ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
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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 4 , 2011**

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 4, 2011, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2011. 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 4, 2011

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 4, 2011

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated November 4, 2011

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Third Quarter 2011 Financial Results

- AMPYRA ® (dalfampridine) Third Quarter Net Revenue of $54.7 million
  - AMPYRA Revenue Growth of 5.6% over Second Quarter
- Allowance of Second U.S. Patent Application Strengthens AMPYRA Patent Protection

HAWTHORNE, N.Y., November 4, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the third quarter ended September 30, 2011.

“We are pleased with the renewed growth of AMPYRA over the last two quarters. Persistence and compliance rates among patients who respond to AMPYRA are high. This will be an important contributor to the long-term growth of the brand,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO.

“In addition, independent market research indicates that our marketing campaigns, which highlight the benefits of AMPYRA in people with early-stage walking impairment, are resonating with prescribers. Surveys also indicate that physicians believe the majority of their current patients who are appropriate for AMPYRA have not yet tried the drug. We are also focusing our programs on reaching the large pool of MS patients with walking impairment who are not yet aware of the potential benefits of AMPYRA.”

FINANCIAL RESULTS

The Company reported GAAP net income of $18.9 million for the quarter ended September 30, 2011, or $0.47 per diluted EPS, including share-based compensation charges totaling $5.1 million, net milestone revenue of $23.3 million relating to Biogen Idec’s receipt of conditional approval from the European Commission for FAMPYRA and accounting adjustments totaling $15.5 million relating to ZANAFLEX CAPSULES due to the Apotex patent infringement trial decision described in the ZANAFLEX CAPSULES section below. The GAAP net income for the third quarter of 2010 was $12.4 million, or $0.31 per diluted EPS including share-based compensation charges of $4.8 million.

Non-GAAP net income, before share-based compensation charges, net milestone revenue and accounting adjustments relating to ZANAFLEX CAPSULES due to the Apotex patent infringement trial court decision for the quarter ended September 30, 2011 was $16.2 million or $0.40 per diluted EPS, compared to a non-GAAP net income of $17.2 million, or $0.43 per diluted EPS for the same quarter in 2010.

AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg net revenue - For the quarter ended September 30, 2011, the Company reported AMPYRA net revenue of $54.7 million, compared to $49.8 million in net revenue for the same quarter in 2010.

AMPYRA revenue is recognized following shipment of the product from the Company’s distribution facility to its network of specialty pharmacies.

The Company reiterates its 2011 net sales guidance for AMPYRA of $205 - $230 million.

ZANAFLEX CAPSULES®(tizanidine hydrochloride) and ZANAFLEX® (tizanidine hydrochloride) tablets net revenue - For the quarter ended September 30, 2011, the Company reported combined net revenue of ZANAFLEX CAPSULES and ZANAFLEX tablets of $10.7 million, compared to combined net revenue of $11.5 million for the same quarter in 2010.

ZANAFLEX revenue is 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.

ZANAFLEX CAPSULES and ZANAFLEX tablets shipments - Total ZANAFLEX CAPSULES and ZANAFLEX tablets shipments for the quarter ended September 30, 2011 were $14.1 million, compared to total shipments of $14.6 million for the same quarter in 2010.

Cost of sales for the quarter ended September 30, 2011 were $26.7 million compared to $11.7 million for the same quarter in 2010. The increase in cost of sales was due to the increase in AMPYRA sales and $14.1 million in accounting adjustments related to the Apotex patent infringement trial court decision.

Research and development expenses for the quarter ended September 30, 2011 were $9.1 million, including $1.5 million of share-based compensation, compared to $8.0 million including $1.5 million of share-based compensation for the same quarter in 2010. Research and development expenses for the quarter included costs related to AMPYRA post-marketing studies and life cycle management programs, and the development of the Company's pipeline products, including Phase 1 clinical trial expenses for Glial Growth Factor 2 (GGF2).

The Company is refining its full year 2011 research and development expense guidance to $35-$40 million excluding share-based compensation charges, from $40-45 million excluding share-based compensation charges.

Sales, general and administrative expenses for the quarter ended September 30, 2011 were $34.7 million, including $3.5 million of share-based compensation and accounting adjustments of $1.1 million to the Paul Royalty Fund (PRF) put/call liability and $336,000 for a sample inventory reserve relating to ZANAFLEX CAPSULES due to the Apotex patent infringement trial court decision described in the ZANAFLEX CAPSULES section below, compared to $30.6 million including $3.3 million of share-based compensation for the same quarter in 2010. The increase in expenses was also due to increases in AMPYRA educational and regulatory activities and other expenses related to the Apotex patent infringement litigation.

