ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 08/03/10 for the Period Ending 08/03/10

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): **August 3, 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 August 3, 2010, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 2010. 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 August 3, 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.

August 3, 2010

By: /s/ David Lawrence
Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated August 3, 2010

CONTACT:

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

Jeff Macdonald
Acorda Therapeutics
(914) 347-4300 ext. 232
jmacdonald@acorda.com

FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Second Quarter 2010 Financial Results

- **AMPYRA ® (dalfampridine) Gross Sales of $29.7 million**
- **4,200 Physicians have Written Prescriptions for AMPYRA as of July 30, 2010**
- **Company Encouraged by Progress with Managed Care Organizations to Address Patient Access to AMPYRA**

HAWTHORNE, N.Y., August 3, 2010 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the second quarter of 2010.

"We are very pleased with the success of the launch to date and the continued strong demand for AMPYRA during the second quarter. As of July 30, 2010, over 4,200 physicians have written at least one prescription for AMPYRA. In addition, our commercial team has taken a number of steps to improve the customer service experience and decrease wait times at AMPYRA Patient Support Services. To that end, we have eliminated the backlog of prescription requests that resulted from initial pent-up demand at launch. We have also implemented a number of process improvements to reduce the time between an AMPYRA prescription being submitted and when the drug is in the hands of the patient," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "We are encouraged by the progress we are making with managed care organizations and continue to meet with them to achieve the broadest possible access for patients."

Financial Results and Product Update
AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg gross sales - For the quarter ended June 30, 2010, the Company reported gross sales of AMPYRA of $29.7 million. Acorda began shipping AMPYRA to specialty pharmacies on March 1, 2010 and recognized gross sales of $3.4 million in the first quarter. Gross sales of AMPYRA are recognized following shipment of the product from the Company's distribution facility to its network of specialty pharmacies.

ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and ZANAFLEX ® (tizanidine hydrochloride) TABLETS gross sales - For the quarter ended June 30, 2010, the Company reported combined gross sales of ZANAFLEX CAPSULES and ZANAFLEX TABLETS of $13.7 million compared to combined gross sales of $14.8 million for the same quarter in 2009. ZANAFLEX gross sales are recognized using a deferred revenue recognition model, meaning ZANAFLEX CAPSULES and ZANAFLEX TABLETS 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. As previously projected, the Company expects sales of ZANAFLEX CAPSULES to decline in 2010.

ZANAFLEX CAPSULES and ZANAFLEX TABLETS shipments - Total ZANAFLEX CAPSULES and ZANAFLEX TABLETS shipments for the quarter ended June 30, 2010 were $13.5 million, compared to total shipments of $16.6 million for the same quarter in 2009.

Research and development expenses for the quarter ended June 30, 2010 were $6.6 million, including $1.4 million of share-based compensation, compared to $7.9 million including $0.9 million of share-based compensation for the same quarter in 2009. Research and development expenses for the quarter ended June 30, 2010 included costs related to AMPYRA long-term extension studies and development of the Company's preclinical products.

Sales, general and administrative expenses for the quarter ended June 30, 2010 were $34.1 million, including $3.2 million of share-based compensation, compared to $23.9 million including $2.1 million of share-based compensation for the same quarter in 2009. The increase in expenses was primarily due to increases in AMPYRA launch activities. The Company expects SG&A expenses to slightly increase over these levels for the remainder of the year.

The Company reported a net loss of $6.8 million for the quarter ended June 30, 2010, or $0.18 per diluted common share, compared to a net loss of $23.3 million, or $0.62 per diluted common share, for the same quarter in 2009.

As of June 30, 2010, Acorda held cash, cash equivalents and short-term investments of $216.4 million.

AMPYRA Update

- Gross sales of AMPYRA were $29.7 million for the quarter ended June 30, 2010.
- Currently, inventory levels at specialty pharmacy providers that distribute AMPYRA represent one month or less of inventory.
- The prescription request backlog at AMPYRA Patient Support Services (APSS) experienced early in the launch has been cleared based on process improvements and staffing adjustments. Processing of most incoming requests now begins within 24 hours of receipt. Patients will still experience a range of times to receive their first shipment based on their insurance requirements. As with any new prescription product, patients who are members of benefit plans that have restrictive prior authorizations may experience delays in receiving their prescription.
- Acorda's Managed Markets representatives continue to meet with payors to provide information on AMPYRA and discuss patient access. Currently, a majority of insured individuals have no or minimal restrictions to access. Consistent with the Company's internal pre-launch projections, a significant minority are subject to more restrictive prior authorizations. Acorda estimates that a mid-single digit percentage of patients are currently blocked from receiving reimbursement for AMPYRA, some of these because their plans have not yet formally reviewed the medication.
- Currently, approximately 10% of shipped product is for no-cost use by patients enrolled in the AMPYRA patient assistance program.
- Acorda has received non-final rejection letters from the U.S. Patent and Trademark Office (USPTO) on two patent applications for AMPYRA filed in late 2004 and early 2005. The Company has six months from the date of issue to respond to the letters.
- The Company presented posters on AMPYRA and compounded 4-aminopyridine at the Consortium of Multiple Sclerosis Centers (CMSC) meeting in June 2010.

