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ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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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): **July 31, 2012**

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.)

420 Saw Mill River Road, Ardsley, NY	**10502**
(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 July 31, 2012, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 2012. 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 July 31, 2012

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.

July 31, 2012

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated July 31, 2012

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Second Quarter 2012 Financial Results

- AMPYRA ® (dalfampridine) Second Quarter Net Revenue of $66.3 Million
- Combined Second Quarter ZANAFLEX Franchise and ex-U.S. FAMPYRA ® Royalty Revenue of $7.1 Million

ARDSLEY, N.Y. – JULY 31, 2012 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the second quarter ended June 30, 2012.

"Acorda made impressive progress across a range of its programs in the second quarter. AMPYRA net sales increased 15.5% compared to the first quarter, and 28% compared to the second quarter of 2011. We are encouraged by the positive physician and consumer response to the promotional initiatives we launched earlier in the year, which have contributed to this growth," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "In addition, we initiated a Phase 2 clinical trial of AMPYRA in people with post-stroke deficits and completed recruitment for the first stage of our proof-of-concept clinical trial of AMPYRA in people with cerebral palsy."

FINANCIAL RESULTS
The Company reported GAAP net income of $4.5 million for the quarter ended June 30, 2012, or $0.11 per diluted EPS, including share-based compensation charges totaling $5.6 million. The GAAP net loss for the second quarter of 2011 was $0.3 million, or $0.01 per diluted EPS including share-based compensation charges of $5.0 million.

Non-GAAP net income, before share-based compensation charges, for the quarter ended June 30, 2012 was $10.8 million, or $0.27 per diluted EPS, compared to a non-GAAP net income of $7.8 million, or $0.19 per diluted EPS for the same quarter in 2011.

AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg net revenue - For the quarter ended June 30, 2012, the Company reported AMPYRA net revenue of $66.3 million, compared to $51.8 million in net revenue for the same quarter in 2011. AMPYRA revenue is recognized following shipment of the product from the Company's distribution facility to its network of specialty pharmacies.

The Company is reiterating 2012 AMPYRA net sales guidance of $255-$275 million.

ZANAFLEX CAPSULES ® (tizanidine hydrochloride), ZANAFLEX ® (tizanidine hydrochloride) tablets and authorized generic tablets net revenue and royalties - For the quarter ended June 30, 2012, the Company reported combined net revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales of $2.5 million. Revenue from the sale of authorized generic tizanidine hydrochloride capsules to Watson totaled $0.3 million and royalties from Watson for the sale of authorized generic tizanidine hydrochloride capsules were $1.8 million. Combined net revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales were $11.1 million for the same quarter in 2011 .

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. Authorized generic product sold to Watson is recorded as sales when shipped.

ZANAFLEX CAPSULES and ZANAFLEX tablets shipments - Total ZANAFLEX CAPSULES and ZANAFLEX tablets shipments for the quarter ended June 30, 2012 were $2.7 million, compared to total shipments of $14.2 million for the same quarter in 2011. The decrease is due to the launch of generic versions of ZANAFLEX CAPSULES during the first quarter of 2012.

FAMPYRA ® (prolonged-release fampridine tablets) royalties - For the quarter ended June 30, 2012, the Company reported FAMPYRA royalties from sales outside of the U.S. of $2.5 million, compared to $0.1 million for the same quarter in 2011.

The Company continues to expect combined ZANAFLEX franchise (including revenues from authorized generic capsules) and ex-U.S. FAMPYRA royalty revenue of at least $25 million.

Cost of sales for the quarter ended June 30, 2012 were $13.6 million, compared to $12.0 million for the same quarter in 2011. Included in cost of sales for the quarter ended June 30, 2012 was $0.3 million in cost of authorized generic tizanidine hydrochloride capsules sold to Watson.