The Company reaffirms its full year 2011 sales, general and administrative expense guidance of $130-$140 million excluding share-based compensation charges.

In the third quarter of 2011, the Company was cash flow positive and closed the quarter in a strong financial position with cash, cash equivalents and short-term investments of $268.8 million.

AMPYRA UPDATE

- As of September 2011, approximately 70% of all people with MS who were prescribed AMPYRA received a first refill. Approximately 40% of people with MS who were prescribed AMPYRA received a sixth refill.
- As of September 2011, the average duration of therapy on AMPYRA was approximately 10 months, up from 5 months in January 2011. The average duration of therapy is expected to increase over time.
- Compliance rates for AMPYRA are high at 90%, with patients currently taking an average of 1.8 tablets per day, compared to the approved dosing of 2 tablets per day.

- On August 10, the United States Patent and Trademark Office (USPTO) allowed U.S. Patent Application No. 11/102,559 entitled "Method of Using Sustained Release Aminopyridine Compositions."
- The USPTO issued the previously allowed patent application 11/010,828 “Sustained Release Aminopyridine Composition.” The USPTO determined that with the final patent term restoration, this patent will extend into May 2027.
- In September, Biogen Idec launched FAMPYRA ® (prolonged-release fampridine tablets) in Germany. Availability in other European countries is expected to follow. FAMPYRA is being developed and marketed by Biogen Idec outside the United States under a licensing agreement from Acorda.
- During the third quarter, Acorda recorded a $25 million milestone payment from Biogen Idec based on EU approval of FAMPYRA. Based on its worldwide license and supply agreement with Elan, Elan received 7% of this milestone payment from Acorda.
- In October, analyses of AMPYRA open-label clinical trial extension studies and one year post-marketing safety data were presented at the 5 th Joint Triennial Congress of European and Americas Committees for Treatment and Research in Multiple Sclerosis (ECTRIMS and ACTRIMS). The safety profile of AMPYRA in both analyses was consistent with that seen in placebo-controlled clinical trials. Analysis of walking speed data from the extension studies showed that people who responded to AMPYRA had sustained improvement compared to non-responders for up to five years on treatment.

ZANAFLEX CAPSULES

- On September 7, Acorda announced that the U.S. District Court for the District of New Jersey ruled against it in its patent litigation against Apotex Corporation and Apotex, Inc. The Court held that the claims of U.S. Patent No. 6,455,557 covering use of multiparticulate tizanidine compositions are invalid and not infringed by Apotex Corporation and Apotex, Inc. The Company is appealing the decision.
- Certain accounting adjustments were made during the third quarter relating to ZANAFLEX CAPSULES as a result of the Apotex patent infringement trial court decision. This included a $13.0 million intangible asset impairment included in cost of sales, a $1.0 million commercial inventory reserve included in cost of sales, a $1.1 million PRF put/call liability adjustment included in SG&A, and a $336,000 sample inventory reserve included in SG&A.

PIPELINE UPDATE

- The Company plans to begin a proof-of-concept clinical study of AMPYRA in adults with cerebral palsy by the end of 2011.
- Based on positive preclinical data, the Company plans to begin a proof-of-concept clinical study of AMPYRA in post-stroke patients in 2012.
- The Company expects to begin enrolling participants in a Phase 2 clinical trial of AC105 in patients with acute spinal cord injury in the second half of 2012.
- The Phase 1, escalating dose clinical trial of GGF2 in heart failure patients, being conducted in collaboration with the Vanderbilt University Heart and Vascular Institute, is ongoing. The Company expects to present initial study results at a meeting in the first half of 2012.
- The Company plans to submit an IND for rHIgM22 in the first half of 2012.

CORPORATE UPDATES

- Enrique J. Carrazana, M.D. joined the Company as Chief Medical Officer.
- Acorda and the National Multiple Sclerosis Society sponsored a Harris Interactive poll of people with MS. The survey found walking difficulties or trouble with balance affect 65% of people with multiple sclerosis, and 70% of people with MS-related walking difficulties report that trouble walking is the most challenging aspect of MS. Yet, 40% of people with MS “rarely or never”

discuss walking problems with their doctor. The survey results were presented at the 2011 ECTRIMS/ACTRIMS conference.

