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 2, 2013**

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 May 2, 2013, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2013. 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 2, 2013

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 2, 2013

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated May 2, 2013

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports First Quarter 2013 Financial Results

- AMPYRA (R) (dalfampridine) First Quarter Net Revenue of $62.3 Million; Reiterating Full Year 2013 Guidance for AMPYRA Net Revenue of $285-$315 Million
- Combined First Quarter Zanaflex (R) Franchise and ex-U.S. FAMPYRA (R) Royalty and License Revenue of $9.5 Million

ARDSLEY, N.Y. – May 2, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the first quarter ended March 31, 2013.

“AMPYRA sales were pressured in the first part of the quarter, consistent with the seasonal pattern we have seen in prior years and in line with our internal projections. Sales rebounded strongly in March and continued to increase in April. Underlying consumer demand also remained strong and we are maintaining our 2013 AMPYRA net sales guidance of $285-$315 million,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “Seasonal factors included patients switching insurance plans as well as some additional year-end inventory build and subsequent destocking.”

“Our advancing pipeline now has five compounds that are in clinical stage development or being prepared for FDA review. Our most recent R&D milestones include a proof-of-concept study of dalfampridine extended release tablets that showed improved walking in people with post-stroke deficits. Based on these data, we plan to prioritize our development program for this indication. Additionally, in April we initiated the first clinical trial of rHIgM22, a novel monoclonal antibody that is being studied as a remyelinating treatment for MS.”

FINANCIAL RESULTS
The Company reported GAAP net loss of $1.1 million for the quarter ended March 31, 2013, or $0.03 per diluted EPS, including share-based compensation charges totaling $4.9 million. GAAP net income in the same quarter of 2012 was $7.8 million, or $0.19 per diluted EPS, including share-based compensation charges totaling $4.2 million.

Non-GAAP net income for the quarter ended March 31, 2013 was $3.8 million, or $0.09 per diluted EPS. Non-GAAP net income in the same quarter of 2012 was $14.5 million or $0.36 per diluted EPS.

AMPYRA (R) (dalfampridine) Extended Release Tablets, 10 mg net revenue - For the quarter ended March 31, 2013, the Company reported AMPYRA net revenue of $62.3 million, compared to $57.4 million in net revenue for the same quarter in 2012. 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 lower in the first quarter compared to the fourth quarter of 2012, affected by several recurring first quarter factors. These included patients switching healthcare plans resulting in a

delay in refilling prescriptions, inventory stocking in the fourth quarter and increased discounts and allowances resulting from Medicare patients entering the “donut hole” at the start of the new year.

Sales rebounded strongly in March, and the Company is reiterating 2013 AMPYRA net sales guidance of $285-$315 million.

ZANAFLEX CAPSULES (R) (tizanidine hydrochloride), ZANAFLEX (R) (tizanidine hydrochloride) tablets and authorized generic capsules net revenue and royalties - For the quarter ended March 31, 2013, the Company reported combined net revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales of $1.3 million; revenue from the sale of authorized generic tizanidine hydrochloride capsules to Actavis, Inc. totaled $0.5 million and royalties from Actavis for the sale of authorized generic tizanidine hydrochloride capsules were $2.6 million, for combined total net revenue of $4.4 million. Combined net revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales were $9.8 million for the same quarter in 2012. The decrease is due to the launch of generic versions of ZANAFLEX CAPSULES during the first quarter of 2012.

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 Actavis is recorded as sales when shipped.

FAMPYRA (R) (prolonged-release fampridine tablets) royalties - For the quarter ended March 31, 2013, the Company reported FAMPYRA royalties from sales outside of the U.S. of $2.9 million, compared to $1.8 million for the same quarter in 2012.

Cost of sales for the quarter ended March 31, 2013 were $13.5 million, compared to $12.5 million for the same quarter in 2012. Included in cost of sales for the quarter ended March 31, 2013 was $0.5 million in cost of authorized generic tizanidine hydrochloride capsules sold to Actavis.

Research and development (R&D) expenses for the quarter ended March 31, 2013 were $12.5 million, including $1.2 million of share-based compensation, compared to $11.0 million including $1.0 million of share-based compensation for the same quarter in 2012. R&D expenses for the quarter ended March 31, 2013 included AMPYRA life cycle management programs, including AMPYRA proof-of-concept post-stroke deficits and cerebral palsy studies, and development of the Company’s pipeline products, including expenses for Glial Growth Factor 2 (GGF2) and Diazepam Nasal Spray.

