ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 11/01/10 for the Period Ending 11/01/10

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): **November 1, 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 November 1, 2010, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 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

Exhibit No.	Description
99.1	Press Release dated November 1, 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.

November 1, 2010

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated November 1, 2010

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Third Quarter 2010 Financial Results

- **AMPYRA ® (dalfampridine) Gross Sales of $52.6 million**
- **Approximately 31,000 People with MS have Filled an AMPYRA Prescription as of September 30, 2010**
- **Approximately 6,300 Physicians have Written at Least One Prescription for AMPYRA as of September 30, 2010**
- **Company Reports $12.4 Million Net Income**

HAWTHORNE, N.Y., November 1, 2010 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the third quarter of 2010.

“We continue to be pleased with the progress of the AMPYRA launch,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “We are gratified by the feedback from patients and physicians, and are proud that AMPYRA is providing unique benefits to people with MS.”

Financial Results
AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg gross sales - For the quarter ended September 30, 2010, the Company reported gross sales of AMPYRA of $52.6 million. Acorda began shipping AMPYRA to specialty pharmacies on March 1, 2010 and recognized gross sales of $3.4 million in the first quarter and $29.7 million in the second quarter. Gross sales of AMPYRA are recognized following shipment of the product from the Company’s distribution facility to its network of specialty pharmacies. Third quarter sales were significantly impacted by the large backlog of prescription requests that were submitted earlier in the year and were not all filled until the third quarter. This backlog was eliminated in the third quarter, and fourth quarter sales may be lower than third quarter sales.

ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and ZANAFLEX ® (tizanidine hydrochloride) tablets gross sales - For the quarter ended September 30, 2010, the Company reported combined gross sales of ZANAFLEX CAPSULES and ZANAFLEX tablets of $13.6 million compared to combined gross sales of $14.5 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 September 30, 2010 were $14.6 million, compared to total shipments of $15.3 million for the same quarter in 2009.

Research and development expenses for the quarter ended September 30, 2010 were $8.0 million, including $1.5 million of share-based compensation, compared to $8.2 million including $0.9 million of share-based compensation for the same quarter in 2009. Research and development expenses for the quarter ended September 30, 2010 included costs related to AMPYRA long-term extension studies and development of the Company's preclinical products. The Company's previous guidance was that R&D expenses would increase in 2010 over 2009. Due to the delay in production of GGF2 clinical study medication announced last quarter as a result of the deficiencies in the vial filling process and the consequent delay in the start of the Phase 1 trial originally targeted for mid-2010, the Company now expects that R&D expenses will slightly decrease in 2010 over 2009.

Sales, general and administrative expenses for the quarter ended September 30, 2010 were $30.7 million, including $3.3 million of share-based compensation, compared to $23.4 million including $2.3 million of share-based compensation for the same quarter in 2009. The increase in expenses was primarily due to increases in AMPYRA launch activities. SG&A expenses decreased in the third quarter from the second quarter, but the Company still expects 2010 SG&A expenses to be substantially higher than in 2009.

The Company reported net income of $12.4 million for the quarter ended September 30, 2010, or $0.32 per basic EPS and $0.31 per diluted EPS, compared to a net loss of $19.4 million, or $0.51 per basic and diluted EPS for the same quarter in 2009.

As of September 30, 2010, Acorda held cash, cash equivalents and short-term investments of $245.8 million.

AMPYRA Update

- From March through September 2010, approximate total prescriptions (TRx) filled for AMPYRA were: 870 (March), 4,880 (April), 8,110 (May), 17,400 (June), 17,310 (July), 18,140 (August) and 18,350 (September). These totals include prescriptions for free drug filled through the AMPYRA patient assistance program.
- From March through September 2010, new patients receiving AMPYRA were approximately: 570 (March), 3,120 (April), 4,250 (May), 6,460 (June), 6,720 (July), 6,230 (August) and 3,970 (September). These totals include prescriptions for free drug filled through the AMPYRA patient assistance program.
- As of September 30, 2010, approximately 31,000 people with MS have filled a prescription for AMPYRA, representing almost 8% of all MS patients in the United States
- The rate of first refill as of September 30, 2010 was 67%, based on a weighted average from a cohort of approximately 17,500 patients who received an initial one-month prescription in March-August.
- Approximately 6,300 healthcare professionals have written at least one prescription for AMPYRA as of September 30, 2010.
- The Company's original target call list included 5,500 physicians, who were selected based on immunomodulator prescribing data. Among those physicians who are in the top five prescribing deciles (the group that writes 50% of prescriptions), approximately 87% have written at least one AMPYRA prescription. Based on analysis of actual AMPYRA prescribers, the Company has expanded its target list to approximately 10,000 physicians.
- Consistent with the product label, AMPYRA is being used both with and without immunomodulators. In a sample of approximately 10,000 AMPYRA patients from two of the largest specialty pharmacy providers (SPPs), approximately 40% were not on immunomodulator therapy.
- Also consistent with the product label, AMPYRA is being prescribed to patients with all types of MS. The patient's type of MS has been specified on approximately 67% of AMPYRA prescription request forms received to date. Of these patients, 66% have been diagnosed with relapsing remitting MS, and 34% have been diagnosed with one of the three progressive forms of MS.
- Inventory on hand at the 12 SPPs that distribute AMPYRA (does not include Kaiser) was approximately two weeks as of September 30, 2010. These SPPs are contractually obligated to hold no more than 30 days of inventory.
- As of September 30, 2010, approximately 75% of commercially-insured individuals have no or limited prior authorizations (PAs) for AMPYRA. Limited PAs are defined as those that require only an MS diagnosis, documentation of no contraindications, and/or simple documentation that the patient has walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. Approximately 20% of commercially-insured individuals are subject to more restrictive PAs, which may include requirements for multiple timed walk tests and/or EDSS score requirements to initiate therapy, and/or objective measures of ambulation improvement to reauthorize AMPYRA therapy. Acorda estimates approximately 5% of commercially-insured individuals are currently blocked from receiving reimbursement for AMPYRA. Access figures have been calculated based on the number of pharmacy lives reported by commercial healthcare plans. Managed care plans continue to evaluate AMPYRA, and may change requirements over time. In addition, some plans have not yet formally reviewed AMPYRA.
- Pent up demand early in the launch of AMPYRA created a backlog of prescriptions that continued to be filled