This press release includes financial results prepared in accordance with accounting principles generally accepted in the United States (GAAP), and also certain historical and forward-looking non-GAAP financial measures. In particular, Acorda has provided its third quarter 2011 and 2010 income (loss), adjusted to exclude share-based compensation charges, the net milestone revenue relating to Biogen Idec's receipt of conditional approval from the European Commission for FAMPYRA in Q3 2011, the ZANAFLEX CAPSULES adjustments due to the Apotex patent infringement trial court decision in Q3 2011 and the upfront payment associated with in-licensing AC105 in Q2 2011. Also, Acorda has provided projected amounts of research and development (R&D) and sales, general, and administrative (SG&A) expenses excluding share-based compensation charges. These non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, we believe the presentation of these non-GAAP financial measures when viewed in conjunction with our GAAP results, provide investors with a more meaningful understanding of our ongoing and projected operating performance because they exclude non-cash charges that are substantially dependent on changes in the market price of our common stock and expenses and income that do not arise from the ordinary course of our business. We believe these non-GAAP financial measures help indicate underlying trends in the company's business and are important in comparing current results with prior period results and understanding projected operating performance. Also, management uses these non-GAAP financial measures to establish budgets and operational goals, and to manage the company's business and to evaluate its performance. A reconciliation of the historical non-GAAP financial results presented in this release to our GAAP financial results is included in the attached financial statements.

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 2011 results.

To participate in the conference call, please dial 866-825-3308 (domestic) or 617-213-8062 (international) and reference the access code 61434160. The presentation will be available via a live webcast at:

http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=4221831

A replay of the call will be available from 11:30 a.m. ET on November 4, 2011 until midnight on November 30, 2011. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 46140115. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at www.acorda.com .

Important Safety Information
AMPYRA can cause seizures; the risk of seizures increases with increasing AMPYRA doses. AMPYRA is contraindicated in patients with a prior history of seizure. Discontinue AMPYRA use if seizure occurs.

AMPYRA is contraindicated in patients with moderate or severe renal impairment (CrCl≤50 mL/min); the risk of seizures in patients with mild renal impairment (CrCl 51–80 mL/min) is unknown, but AMPYRA plasma levels in these patients may approach those seen at a dose of 15 mg twice daily, a dose that may be associated with an increased risk of seizures; estimated CrCl should be known before initiating treatment with AMPYRA.

AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

Urinary tract infections were reported more frequently as adverse reactions in patients receiving AMPYRA 10 mg twice daily compared to placebo.

The most common adverse events (incidence ≥2% and at a rate greater than the placebo rate) for AMPYRA in MS patients were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain.

For full U.S. Prescribing Information and Medication Guide for AMPYRA, please visit: www.AMPYRA.com.

About AMPYRA (dalfampridine)
AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed. AMPYRA, which was previously referred to as Fampridine-SR, is an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), and is known as prolonged-, modified, or sustained-release fampridine (FAMPYRA ®) in some countries outside the United States (U.S).

In laboratory studies, dalfampridine extended release tablets has been found to improve impulse conduction in nerve fibers in which the insulating layer, called myelin, has been damaged. AMPYRA is being developed and commercialized in the U.S. by Acorda Therapeutics; FAMPYRA is being developed and commercialized by Biogen Idec in markets outside the U.S. based on a licensing agreement with Acorda. AMPYRA and FAMPRYA are manufactured globally by Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, based on a supply agreement with Acorda.

AMPYRA is available by prescription in the United States. For more information about AMPYRA, including patient assistance and co-pay programs, healthcare professionals and people with MS can contact AMPYRA Patient Support Services at 888-881-1918.

AMPYRA Patient Support Services is available Monday through Friday, from 8:00 a.m. to 8:00 p.m. Eastern Time at 888-881-1918. For full U.S. Prescribing Information and Medication Guide, please visit: www.AMPYRA.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 is commercializing and marketing AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, in the United States. AMPYRA is 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. AMPYRA was developed using Alkermes' Matrix Drug Absorption System (MXDAS ®) technology and is manufactured by Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, based on a supply agreement with Acorda.

