ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 10/31/13 for the Period Ending 10/31/13

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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): **October 31, 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 October 31, 2013, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 October 31, 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.

October 31, 2013

By: /s/Michael Rogers
Name: Michael Rogers
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated October 31, 2013

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Third Quarter 2013 Financial Results

- AMPYRA ® (dalfampridine) Third Quarter Net Revenue of $77.8 Million
- Narrowing 2013 AMPYRA Net Revenue Guidance to $295-$305 Million
- Lowering R&D Expense Guidance to $45-$55 Million; Lowering SG&A Expense Guidance to $165-$175 Million

ARDSLEY, N.Y. – October 31, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the third quarter ended September 30, 2013.

"We are pleased with the continued growth and progress of the Company. AMPYRA net sales for the third quarter were in line with our expectations and we are encouraged by fourth quarter sales to date. We also have a strong cash position of approximately $350 million. The strength of the AMPYRA franchise and our balance sheet is enabling us to invest in our pipeline of promising clinical-stage compounds, which have attained a number of important milestones in 2013," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. "Pending agreement with FDA, we anticipate beginning a Phase 2b/3 study of a once-daily formulation of dalfampridine in post-stroke walking deficits in the second quarter of 2014. In addition, our Diazepam Nasal Spray NDA filing is on track for this year. Acorda now has six innovative products in clinical development, positioning us well for future growth."

FINANCIAL RESULTS
The Company reported GAAP net income of $7.5 million for the quarter ended September 30, 2013, or $0.18 per diluted share, including share-based compensation charges totaling $6.5 million. GAAP net income in the same quarter of 2012 was $9.6 million, or $0.24 per diluted share, including share-based compensation charges totaling $5.6 million.

Non-GAAP net income for the quarter ended September 30, 2013 was $15.0 million, or $0.36 per diluted share. Non-GAAP net income in the same quarter of 2012 was $15.2 million, or $0.38 per diluted share.

AMPYRA ®(dalfampridine) Extended Release Tablets, 10 mg net revenue - For the quarter ended September 30, 2013, the Company reported AMPYRA net revenue of $77.8 million, compared to $69.8 million in net revenue for the same quarter in 2012. Through the first three quarters of 2013, net sales increased 13% over the same period in 2012.

The Company narrowed 2013 AMPYRA net revenue guidance to $295-$305 million, from $285-$315 million.

ZANAFLEX CAPSULES ®(tizanidine hydrochloride), ZANAFLEX ®(tizanidine hydrochloride) tablets and authorized generic capsules net revenue and royalties - For the quarter ended September 30, 2013, the Company reported that combined net revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales was $0.8 million, revenue from the sale of authorized generic tizanidine hydrochloride capsules to Actavis, Inc. was $1.0 million and royalties from Actavis for the sale of authorized generic tizanidine hydrochloride capsules were $0.9 million, for combined total net revenue of $2.7 million. Combined net

revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales and royalties from Actavis were $3.8 million for the same quarter in 2012.

FAMPYRA ® (prolonged-release fampridine tablets) royalties - For the quarter ended September 30, 2013, the Company reported FAMPYRA royalties from sales outside of the U.S. of $2.0 million, compared to $1.5 million for the same quarter in 2012.

Cost of sales for the quarter ended September 30, 2013 were $17.2 million, compared to $14.8 million for the same quarter in 2012. Included in cost of sales for the quarter ended September 30, 2013 was $1.0 million in cost of authorized generic tizanidine hydrochloride capsules sold to Actavis.

Research and development (R&D) expenses for the quarter ended September 30, 2013 were $13.8 million, including $1.6 million of share-based compensation, compared to $12.0 million including $1.4 million of share-based compensation for the same quarter in 2012. R&D expenses for the quarter ended September 30, 2013 included the development of the Company's pipeline products, including expenses for dalfampridine-QD, Glial Growth Factor 2 (GGF2), rHIgM22, AC105 and Diazepam Nasal Spray.