Research and development (R&D) expenses for the quarter ended June 30, 2012 were $12.6 million, including $1.3 million of share-based compensation, compared to $12.0 million including $1.5 million of share-based compensation for the same quarter in 2011. R&D expenses for the quarter ended June 30, 2012 included costs related to the Neuronex agreement, AMPYRA post-marketing studies and life cycle management programs, and the development of the Company's pipeline products, including clinical trial expenses for Glial Growth Factor 2 (GGF2) and AMPYRA proof-of-concept cerebral palsy and post-stroke deficits studies.

The Company continues to expect R&D expenses for the full year 2012 to be $50-$60 million, excluding share-based compensation.

Sales, general and administrative (SG&A) expenses for the quarter ended June 30, 2012 were $44.2 million, including $4.3 million of share-based compensation, compared to $40.1 million including $3.5 million of share-based compensation for the same quarter in 2011.

The Company continues to expect SG&A expenses for the full year 2012 to be $145-$160 million, excluding share-based compensation charges.

For the quarter ended June 30, 2012, the Company closed in a strong financial position with cash, cash equivalents and short-term and long-term investments of $303.0 million, up from $295.3 million in the first quarter.

AMPYRA UPDATE

- A post-approval commitment study examining the use of a 5mg dose of AMPYRA has completed enrollment. The Company expects to announce results of the study in August.
- In June, the Company received an untitled letter from FDA instructing the Company to discontinue use of certain promotional material. The Company has complied with the FDA request.
- In May, the Company presented research at the 4 th Collaborative Meeting of the Consortium of Multiple Sclerosis Centers (CMSC) and Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) that examined the impact of walking impairment on different aspects of the lives of people with MS, as well as the use of AMPYRA in the United States.

PIPELINE UPDATE

- The proof-of-concept clinical study of AMPYRA in patients with post-stroke deficits was initiated in the second quarter. The Company expects to announce initial results in early 2013.
- The proof-of-concept clinical study of AMPYRA in adults with cerebral palsy is ongoing. Recruitment for the single-dose phase of the trial has been completed, and the Company expects to announce initial results for this stage by the end of the year.

CORPORATE UPDATES

- The Company was recognized with an American Business Awards "Stevie" as Best Company of the Year in the pharmaceutical category.
- Medical Marketing & Media has named AMPYRA.com as a finalist for the "Best Branded Website" of 2012.

In May, the Company received a Warning Letter from the U.S. Food and Drug Administration (FDA) regarding the timeliness of adverse event (AE) reporting and AE record-keeping procedures. The Company has taken actions to improve internal processes and ensure compliance with AE reporting regulations, and is providing regular updates to the FDA.

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 income (loss), adjusted to exclude share-based compensation charges and the payments associated with Neuronex in 2012 and the AC105 license fee in 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 second quarter 2012 results.

To participate in the conference call, please dial 866-804-6928 (domestic) or 857-350-1674 (international) and reference the access code 49836380. The presentation will be available via a live webcast on the Investor section of www.acorda.com.

A replay of the call will be available from 10:30 a.m. ET on July 31, 2012 until midnight on August 31, 2012. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 63308993. 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 less-than or equal to 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 greater-than or equal to 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 focused on developing therapies that restore function and improve the lives of people with MS, spinal cord injury and other neurological conditions.

Acorda markets AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, in the United States as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an improvement in walking speed. AMPYRA is marketed outside the United States as FAMPYRA® (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda. AMPYRA and FAMPYRA are manufactured under license from Alkermes Pharma Ireland Limited.

The Company also markets ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity. Acorda also receives sales royalties on tizanidine hydrochloride capsules, an authorized generic version of ZANAFLEX CAPSULES distributed by Watson Pharmaceutics, Inc. under its agreement with Acorda.

Acorda is developing an industry-leading pipeline of novel neurological therapies. The Company is studying AMPYRA to improve a range of functional impairments caused by MS, as well as its use in other neurological conditions, including cerebral palsy and chronic stroke. In addition, Acorda is developing

clinical stage compounds AC105 for acute treatment of spinal cord injury and GGF2 for treatment of heart failure. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and spinal cord injury. Additional preclinical programs include rHIgM22, a remyelinating monoclonal antibody for the treatment of MS, and chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury.

