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): **May 3, 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.)

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 May 3, 2012, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 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 May 3, 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.

May 3, 2012

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated May 3, 2012

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports First Quarter 2012 Financial Results

- AMPYRA ® (dalfampridine) First Quarter Net Revenue of $57.4 Million
- AMPYRA 2012 Net Revenue Guidance of $255-$275 Million Reaffirmed
- Combined First Quarter ZANAFLEX Franchise and ex-U.S. FAMPYRA ® Royalty Revenue of $11.6 Million

HAWTHORNE, N.Y. – May 3, 2012 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the first quarter ended March 31, 2012.

“AMPYRA continues to make unique and important contributions to the lives of people with MS. We were pleased to see consumer demand for AMPYRA increase progressively beginning in February, in response to our outreach programs,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “We are excited about the potential for AMPYRA also to help patients with other neurological conditions, such as post-stroke deficits and cerebral palsy. We have accelerated the start of our proof-of-concept post-stroke deficit study, which we now expect to begin in the second quarter of 2012, and we expect initial results from our cerebral palsy study by the end of the year.”

“In addition to AMPYRA, we are encouraged by the progress of the rest of our pipeline, which now includes two therapies at the clinical development stage, GGF2 for heart failure and AC105 for acute neurotrauma, as well as a third drug candidate nearing clinical stage development, rHIgM22, a remyelinating monoclonal antibody. We also can, at our option, acquire a novel, intranasal form of diazepam, which is at the pre-NDA stage.”

FINANCIAL RESULTS
The Company reported GAAP net income of $7.8 million for the quarter ended March 31, 2012, or $0.19 per diluted EPS, including share-based compensation charges totaling $4.2 million. The GAAP net loss for the first quarter of 2011 was $0.7 million, or $0.02 per diluted EPS including share-based compensation charges of $3.8 million.

Non-GAAP net income, before share-based compensation charges, for the quarter ended March 31, 2012 was $14.5 million, or $0.36 per diluted EPS, compared to a non-GAAP net income of $3.1 million, or $0.08 per diluted EPS for the same quarter in 2011.

AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg net revenue - For the quarter ended March 31, 2012, the Company reported AMPYRA net revenue of $57.4 million, compared to $46.8 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.

AMPYRA net sales were flat in the first quarter compared to the fourth quarter of 2011, primarily due to weak demand in January. Sales rebounded beginning in February, and the Company is reiterating 2012 AMPYRA net sales guidance of $255-$275 million.

ZANAFLEX CAPSULES ® (tizanidine hydrochloride), ZANAFLEX ® (tizanidine hydrochloride) tablets and authorized generic capsules net revenue and royalties - For the quarter ended March 31, 2012, the

Company reported combined net revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales of $7.2 million. Revenue from the sale of authorized generic tizanidine hydrochloride capsules to Watson totaled $1.1 million and royalties from Watson for the sale of authorized generic capsules were $1.5 million. Combined net revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales were $12.2 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 capsules 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 March 31, 2012 were $9.2 million, compared to total shipments of $16.9 million for the same quarter in 2011. The decrease is due to the launch of a generic version of ZANAFLEX CAPSULES during the quarter ended March 31, 2012.

FAMPYRA ® (prolonged-release fampridine tablets) royalties - For the quarter ended March 31, 2012, the Company reported FAMPYRA royalties from sales outside of the U.S. of $1.8 million, compared to $0.1 million for the same quarter in 2011.

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

Cost of sales for the quarter ended March 31, 2012 were $12.5 million, compared to $12.1 million for the same quarter in 2011. Included in cost of sales for the quarter ended March 31, 2012 was $1.1 million in cost of authorized generic capsules product sold to Watson.

Research and development (R&D) expenses for the quarter ended March 31, 2012 were $11.0 million, including $1.0 million of share-based compensation, compared to $10.7 million including $1.1 million of share-based compensation for the same quarter in 2011. R&D expenses for the quarter ended March 31, 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 an AMPYRA cerebral palsy proof-of-concept study.

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 March 31, 2012 were $38.7 million, including $3.2 million of share-based compensation, compared to $37.9 million including $2.7 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 March 31, 2012, the Company closed in a strong financial position with cash, cash equivalents and short-term and long-term investments of $295.3 million.

AMPYRA UPDATE

- In January, the First Step program, which allows patients to trial AMPYRA free for 60 days, was expanded with direct-to-consumer outreach. Vouchers for the program are available at ampyra.com, consumer speaker programs, and WalkMS events. In the first quarter, a significant percentage of new prescription requests were generated through the First Step program.
- As of February 2012, approximately 70% of all people with MS who were prescribed AMPYRA received a first refill and approximately 40% of all people with MS who were prescribed AMPYRA received a sixth refill, consistent with previously reported trends.

- In April, the post-approval study evaluating dalfampridine 10 mg twice daily compared to 5 mg twice daily completed enrollment, and the Company expects to have initial results in the third quarter of this year. The study includes endpoints that may be usable in future scientific and promotional communications.

- In April, the Company launched a new interactive patient website, Ampyra Journeys, which features stories of people living with MS who have experienced walking problems and took action to get treatment. Their stories explore the impact that walking problems can have for people living with MS, and the positive impact that taking AMPYRA has had on their lives.