The Company continues to expect R&D expenses for the full year 2013 to be $60-$70 million , excluding share-based compensation. This guidance excludes costs associated with the acquisition of NeurogesX, Inc. assets.

Sales, general and administrative (SG&A) expenses for the quarter ended March 31, 2013 were $48.2 million, including $3.8 million of share-based compensation, compared to $38.7 million including $3.2 million of share-based compensation for the same quarter in 2012. The increase was primarily due to increases in expenses related to the overall growth of the organization to support AMPYRA, to support the possible commercialization of Diazepam Nasal Spray, if approved, and to support the development of our pipeline products.

The Company continues to expect SG&A expenses for the full year 2013 to be $170-$180 million , excluding share-based compensation. This guidance excludes costs associated with the acquisition of NeurogesX, Inc. assets.

For the quarter ended March 31, 2013, the Company closed in a strong financial position with cash, cash equivalents and short-term and long-term investments of $324.9 million.

AMPYRA UPDATE

- The Company presented three new studies on AMPYRA at the American Academy of Neurology (AAN) 65th Annual Meeting.

PIPELINE UPDATE

- In April, the Company announced top-line data from two separate proof-of-concept trials of dalfampridine extended release (ER) tablets, marketed as AMPYRA, in treating post-stroke deficits and cerebral palsy (CP).
    - Data showed improved walking in people with post-stroke deficits. The Company plans to proceed with a clinical development program for this indication.
    - Efficacy data from the CP study suggested potential treatment activity on measures of walking and hand strength; however, these data are still being analyzed to determine if they are sufficiently robust to warrant further clinical studies.
- The Company presented data at the AAN 65th Annual Meeting that demonstrated Diazepam Nasal Spray had comparable bioavailability to diazepam rectal gel. The Company remains on track to submit a New Drug Application (NDA) for Diazepam Nasal Spray to the FDA in 2013.
- In March, the Company presented data from the first clinical trial of GGF2 at the American College of Cardiology 62nd Annual Scientific Session. In this study, a single dose of GGF2 in patients with heart failure was generally well tolerated up to 0.75 mg/kg. The study also found that trial participants receiving GGF2 showed a consistent and dose-responsive trend of improved left ventricular ejection fraction over 28 and 90 days compared to placebo.
- The Company has discussed the findings from the initial GGF2 study with the U.S. Food and Drug Administration (FDA) and has reached agreement on the design of the next clinical study of GGF2 in heart failure.
- In April, the first participant was enrolled in the first Phase 1 study of rHIgM22, a remyelinating antibody for the treatment of multiple sclerosis.

CORPORATE UPDATE

- In April, the Company agreed to acquire rights in the United States, Canada, Latin America and certain other markets to two assets from NeurogesX, Inc., Qutenza(R) (capsaicin) 8% patch and NGX-1998. This agreement is subject to NeurogesX shareholder approval and several other contingencies.
- In April, President and CEO Ron Cohen was named Vice Chair of the Biotechnology Industry Organization (BIO) Health Section.
- The Company's intranet was named as one of the ten best in the world by the Nielsen Norman Group, leading experts in web usability, which annually recognizes the global top 10 intranet sites for innovation and usability.

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, adjusted to exclude share-based compensation charges and the payments associated with Neuronex in 2012. 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 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 2013 results.

To participate in the conference call, please dial 866-713-8563 (domestic) or 617-597-5311 (international) and reference the access code 86715243. 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 May 2, 2013 until midnight on June 2, 2013. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 81142086. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at www.acorda.com.

Important New Safety Information
Do not take AMPYRA if you are allergic to dalfampridine (4-aminopyridine), the active ingredient in AMPYRA.

Important Safety Information
Do not take AMPYRA if you have ever had a seizure, or have certain types of kidney problems, or are allergic to dalfampridine (4-aminopyridine), the active ingredient in AMPYRA.

Take AMPYRA exactly as prescribed by your doctor.

You could have a seizure even if you never had a seizure before. Your chance of having a seizure is higher if you take too much AMPYRA or if your kidneys have a mild decrease of function, which is common after age 50.

Your doctor may do a blood test to check how well your kidneys are working, if that is not known before you start taking AMPYRA.