during the third quarter. This backlog was eliminated by the end of the third quarter.

- Currently, approximately 10% of shipped product is free to patients enrolled in the AMPYRA patient assistance program.
- In October 2010, the European Patent Office posted a “Communication of Intent to Grant a Patent” for a patent submitted by the Company with “composition for use” and other use claims directed to sustained release aminopyridine compositions for, among other things, increased walking speed, improving lower extremity muscle strength, or improving lower extremity muscle tone, in patients with MS. A corresponding patent is currently under review by the U.S. Patent and Trademark Office.
- Data on AMPYRA was presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) meeting in October 2010.

Pipeline

- Preclinical stroke data on Glial Growth Factor 2 (GGF2) was published in *Neuropharmacology* . Data from two studies showed GGF2 promoted functional recovery from stroke with treatment initiated up to seven days after the event.
- The Company has resolved the vial filling issues associated with GGF2 production and is now completing preparations for its Phase 1 clinical trial in patients with heart failure.

Webcast and Conference Call

Ron Cohen, President and Chief Executive Officer, David Lawrence, Chief Financial Officer and Lauren Sabella, Executive Vice President, Commercial Development will host a conference call today at 8:30 a.m. ET to review the Company's third quarter 2010 results.

To participate in the conference call, please dial 800-798-2796 (domestic) or 617-614-6204 (international) and reference the access code 30613175. The presentation will be available via a live webcast at:

http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID= 2652918

A replay of the call will be available from 12:30 p.m. ET on November 1, 2010 until midnight on January 1, 2011. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 78668201. The archived webcast will be available for 30 days in the Investor Events 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; third party payors (including governmental agencies) may not reimburse for the use of Ampyra at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; 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. Forward-looking statements made in this release are made only as of the date hereof, and 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, 2010	December 31, 2009
Assets		
Cash, cash equivalents and short-term investments	$ 245,817	$ 272,092
Trade receivable, net	18,369	5,879
Other current assets	9,145	8,417
Finished goods inventory	26,182	6,893
Property and equipment, net	3,321	1,891
Intangible assets, net	22,013	17,149
Other assets	6,574	7,150
Total assets	$ 331,421	$ 319,471
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 43,167	$ 26,589
Deferred product revenue	29,327	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	6,381	6,179
Long term notes payable	6,132	7,112
Non-current portion of revenue interest liability	4,693	6,268
Non-current portion of deferred license revenue	88,786	95,857
Stockholders' equity	142,362	137,333
Total liabilities and stockholders' equity	$ 331,421	$ 319,471

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	**2009**	**2010**	**2009**
Revenues:				
Gross product sales	$ 66,188	$ 14,463	$126,885	$ 43,835
Less: discounts and allowances	(4,923)	(1,606)	(9,751)	(5,959)
Net sales	61,265	12,857	117,134	37,876
License revenue	2,357	2,357	7,071	2,357
Total revenues	63,622	15,214	124,205	40,233
Costs and expenses:				
Cost of sales	11,666	2,602	22,574	8,112
Research and development	7,970	8,198	22,628	23,982
Selling, general and administrative	30,723	23,415	91,549	67,363
Total operating expenses	50,359	34,215	136,751	99,457
Operating income (loss)	$ 13,263	$ (19,001)	$ (12,546)	$ (59,224)
Other expense, net	(825)	(429)	(2,894)	(2,243)
Net income (loss)	$ 12,438	$ (19,430)	$ (15,440)	$ (61,467)
Net income (loss) per common share - basic	$ 0.32	$ (0.51)	$ (0.40)	$ (1.63)
Net income (loss) per common share - diluted	$ 0.31	$ (0.51)	$ (0.40)	$ (1.63)
Weighted average per common share - basic	38,450	37,750	38,261	37,701
Weighted average per common share - diluted	39,988	37,750	38,261	37,701