded a license revenue receivable and deferred revenue of $110.0 million for the upfront payment due to Acorda from Biogen Idec for the collaboration agreement entered into on June 30, 2009, for the development and commercialization of Fampridine-SR in markets outside of the U.S. Also, as a result of this collaboration agreement, a payment of $7.7 million became payable by Acorda to Elan and was recorded as a cost of license revenue payable and deferred expense recorded in other assets. The license payment of $110.0 million was received from Biogen on July 1, 2009 and the payment of $7.7 million was made to Elan on July 7, 2009. Given the multiple components of the contract, the Company is assessing the accounting implications of these transactions.

The Company reported a net loss of $23.3 million for the quarter ended June 30, 2009, or $0.62 per diluted common share, compared to a net loss of $18.8 million, or $0.58 per basic and diluted common share, for the same quarter in 2008.

As of June 30, 2009 Acorda held cash, cash equivalents, and short-term investments of $212.4 million. The Company expects this balance, in addition to the net proceeds of $102.3 million from the Biogen collaboration agreement, will provide a year-end 2009 cash, cash equivalents and short-term investment balance in excess of $250 million.

Fampridine-SR Update

- Acorda and Biogen Idec announced an ex-U.S. collaboration to develop and commercialize Fampridine-SR on July 1. Under the terms of the agreement, Acorda received an upfront payment of $110 million and can receive additional payments of up to $400 million based on the successful achievement of future regulatory and sales milestones. Biogen Idec will make tiered, double-digit royalty payments to Acorda on ex-U.S. sales. Biogen will be responsible for all development and commercialization activities outside the U.S.
- The FDA accepted the Fampridine-SR NDA for filing on May 5, 2009 and assigned it Priority Review with a Prescription Drug User Fee Act (PDUFA) date of October 22, 2009.
- The FDA has notified the Company that a Peripheral and Central Nervous System Drugs Advisory Committee meeting will be held for Fampridine-SR. The date of the meeting will be posted in the Federal Register when finalized.
- Acorda received notification from the European Medicines Agency (EMEA) that Fampridine-SR is eligible to be submitted for a centralized filing, and also qualifies as a New Active Substance (NAS), which confers 10 years of market exclusivity if approved. The Company also disclosed the submission of an Intent to File letter to the EMEA on April 8, 2009.
- Data from Fampridine-SR extension studies have been accepted for a platform presentation at the 25 th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) on September 10. Data from the Fampridine-SR thorough QT study will also be presented at the meeting, being held September 9-12 in Dusseldorf, Germany.

- Data on the extension studies have also been accepted for presentation at the13 th Congress of the European Federation of Neurological Societies (EFNS), being held September 12-15 in Florence, Italy.
- As of June 30, 2009, 177 subjects from MS-F202 had been enrolled in an extension trial and 84, or approximately 47 percent, remained active in the trial, with duration of treatment ranging from 3.39 to 5.32 years. As of the same date, 269 patients from MS-F203 had been enrolled in a separate extension study and 180 of these, or approximately 66.9 percent, remained active, with duration of treatment ranging from 1.08 to 3.59 years. Also, as of this same date, 214 patients from MS-F204 had been enrolled in a third extension study and 176, or approximately 82 percent, remained active, with duration of treatment ranging from 14.33 months to 22.43 months. The total exposure to Fampridine-SR in our MS studies to date, including both double-blind and open label studies, is approximately 1750 patient-years.
- To ensure consistency of reporting, adverse event terms were standardized across all studies. Below is an updated table of adverse events for the three key controlled MS studies, MS-F202, MS-F203 and MS-F204.

MS-F202, MS-F203 and MS-F204: Most Frequent (>5%) Adverse Events

	Placebo (N = 238)	Fampridine-SR 10 mg BID (N = 400)
Falls	**16.4%**	**16.0%**
Urinary tract infection	**9.2%**	**14.5%**
Insomnia	**3.8%**	**9.3%**
Asthenia	**4.2%**	**8.3%**
Dizziness	**4.2%**	**7.8%**
Headache	**4.2%**	**7.5%**
Nausea	**2.5%**	**7.0%**
Fatigue	**4.6%**	**6.5%**
Upper Resp. Tract Inf.	**7.1%**	**5.8%**
Balance disorder	**1.3%**	**5.8%**
Back pain	**2.1%**	**5.5%**
MS relapse	**3.8%**	**5.3%**

Some of the percentages reported in earlier tables have changed, which in some cases affects their rank order. The only new AE that now reports at over 5% is MS relapse, at 5.3% for the Fampridine-SR treated group, vs. 3.8% for placebo. The imbalance between treatment groups for this event was due to worsening of MS symptoms occurring after discontinuation of drug.

Corporate Update

- Acorda supported a study by the North American Research Committee on Multiple Sclerosis (NARCOMS) that showed people with multiple sclerosis (MS) experience reduced income and earning potential as their mobility impairment increases. The data were presented at the American Academy of Neurology (AAN) 61 st Annual Meeting in April 2009.

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 second quarter 2009 results.

To participate in the conference call, please dial 866-804-6925 (domestic) or 857-350-1671 (international) and reference the access code 65868262. The presentation will be available via a live webcast at:

http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2331061

A replay of the call will be available from 12:30 p.m. ET on August 4, 2009 until midnight on August 25, 2009. To access the replay, please dial 888-268-8010 (domestic) or 617-801-6888 (international) and reference the access code 68339805. 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)

	June 30, 2009	December 31, 2008
Assets		
Cash, cash equivalents and short-term investments	$ 212,395	$ 246,049
License revenue receivable	110,000	—
Trade receivable, net	5,470	4,762
Other current assets	7,096	5,094
Finished goods inventory	6,072	6,144
Property and equipment, net	3,044	2,348
Intangible assets, net	15,924	16,565
Other assets	8,169	539
Total assets	$ 368,170	$ 281,501
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 25,809	$ 24,119
Cost of license revenue payable	7,700	—
Deferred product revenue	26,819	24,304
Current portion of revenue interest liability	7,258	6,181
Deferred license revenue	110,000	—
Long term notes payable	7,008	6,905
Non-current portion of revenue interest liability	11,779	12,835
Stockholders' equity	171,797	207,157
Total liabilities and stockholders' equity	$ 368,170	$ 281,501

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Gross sales - Zanaflex	$ 14,754	$ 13,099	$ 29,372	$ 25,775
Less: discounts and allowances	(2,204)	(1,740)	(4,353)	(2,929)
Net sales	12,550	11,359	25,019	22,846
Grant revenue	—	27	—	53
Total net revenue	12,550	11,386	25,019	22,899
Cost of sales	(2,952)	(2,830)	(5,511)	(5,816)
Gross profit	9,598	8,556	19,508	17,083
Operating expenses:				
Research and development	7,867	8,058	15,784	17,650
Sales and marketing	15,682	11,732	28,556	21,929
General and administrative	8,244	5,838	15,391	10,901
Total operating expenses	31,793	25,628	59,731	50,480
Operating loss	$ (22,195)	$ (17,072)	$ (40,223)	$ (33,397)
Other expense, net	(1,134)	(1,750)	(1,814)	(1,856)
Net loss	(23,329)	(18,822)	(42,037)	(35,253)
Net loss per common share - basic and diluted	$ (0.62)	$ (0.58)	$ (1.12)	$ (1.12)
Weighted average per common share - basic and diluted	37,708	32,557	37,676	31,451