AMPYRA may cause serious allergic reactions, including rare occurrence of anaphylaxis. Stop taking Ampyra and call your doctor right away or get emergency medical help if you have shortness of breath or trouble breathing, swelling of your throat or tongue, or hives.

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

The most common adverse events for AMPYRA in MS patients were urinary tract infection, trouble sleeping, dizziness, headache, nausea, weakness, back pain, and problems with balance.

Before taking AMPYRA tell your doctor if you are pregnant or plan to become pregnant. It is not known if AMPYRA will harm your unborn baby.

Tell your doctor if you are breast-feeding or plan to breast-feed. It is not known if AMPYRA passes into your breast milk. You and your doctor should decide if you will take AMPYRA or breast-feed. You should not do both.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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 (R)) 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 FAMPYRA 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.

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 (R) (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 (R) (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 (R) (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 Actavis, Inc. under its agreement with Acorda.

Acorda has one of the leading pipelines in the industry of novel neurological therapies. The Company is developing Diazepam Nasal Spray for treatment of certain epileptic seizures. It is also studying AMPYRA to improve a range of functional impairments caused by MS, as well as its potential for use in other neurological conditions, including cerebral palsy and post-stroke deficits. In addition, Acorda is developing clinical stage compounds AC105 for acute treatment of spinal cord injury, GGF2 for treatment of heart failure and rHIgM22, a remyelinating monoclonal antibody, for the treatment of MS. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and peripheral nerve damage. Chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury, is in preclinical development.

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 or our other products 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 Diazepam Nasal Spray or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market Diazepam Nasal Spray or other products under development; 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; failure to comply with regulatory requirements could result in adverse action by regulatory agencies; 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 & Exchange Commission. Acorda 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 disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this release.

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

(Unaudited)

	March 31, 2013	December 31, 2012
Assets		
Cash, cash equivalents, short-term and long-term investments	$ 324,905	$ 333,188
Trade receivable, net	23,288	26,327
Other current assets	18,700	16,863
Finished goods inventory	28,586	20,957
Property and equipment, net	16,936	16,706
Deferred tax asset	138,500	136,727
Intangible assets, net	9,446	9,319
Other assets	5,062	5,245
Total assets	$ 565,423	$ 565,332
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 55,863	$ 58,261
Deferred product revenue	29,620	29,275
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	1,180	1,134
Long-term liabilities	9,361	10,415
Non-current portion of revenue interest liability	1,138	1,440
Non-current portion of deferred license revenue	66,421	68,685
Stockholders' equity	391,639	385,921
Total liabilities and stockholders' equity	$ 565,423	$ 565,332

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

	Three Months Ended March 31,	
	2013	**2012**
Revenues:		
Net product revenues	$ 64,084	$ 65,673
Royalty revenues	5,516	3,310
License revenue	2,265	2,265
Total revenues	71,865	71,248
Costs and expenses:		
Cost of sales	13,484	12,464
Cost of license revenue	159	159
Research and development	12,520	11,025
Selling, general and administrative	48,198	38,745
Total operating expenses	74,361	62,393
Operating (loss) income	$ (2,496)	$ 8,855
Other expense, net	(418)	(637)
(Loss) income before income taxes	(2,914)	8,218
Benefit from (provision for) income taxes	1,775	(372)
Net (loss) income	$ (1,139)	$ 7,846
Net (loss) income per common share - basic	$ (0.03)	$ 0.20
Net (loss) income per common share - diluted	$ (0.03)	$ 0.19
Weighted average per common share - basic	39,832	39,340
Weighted average per common share - diluted	39,832	40,407

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

	Three Months Ended March 31,	
	2013	**2012**
GAAP net (loss) income	$ (1,139)	$ 7,846
Pro forma adjustments:		
Neuronex payments included in R&D	-	2,500
Share-based compensation expenses included in R&D	1,151	989
Share-based compensation expenses included in SG&A	3,782	3,202
Total share-based compensation expenses	4,933	4,191
Total pro forma adjustments	4,933	6,691
Non-GAAP net income	$ 3,794	$ 14,537
Net income per common share - basic	$ 0.10	$ 0.37
Net income per common share - diluted	$ 0.09	$ 0.36
Weighted average per common share - basic	39,832	39,340
Weighted average per common share - diluted	41,038	40,407