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): **August 1, 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 August 1, 2011, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 1, 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.

August 1, 2011

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated August 1, 2011

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Second Quarter 2011 Financial Results

- AMPYRA ® (dalfampridine) Net Revenue of $51.8 Million
- European Commission Approval of FAMPYRA ® in Europe Triggers $25 Million Payment to Acorda from Biogen Idec in Third Quarter
- In-Licensing of Worldwide Development and Commercialization Rights for AC105 Leverages Company Expertise in Spinal Cord Injury

HAWTHORNE, N.Y., August 1, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the second quarter ended June 30, 2011.

“We are encouraged by the positive prescriber response to programs we initiated in the second quarter. These programs highlight AMPYRA’s efficacy across a wide range of walking disability, from mild to severe, in people with MS,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “Our market research shows that an increasing number of physicians intend to prescribe AMPYRA in relapsing remitting MS patients, who typically have less severe walking impairment than progressive patients.”

“We are also excited about the approval of FAMPYRA in Europe. People with MS in the European Union will now have access to this important medication which addresses walking impairment, one of the most devastating aspects of this disease. Royalties and milestone payments from ex-US sales of FAMPYRA will enable us to invest further in developing and expanding our pipeline of innovative neurological therapies. In this regard, we recently acquired worldwide rights to AC105, which we will study in Phase 2 trials for treatment of acute spinal cord injury.”

FINANCIAL RESULTS

The Company reported GAAP net loss of $0.3 million for the quarter ended June 30, 2011, or $0.01 per basic and diluted EPS, including share-based compensation charges totaling $5.0 million and an upfront license agreement expense for AC105 of $3.0 million. The GAAP net loss for the second quarter of 2010 was $6.8 million, or $0.18 per basic and diluted EPS including share-based compensation charges of $4.6 million.

Non-GAAP net income, before share-based compensation charges and the upfront license agreement expense for AC105, for the quarter ended June 30, 2011 was $7.8 million or $0.19 per diluted EPS, compared to a non-GAAP net loss of $2.2 million, or $0.06 per basic and diluted EPS for the same quarter in 2010.

AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg net revenue - For the quarter ended June 30, 2011, the Company reported AMPYRA net revenue of $51.8 million, compared to $28.0 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 reaffirms its 2011 AMPYRA net revenue guidance range of $205-$230 million.

ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and ZANAFLEX ® (tizanidine hydrochloride) tablets net revenue - For the quarter ended June 30, 2011, the Company reported combined net revenue of ZANAFLEX CAPSULES and ZANAFLEX tablets of $11.1 million, compared to combined net revenue of $12.5 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 June 30, 2011 were $14.2 million, compared to total shipments of $13.5 million for the same quarter in 2010.

Research and development expenses for the quarter ended June 30, 2011 were $12.0 million, including the upfront license agreement expense for AC105 of $3.0 million and $1.5 million of share-based compensation, compared to $6.6 million including $1.4 million of share-based compensation for the same quarter in 2010. Research and development expenses for the quarter also 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 reaffirms its full year 2011 research and development expense guidance of $40-$45 million excluding share-based compensation charges.

Sales, general and administrative expenses for the quarter ended June 30, 2011 were $40.3 million, including $3.5 million of share-based compensation, compared to $34.1 million including $3.2 million of share-based compensation for the same quarter in 2010. The increase in expenses was primarily due to increases in AMPYRA sales and marketing activities and expenses related to ZANAFLEX CAPSULES 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 second 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 $228.2 million.

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 second quarter 2011 and 2010 income (loss), adjusted to exclude share-based compensation charges and the upfront payment associated with in-licensing AC105. 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 income (loss) and projected R&D and SG&A expenses excluding share-based compensation charges and expenses associated with events such as the AC105 license fee, 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 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.

AMPYRA UPDATE

- On July 20, the European Commission granted conditional approval for FAMPYRA ® (prolonged-release fampridine tablets) to improve walking in adult patients with multiple sclerosis (MS) who have walking disabilities (EDSS 4-7). FAMPYRA is the trade name in Europe for AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg. FAMPYRA is being developed and marketed by Biogen Idec outside the United States under a licensing agreement from Acorda. FAMPYRA will be available in Europe, on a country-by-country basis, beginning with Germany in September 2011. The approval triggers a $25 million milestone payment to Acorda from Biogen Idec.
- There were approximately 11,000 new patients to AMPYRA therapy in the first half of 2011.
- New clinical data analyses on AMPYRA presented at the Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting in June 2011 showed that people with MS who responded to AMPYRA had comparable improvements in their walking regardless of baseline walking speed or overall level of MS-related disability as measured by patient self-report on the 12-Item Multiple Sclerosis Walking Scale (MSWS-12).

ZANAFLEX CAPSULES

- The litigation against Apotex Inc. in connection with its application for approval of a generic version of ZANAFLEX CAPSULES continues. The trial of the case concluded in May 2011 and the parties are completing post-trial briefs, after which a Court decision is expected.