The Company revised R&D expense guidance for the full year 2013 to $45-$55 million, from $60-$70 million, as a result of the decision to not move forward with a clinical program for dalfampridine in cerebral palsy and adjustments in other R&D programs. This guidance excludes share-based compensation and costs associated with expenditures related to the potential acquisition of new products or other business development activities. R&D expenses are expected to increase in 2014 as the Company's clinical programs advance.

Sales, general and administrative (SG&A) expenses for the quarter ended September 30, 2013 were $42.3 million, including $5.0 million of share-based compensation, compared to $40.1 million including $4.2 million of share-based compensation for the same quarter in 2012. The increase was primarily due to increases in expenses related to support for AMPYRA and the dalfampridine franchise, the possible commercialization of Diazepam Nasal Spray, if approved, and the development of our pipeline products.

The Company revised SG&A expense guidance for the full year 2013 to $165-$175 million, from $170-$180 million, based on changes in program timing. This guidance excludes share-based compensation and costs associated with expenditures related to the potential acquisition of new products or other business development activities. SG&A expenses are expected to increase in 2014 as the Company moves closer to the potential launch of Diazepam Nasal Spray.

For the quarter ended September 30, 2013 the Company closed in a strong financial position with cash, cash equivalents and short-term and long-term investments of $349.4 million.

AMPYRA UPDATE

- The Company presented two posters at the 29 th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). One reported on the effect of AMPYRA on gait and balance in people with MS. A second poster examined rates of urinary tract infections (UTI) among people with MS in a recent double-blind clinical trial, finding that there was a comparable rate of confirmed infections between those taking AMPYRA and those taking placebo.

PIPELINE UPDATE

- The Company is planning to move forward with a Phase 2b/3 study that will assess the use of a once-daily formulation of dalfampridine as a treatment for post-stroke walking deficits, pending discussions with FDA and results of a second PK study of the once-daily formulation. The Company plans to begin the trial in the second quarter of 2014.
- In October, the Company presented clinical data on dalfampridine-ER in the treatment of post-stroke deficits at the 2013 American Neurological Association Annual Meeting. In the study, treatment with dalfampridine-ER was well tolerated and improved walking, as measured by the

Timed 25-Foot Walk test. The safety findings in this study were consistent with previous clinical trials and post-marketing experience of dalfampridine-ER in multiple sclerosis (MS).

- After a thorough analysis of the dalfampridine-ER proof-of-concept study in cerebral palsy (CP), the Company concluded that although there were some signs of biological activity the data were not strong enough to justify additional clinical development and will not proceed with additional CP trials.
- In October, the Company announced that the first patient had been enrolled in the second clinical trial of Glial Growth Factor 2 (GGF2) for the treatment of heart failure. This Phase 1b single-infusion trial in people with heart failure will assess tolerability of three dose levels of GGF2, and also includes several explorative measures of efficacy.
- In September, the Company announced the first patient was enrolled in a Phase 2 trial evaluating the safety and tolerability of AC105 in people with traumatic spinal cord injury. The study also incorporates several exploratory efficacy measures.

CORPORATE UPDATE

- Michael Rogers joined the Company as Chief Financial Officer (CFO). He is responsible for the Finance and Investor Relations departments.
- David Lawrence was appointed Chief of Business Operations (CBO), transitioning to a new role from his former position as CFO. He is responsible for the Company's Technical Operations/Manufacturing, Information Technology, Project Management and Facilities Management departments.

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 product acquisitions. These non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, the Company believes 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. The Company believes 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, M.D., President and Chief Executive Officer, and Michael Rogers, Chief Financial Officer, will host a conference call today at 8:30 a.m. ET to review the Company's third quarter 2013 results.

To participate in the conference call, please dial 866-515-2910 (domestic) or 617-399-5124 (international) and reference the access code 51455130. 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 October 31, 2013 until midnight on November 28, 2013. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 55312957. The archived webcast will be available on the Investor Relations section of the Acorda website at www.acorda.com.