Acorda also markets 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; 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, including the impact of anticipated potential generic competition on Zanaflex Capsules revenues; failure to protect Acorda Therapeutics' intellectual property, to defend against the intellectual

property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; the ability to obtain additional financing to support Acorda Therapeutics' operations; and, unfavorable results from our research and development 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, 2011	December 31, 2010
Assets		
Cash, cash equivalents and short-term investments	$ 268,813	$ 240,029
Trade receivable, net	20,608	22,272
Other current assets	15,183	10,449
Finished goods inventory	29,769	38,418
Property and equipment, net	3,595	3,203
Intangible assets, net	7,053	21,336
Other assets	6,077	6,394
Total assets	$ 351,098	$ 342,101
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 33,182	$ 50,730
Deferred product revenue	29,319	31,296
Current portion of deferred license revenue	9,057	9,429
Current portion of notes payable	1,144	1,144
Current portion of revenue interest liability	1,735	1,297
Long term liabilities	5,663	6,538
Non-current portion of revenue interest liability	4,075	3,977
Non-current portion of deferred license revenue	80,007	86,429
Stockholders' equity	186,916	151,261
Total liabilities and stockholders' equity	$ 351,098	$ 342,101

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	**2010**	**2011**	**2010**
Revenues:				
Net revenues	$ 65,420	$ 61,265	$ 187,222	$ 117,134
Milestone revenue	25,000	-	25,000	-
License revenue	2,264	2,357	6,793	7,071
Royalty revenue	347	-	578	-
Total revenues	93,031	63,622	219,593	124,205
Costs and expenses:				
Cost of sales	26,651	11,666	50,749	22,574
Cost of milestone and license revenue	1,908	165	2,225	495
Research and development	9,088	7,970	31,804	22,628
Selling, general and administrative	34,718	30,558	112,788	91,054
Total operating expenses	72,365	50,359	197,566	136,751
Operating income (loss)	$ 20,666	$ 13,263	$ 22,027	$ (12,546)
Other expense, net	(813)	(825)	(2,951)	(2,894)
Income (loss) before income taxes	19,853	12,438	19,076	(15,440)
Provision for income taxes	(986)	-	(1,165)	-
Net income (loss)	$ 18,867	$ 12,438	$ 17,911	$ (15,440)
Net income (loss) per common share - basic	$ 0.48	$ 0.32	$ 0.46	$ (0.40)
Net income (loss) per common share - diluted	$ 0.47	$ 0.31	$ 0.45	$ (0.40)
Weighted average per common share - basic	39,100	38,450	38,940	38,261
Weighted average per common share - diluted	40,174	39,988	40,035	38,261

Acorda Therapeutics, Inc.
Non-GAAP Income (Loss) and Income (Loss) per Common Share Reconciliation
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
GAAP net income (loss)	$ 18,867	$ 12,438	$ 17,911	$ (15,440)
Pro forma adjustments:				
Collaboration milestone revenue (Note 1)	(25,000)	-	(25,000)	-
Cost of milestone revenue (Note 1)	1,750	-	1,750	-
Zanaflex Capsule adjustments (Note 2)	15,477	-	15,477	-
License agreement expense (Note 3)	-	-	3,000	-
Share-based compensation expenses included in R&D	1,532	1,414	4,122	3,618
Share-based compensation expenses included in SG&A	3,524	3,374	9,725	8,940
Total share-based compensation expenses	5,056	4,788	13,847	12,558
Total pro forma adjustments	(2,717)	4,788	9,074	12,558
Non-GAAP net income (loss)	$ 16,150	$ 17,226	$ 26,985	$ (2,882)
Net income (loss) per common share - basic	$ 0.41	$ 0.45	$ 0.69	$ (0.08)
Net income (loss) per common share - diluted	$ 0.40	$ 0.43	$ 0.67	$ (0.08)
Weighted average per common share - basic	39,100	38,450	38,940	38,261
Weighted average per common share - diluted	40,174	39,988	40,035	38,261

Note 1: $25 million milestone revenue relating to Biogen Idec receipt of conditional approval from the European Commission for Fampyra in Q3 2011. Based on Acorda's worldwide license and supply agreement with Elan, Elan received 7% of this milestone payment from Acorda during the same period which was recorded as cost of milestone revenue.
Note 2: Adjustments relating to Zanaflex Capsules due to Apotex patent infringement trial court decision in Q3 2011. ($13,038 Intangible asset impairment included in cost of sales, $1,020 commercial inventory reserve included in cost of sales, $1,083 PRF put/call liability adjustment included in SG&A, $336 sample inventory reserve included in SG&A).
Note 3: $3 million upfront expense related to licensed worldwide development and commercialization rights to a proprietary magnesium formulation from Medtronic, Inc. (AC105) included in R&D Q2 2011.