PIPELINE

- Acorda in-licensed worldwide development and commercialization rights to a proprietary magnesium formulation from Medtronic, Inc., now referred to as AC105. The Company will be developing AC105 in Phase 2 studies as an acute treatment for patients who have suffered neurological trauma, such as spinal cord injury (SCI) and traumatic brain injury (TBI). There are approximately 11,000 new spinal cord injuries reported in the United States each year, and approximately 275,000 hospitalizations for TBI. Acorda made an upfront payment to Medtronic of $3 million and will make up to $32 million in regulatory and development milestone payments. A single-digit sales royalty will also be paid by Acorda to Medtronic if AC105 is commercialized by Acorda.
- The Phase 1 GGF2 clinical trial in heart failure patients, being conducted in collaboration with the Vanderbilt University Heart and Vascular Institute, is ongoing.
- A paper published in the July 2011 edition of *Nature* showed that treatment with chondroitinase, in combination with a peripheral nerve graft, led to significant recovery of diaphragmatic function in a preclinical model of spinal cord injury. Improving or restoring respiratory function is a critical therapeutic need in spinal cord injury, as impaired breathing is one of the leading causes of death in people with SCI.

CORPORATE UPDATES

- Acorda announced that it plans to relocate its corporate headquarters to the Ardsley Park life science campus in Ardsley, NY. The Company plans to relocate all employees currently based at its location in Hawthorne, NY to the Ardsley facility by June 2012.
- Acorda was ranked fifth among small life sciences companies, and fifth overall among both large and small companies, in the 9 th annual Best Places to Work in Industry 2011 survey conducted by *The Scientist* .
- Acorda was recognized as one of the Best Companies to Work in New York. This recognition was based on a survey conducted by BCG, an independent company that manages Best Places to Work programs on state, regional and national levels. Acorda was ranked third among large companies, defined as employing more than 250 people.

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 2011 results.

To participate in the conference call, please dial 866-770-7146 (domestic) or 617-213-8068 (international) and reference the access code 27646709. The presentation will be available via a live webcast at:

phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=4155738

A replay of the call will be available from 11:30 a.m. ET on August 1, 2011 until midnight on August 30, 2011. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 98995716. 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), which was previously called fampridine, and remains known by that name outside the US. In laboratory studies, dalfampridine 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 United States by Acorda Therapeutics, and by Biogen Idec in markets outside the U.S. based on a licensing agreement with Acorda. AMPYRA is manufactured globally by Elan 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 Unites 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 Elan's Matrix Drug Absorption System (MXDAS ®) technology and is manufactured by Elan 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 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, 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)

	June 30, 2011	December 31, 2010
Assets		
Cash, cash equivalents and short-term investments	$ 228,200	$ 240,029
Trade receivable, net	23,416	22,272
Other current assets	12,092	10,449
Finished goods inventory	42,145	38,418
Property and equipment, net	3,543	3,203
Intangible assets, net	20,502	21,336
Other assets	6,197	6,394
Total assets	$ 336,095	$ 342,101
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 41,704	$ 51,082
Deferred product revenue	28,874	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	1,797	1,297
Long term notes payable	5,136	6,186
Non-current portion of revenue interest liability	3,360	3,977
Non-current portion of deferred license revenue	82,271	86,429
Stockholders' equity	162,752	151,261
Total liabilities and stockholders' equity	$ 336,095	$ 342,101

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	**2010**	**2011**	**2010**
Revenues:				
Net revenues	$ 62,878	$ 40,478	$ 121,803	$ 55,869
License and royalty revenue	2,398	2,357	4,759	4,714
Total revenues	65,276	42,835	126,562	60,583
Costs and expenses:				
Cost of sales	12,048	7,832	24,098	10,908
Research and development	12,008	6,596	22,716	14,658
Selling, general and administrative	40,300	34,112	78,387	60,826
Total operating expenses	64,356	48,540	125,201	86,392
Operating income (loss)	$ 920	$ (5,705)	$ 1,361	$ (25,809)
Other expense, net	(1,143)	(1,059)	(2,139)	(2,069)
Loss before income taxes	(223)	(6,764)	(778)	(27,878)
Provision for income taxes	(62)	-	(179)	-
Net loss	$ (285)	$ (6,764)	$ (957)	$ (27,878)
Net loss per common share - basic	$ (0.01)	$ (0.18)	$ (0.02)	$ (0.73)
Net loss per common share - diluted	$ (0.01)	$ (0.18)	$ (0.02)	$ (0.73)
Weighted average per common share - basic	38,937	38,306	38,859	38,164
Weighted average per common share - diluted	38,937	38,306	38,859	38,164

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	**2010**	**2011**	**2010**
GAAP net loss	$ (285)	$ (6,764)	$ (957)	$ (27,878)
Pro forma adjustments:				
License agreement expense (Note 1)	3,000	-	3,000	-
Share-based compensation expenses included in R&D	1,487	1,414	2,590	2,204
Share-based compensation expenses included in SG&A	3,549	3,171	6,201	5,566
Total share-based compensation expenses	5,036	4,585	8,791	7,770
Total pro forma adjustments	8,036	4,585	11,791	7,770
Non-GAAP net income (loss)	$ 7,751	$ (2,179)	$ 10,834	$ (20,108)
Net income (loss) per common share - basic	$ 0.20	$ (0.06)	$ 0.28	$ (0.53)
Net income (loss) per common share - diluted	$ 0.19	$ (0.06)	$ 0.27	$ (0.53)
Weighted average per common share - basic	38,937	38,021	38,859	38,021
Weighted average per common share - diluted	40,158	38,021	39,964	38,021

Note 1: $3 million upfront expense related to licensed worldwide development and commercialization rights to a proprietary magnesium formulation from Medtronic, Inc. (AC105).