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. 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 Acorda Therapeutics
Founded in 1995, Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with neurological conditions.

Acorda markets three FDA-approved therapies including: AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in patients with multiple sclerosis (MS); ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity; and QUTENZA ® (capsaicin) 8% Patch, for the management of neuropathic pain associated with postherpetic neuralgia. AMPYRA is marketed outside the United States as FAMPYRA ® (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda.

Acorda has one of the leading pipelines in the industry of novel neurological therapies. The Company is currently developing six clinical-stage therapies and one preclinical stage therapy that address a range of disorders including post-stroke deficits, epilepsy, stroke, peripheral nerve damage, spinal cord injury, neuropathic pain, and heart failure. For more information, please visit the Company’s website at: www.acorda.com.

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)

	September 30, 2013	December 31, 2012
Assets		
Cash, cash equivalents, short-term and long-term investments	$ 349,378	$ 333,188
Trade receivable, net	24,998	26,327
Other current assets	15,311	16,863
Finished goods inventory	26,245	20,957
Property and equipment, net	17,752	16,706
Deferred tax asset	130,665	136,727
Intangible assets, net	17,590	9,319
Other assets	4,708	5,245
Total assets	$ 586,647	$ 565,332
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 45,827	$ 58,261
Deferred product revenue	31,221	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	1,009	1,134
Long-term liabilities	9,447	10,415
Non-current portion of revenue interest liability	659	1,440
Non-current portion of deferred license revenue	61,892	68,685
Stockholders' equity	426,391	385,921
Total liabilities and stockholders' equity	$ 586,647	$ 565,332

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	**2012**	**2013**	**2012**
Revenues:				
Net product revenues	$ 79,760	$ 72,206	$ 223,969	$ 206,992
Royalty revenues	2,895	2,967	13,076	10,557
License revenue	2,264	2,264	6,793	6,793
Total revenues	84,919	77,437	243,838	224,342
Costs and expenses:				
Cost of sales	17,213	14,761	47,631	40,802
Cost of license revenue	159	159	476	476
Research and development	13,839	12,031	39,575	35,690
Selling, general and administrative	42,336	40,121	138,538	123,096
Total operating expenses	73,547	67,072	226,220	200,064
Operating income	$ 11,372	$ 10,365	$ 17,618	$ 24,278
Other expense, net	(382)	(238)	(1,383)	(1,108)
Income before income taxes	10,990	10,127	16,235	23,170
Provision for income taxes	(3,513)	(533)	(5,985)	(1,185)
Net income	$ 7,477	$ 9,594	$ 10,250	$ 21,985
Net income per common share - basic	$ 0.19	$ 0.24	$ 0.26	$ 0.56
Net income per common share - diluted	$ 0.18	$ 0.24	$ 0.25	$ 0.55
Weighted average per common share - basic	40,315	39,463	40,037	39,412
Weighted average per common share - diluted	41,996	40,159	41,541	40,222

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	**2012**	**2013**	**2012**
GAAP net income	$ 7,477	$ 9,594	$ 10,250	$ 21,985
Pro forma adjustments:				
Product related payments included in R&D	1,000	-	1,000	3,200
Share-based compensation expenses included in R&D	1,550	1,354	4,245	3,682
Share-based compensation expenses included in SG&A	4,980	4,211	13,756	11,667
Total share-based compensation expenses	6,530	5,565	18,001	15,349
Total pro forma adjustments	7,530	5,565	19,001	18,549
Non-GAAP net income	$ 15,007	$ 15,159	$ 29,251	$ 40,534
Net income per common share - basic	$ 0.37	$ 0.38	$ 0.73	$ 1.03
Net income per common share - diluted	$ 0.36	$ 0.38	$ 0.70	$ 1.01
Weighted average per common share - basic	40,315	39,463	40,037	39,412
Weighted average per common share - diluted	41,996	40,159	41,541	40,222