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 our ability to successfully market and sell Ampyra in the U.S.; third party payers (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 or from our other research and development programs, including any acquired or in-licensed programs; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of generic competition on Zanaflex Capsules revenues; failure to protect our 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; and the ability to obtain additional financing to support our operations. 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 press 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.

Acorda Therapeutics, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	June 30, 2012	December 31, 2011
Assets		
Cash, cash equivalents and short-term investments	$ 255,850	$ 295,907
Trade receivable, net	23,607	22,828
Other current assets	18,367	13,825
Finished goods inventory	29,413	28,382
Long-term investments	47,118	-
Property and equipment, net	14,290	3,858
Intangible assets, net	8,755	8,769
Other assets	5,653	5,919
Total assets	$ 403,053	$ 379,488
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 47,926	$ 45,542
Deferred product revenue	28,991	30,599
Current portion of deferred license revenue	9,057	9,057
Current portion of notes payable	1,144	1,144
Current portion of revenue interest liability	1,315	1,001
Long-term liabilities	9,708	6,266
Non-current portion of revenue interest liability	2,048	2,928
Non-current portion of deferred license revenue	73,214	77,742
Stockholders' equity	229,650	205,209
Total liabilities and stockholders' equity	$ 403,053	$ 379,488

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	**2011**	**2012**	**2011**
Revenues:				
Net product revenues	$ 69,112	$ 62,878	$ 134,785	$ 121,803
License revenue	2,264	2,264	4,529	4,529
Royalty revenues	4,280	134	7,590	230
Total revenues	75,656	65,276	146,904	126,562
Costs and expenses:				
Cost of sales	13,576	12,048	26,040	24,098
Cost of license revenue	158	159	317	317
Research and development	12,634	12,008	23,659	22,716
Selling, general and administrative	44,230	40,141	82,975	78,070
Total operating expenses	70,598	64,356	132,991	125,201
Operating income	$ 5,058	$ 920	$ 13,913	$ 1,361
Other expense, net	(233)	(1,143)	(870)	(2,139)
Income (loss) before income taxes	4,825	(223)	13,043	(778)
Provision for income taxes	(280)	(62)	(652)	(179)
Net income (loss)	$ 4,545	$ (285)	$ 12,391	$ (957)
Net income (loss) per common share - basic	$ 0.12	$ (0.01)	$ 0.31	$ (0.02)
Net income (loss) per common share - diluted	$ 0.11	$ (0.01)	$ 0.31	$ (0.02)
Weighted average per common share - basic	39,433	38,937	39,387	38,859
Weighted average per common share - diluted	40,099	38,937	40,253	38,859

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
GAAP net income (loss)	$ 4,545	$ (285)	$ 12,391	$ (957)
Pro forma adjustments:				
Neuronex payments included in R&D (Note 1)	700	-	3,200	-
License agreement expense in R&D (Note 2)	-	3,000	-	3,000
Share-based compensation expenses included in R&D	1,339	1,487	2,328	2,590
Share-based compensation expenses included in SG&A	4,254	3,549	7,456	6,201
Total share-based compensation expenses	5,593	5,036	9,784	8,791
Total pro forma adjustments	6,293	8,036	12,984	11,791
Non-GAAP net income	$ 10,838	$ 7,751	$ 25,375	$ 10,834
Net income per common share - basic	$ 0.27	$ 0.20	$ 0.64	$ 0.28
Net income per common share - diluted	$ 0.27	$ 0.19	$ 0.63	$ 0.27
Weighted average per common share - basic	39,433	38,937	39,387	38,859
Weighted average per common share - diluted	40,099	40,158	40,253	39,964

Note 1: $2.0 million upfront payment and $1.2 million in R&D payments per agreement with Neuronex.
Note 2: $3.0 million upfront expense related to licensed worldwide development and commercialization rights to a proprietary magnesium formulation from Medtronic, Inc. (AC105).