ZANAFLEX CAPSULES Update

- On July 2, the U.S. District Court held a Markman hearing to determine the interpretation of certain terms in the Company's ZANAFLEX CAPSULES patent that is at issue in its litigation against Apotex, Inc. and Apotex Corporation, in connection with Apotex Inc.'s Paragraph 4 ANDA (Abbreviated New Drug Application) certification. The Company is pleased that the Court ruled favorably on a number of those terms, and the case is proceeding.

Preclinical

- There was a delay in completing production of GGF2 clinical study medication due to deficiencies in the vial filling process. These are being remediated, but there will be a consequent delay in the start of the Phase 1 trial, which was originally targeted for mid-2010.
- Acorda and Vanderbilt University received a $1 million Cardiac Translational Research Implementation Program (C-TRIP) grant from the National Heart, Lung and Blood Institute (NHLBI) to support research on Glial Growth Factor 2 (GGF2). If these studies are successful, Acorda and Vanderbilt will be eligible to apply for a second phase C-TRIP grant of at least $7.5 million.

Corporate Update

- Douglas Kargman, M.D., M.S., joined the Company as Vice President of Drug Safety.
- Kent Rogers was promoted to Vice President, Managed Markets.
- Jennifer Burstein was promoted to Vice President, Finance.
- In May 2010, Ron Cohen was named Chair of the Biotechnology Industry Organization (BIO) Emerging Companies Section.
- The National Organization for Rare Disorders (NORD) recognized Acorda for the Company's contribution to advancing care for people with rare diseases at the NORD Partners in Progress Gala in May 2010.
- Chief Scientific Officer Andrew Blight, Ph.D. presented the keynote lecture at the American Spinal Injury Association (ASIA) annual meeting in May 2010. He was also the recipient of the inaugural Purchase College Science Entrepreneurship Award, which recognizes individuals for their scientific excellence, ability to integrate science with business, vision and innovation, social responsibility.

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 2010 results.

To participate in the conference call, please dial 866-510-0704 (domestic) or 617-597-5362 (international) and reference the access code 15998123. The presentation will be available via a live webcast at: http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2652916 .

A replay of the call will be available from 12:30 p.m. ET on August 3, 2010 until midnight on September 2, 2010. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 27725709. 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)

	June 30, 2010	December 31, 2009
Assets		
Cash, cash equivalents and short-term investments	$ 216,439	$ 272,092
Trade receivable, net	18,065	5,879
Other current assets	9,262	8,417
Finished goods inventory	20,015	6,893
Property and equipment, net	2,788	1,891
Intangible assets, net	22,657	17,149
Other assets	6,762	7,150
Total assets	$ 295,988	$ 319,471
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 24,475	$ 26,589
Deferred product revenue	29,166	30,704
Current portion of deferred license revenue	9,429	9,429
Current portion of notes payable	1,144	-
Current portion of revenue interest liability	6,552	6,179
Long term notes payable	6,079	7,112
Non-current portion of revenue interest liability	5,301	6,268
Non-current portion of deferred license revenue	91,143	95,857
Stockholders' equity	122,699	137,333
Total liabilities and stockholders' equity	$ 295,988	$ 319,471

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	**2009**	**2010**	**2009**
Revenues:				
Gross product sales	$ 43,443	$ 14,754	$ 60,697	$ 29,372
Less: discounts and allowances	(2,965)	(2,204)	(4,828)	(4,353)
Net sales	40,478	12,550	55,869	25,019
License revenue	2,357	-	4,714	-
Total revenues	42,835	12,550	60,583	25,019
Costs and expenses:				
Cost of sales	7,832	2,952	10,908	5,511
Research and development	6,596	7,867	14,658	15,784
Selling, general and administrative	34,112	23,926	60,826	43,947
Total operating expenses	48,540	34,745	86,392	65,242
Operating loss	$ (5,705)	$ (22,195)	$ (25,809)	$ (40,223)
Other expense, net	(1,059)	(1,134)	(2,069)	(1,814)
Net loss	$ (6,764)	$ (23,329)	$ (27,878)	$ (42,037)
Net loss per common share - basic and diluted	$ (0.18)	$ (0.62)	$ (0.73)	$ (1.12)
Weighted average per common share - basic and diluted	38,306	37,708	38,164	37,676