- In April, an analysis of AMPYRA open-label clinical trial extension studies was presented at the 64 th American Academy of Neurology (AAN) Annual Meeting. The data showed that the increase in walking speed demonstrated by people with MS who responded to treatment with AMPYRA during three-month Phase 3 clinical trials was also observed for up to five years in open-label extension studies. In addition, the long-term safety and tolerability of AMPYRA was consistent with that observed in clinical trials, with no new safety signals emerging.

- In March 2012, oppositions were filed with the European Patent Office (EPO) challenging a European patent granted in 2011 with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine, to increase walking speed. This European patent is the counterpart to U.S. patent application (U.S.S.N.: 11/102,559), which was allowed in 2011 but had not yet issued. In light of the European oppositions, the Company had requested further review of the allowed U.S. case by the United States Patent and Trademark Office (USPTO). The USPTO has conducted its further review and issued a new Notice of Allowance. This action did not affect the patent (U.S. Patent No.: 8,007,826) which issued in August 2011. Based on the USPTO's final patent term adjustment calculation, this patent will extend into 2027 and is listed in the FDA Orange Book.

PIPELINE UPDATE

- The proof-of-concept clinical study of AMPYRA in adults with cerebral palsy is ongoing. The Company expects to announce initial study results by the end of the year.
- The Company plans to initiate a proof-of-concept clinical study of AMPYRA in patients with post-stroke deficits in the second quarter of 2012, earlier than previously expected.
- 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 is ongoing. The Company expects to announce initial study results in the second half of 2012.
- The Company has delayed filing an Investigational New Drug (IND) application for rHIgM22, pending completion of a bioactivity assay.

CORPORATE UPDATES

- The Company hosted an R&D Day for investors on April 17 at which Acorda senior management and external experts provided updates on the Company's clinical and preclinical programs. A webcast of the presentations can be viewed at: http://ir.acorda.com/phoenix.zhtml?c=194451&p=irol-EventDetails&EventId=4736842.
- The Company was named one of the "100 Most Trustworthy Companies" by Forbes. The assessments were conducted by GMI Ratings, identifying companies that have consistently demonstrated transparent and conservative accounting practices and solid corporate governance and management.
- For the second year in a row, the Company has been ranked in the top 10 of the Best Companies to Work for in New York in the large company category, based on an independent survey identifying the best places of employment in the State of New York. Acorda was ranked seventh among large companies, defined as employing more than 250 people. This ranking reflected feedback from employees about company culture, benefits and overall job satisfaction.

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 Q1 2012. 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 first quarter 2012 results.

To participate in the conference call, please dial 800-510-0219 (domestic) or 617-614-3451 (international) and reference the access code 14197709. The presentation will be available via a live webcast at:

http://ir.acorda.com/phoenix.zhtml?c=194451&p=irol-eventDetails&EventId=4742657

A replay of the call will be available from 10:30 a.m. ET on May 3, 2012 until midnight on June 3, 2012. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 60542191. 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 tablets, 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 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)

	March 31, 2012	December 31, 2011
Assets		
Cash, cash equivalents and short-term investments	$ 278,245	$ 295,907
Trade receivable, net	21,526	22,828
Other current assets	19,284	13,825
Finished goods inventory	28,659	28,382
Long-term investments	17,046	-
Property and equipment, net	6,521	3,858
Intangible assets, net	8,950	8,769
Other assets	5,821	5,919
Total assets	$ 386,052	$ 379,488
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 40,497	$ 45,542
Deferred product revenue	30,155	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	1,204	1,001
Long-term liabilities	7,020	6,266
Non-current portion of revenue interest liability	2,403	2,928
Non-current portion of deferred license revenue	75,478	77,742
Stockholders' equity	219,094	205,209
Total liabilities and stockholders' equity	$ 386,052	$ 379,488

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

	Three Months Ended March 31,	
	2012	**2011**
Revenues:		
Net product revenues	$ 65,673	$ 58,925
License revenue	2,265	2,265
Royalty revenues	3,310	96
Total revenues	71,248	61,286
Costs and expenses:		
Cost of sales	12,464	12,050
Cost of license revenue	159	159
Research and development	11,025	10,708
Selling, general and administrative	38,745	37,928
Total operating expenses	62,393	60,845
Operating income	$ 8,855	$ 441
Other expense, net	(637)	(996)
Income (loss) before income taxes	8,218	(555)
Provision for income taxes	(372)	(117)
Net income (loss)	$ 7,846	$ (672)
Net income (loss) per common share - basic	$ 0.20	$ (0.02)
Net income (loss) per common share - diluted	$ 0.19	$ (0.02)
Weighted average per common share - basic	39,340	38,781
Weighted average per common share - diluted	40,407	38,781

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

	Three Months Ended March 31,	
	2012	**2011**
GAAP net income (loss)	$ 7,846	$ (672)
Pro forma adjustments:		
Neuronex payment included in R&D	2,500	-
Share-based compensation expenses included in R&D	989	1,103
Share-based compensation expenses included in SG&A	3,202	2,652
Total share-based compensation expenses	4,191	3,755
Total pro forma adjustments	6,691	3,755
Non-GAAP net income	$ 14,537	$ 3,083
Net income per common share - basic	$ 0.37	$ 0.08
Net income per common share - diluted	$ 0.36	$ 0.08
Weighted average per common share - basic	39,340	38,781
Weighted average per common share - diluted	40,407	39,769