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): **October 30, 2014**

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 30, 2014, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2014. 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 30, 2014

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 30, 2014

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated October 30, 2014

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Third Quarter 2014 Financial Results

- AMPYRA ® (dalfampridine) Third Quarter Net Revenue of $96.4 Million; 24% Increase from 3Q 2013
- Raising Full Year 2014 Guidance for AMPYRA Net Revenue from $328-$335 Million to $345-$350 Million
- Completed Acquisition of Civitas Therapeutics; Obtained Global Rights to Phase 3 Parkinson's Disease Treatment

ARDSLEY, N.Y. – October 30, 2014 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the third quarter ended September 30, 2014.

"AMPYRA sales this quarter were strong, representing a 24% increase over the third quarter of 2013. Our educational programs have steadily raised awareness among consumers, and neurologists increasingly view AMPYRA as a standard of care," said Ron Cohen, M.D., Acorda Therapeutics' President and CEO.

"In October, we completed our acquisition of Civitas Therapeutics, which adds to Acorda's pipeline CVT-301, a Phase 3 product that has the potential to transform treatment for people with Parkinson's disease who experience OFF episodes. The acquisition also brings the ARCUS technology platform for pulmonary delivery; we believe this technology has applications in multiple disease areas. We expect to start the CVT-301 Phase 3 program by the first quarter of 2015 and plan to file a new drug application in the United States by the end of 2016."

FINANCIAL RESULTS
The Company reported GAAP net income of $12.0 million for the quarter ended September 30, 2014, or $0.28 per diluted share. GAAP net income in the same quarter of 2013 was $7.5 million, or $0.18 per diluted share.

Non-GAAP net income for the quarter ended September 30, 2014 was $27.6 million, or $0.65 per diluted share. Non-GAAP net income in the same quarter of 2013 was $18.1 million, or $0.43 per diluted share. Non-GAAP net income excludes share based compensation charges, non-cash convertible debt, acquisition related expenses and tax adjustments. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the attached financial statements.

AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg - For the quarter ended September 30, 2014, the Company reported AMPYRA net revenue of $96.4 million compared to $77.8 million for the same quarter in 2013. Through the first three quarters of 2014, net sales increased 18% over the same period in 2013.

ZANAFLEX CAPSULES ® (tizanidine hydrochloride), ZANAFLEX ® (tizanidine hydrochloride) tablets and authorized generic capsules - For the quarter ended September 30, 2014, the Company reported combined net revenue and royalties from ZANAFLEX and tizanidine of $4.5 million compared to $2.7 million for the same quarter in 2013.

FAMPYRA ® (prolonged-release fampridine tablets) - For the quarter ended September 30, 2014, the Company reported FAMPYRA royalties from sales outside of the U.S. of $2.5 million compared to $2.0 million for the same quarter in 2013.

Research and development (R&D) expenses for the quarter ended September 30, 2014 were $16.6 million, including $1.4 million of share-based compensation, compared to $13.8 million including $1.6 million of share-based compensation for the same quarter in 2013.

Sales, general and administrative (SG&A) expenses for the quarter ended September 30, 2014 were $47.8 million, including $5.8 million of share-based compensation, compared to $42.3 million including $5.0 million of share-based compensation for the same quarter in 2013.

The Company is reiterating its 2014 R&D and SG&A expense guidance of $60-$70 million and $180-$190 million, respectively . This guidance excludes share-based compensation and costs associated with expenditures related to the Civitas acquisition . R&D expenses are expected to be significantly higher in 2015 based on initiation of Phase 3 clinical trials and advancement of other pipeline products. The Company will provide 2015 R&D and SG&A guidance in January 2015.

Provision for income taxes for the quarter ended September 30, 2014 was $4.5 million, including $0.6 million of cash taxes, compared to $3.5 million, including $0.4 million of cash taxes for the same quarter in 2013.

At September 30, 2014 the Company had cash, cash equivalents and investments of $766.4 million.

AMPYRA Update

- More than 60% of new AMPYRA patients enroll in First Step, which provides two months of AMPYRA at no cost. The program is in its fourth year, and data show that First Step participants have higher compliance and persistency rates over time compared to non-First Step patients.
- Approximately 100,000 people with multiple sclerosis in the United States have tried AMPYRA since its launch in 2010.

Pipeline Update

- The Company is on track to initiate a Phase 3 clinical trial studying the use of dalfampridine administered twice-daily (BID) to improve walking in people who have experienced an ischemic stroke by the end of the year.
- The Company is re-prioritizing its pipeline based on its recent acquisition of Civitas Therapeutics and will provide an update in January 2015.

Corporate Update

- In October, the Company completed the acquisition of Civitas Therapeutics, a privately-held biotechnology company, for $525 million. Acorda obtained global rights to CVT-301, a Phase 3 product for the treatment of OFF episodes, which are an unexpected and rapid return of Parkinson's disease symptoms in people taking an optimized levodopa regimen. Acorda also obtained global rights to the proprietary ARCUS ® pulmonary delivery technology, including a manufacturing facility with commercial-scale capabilities based in Chelsea, MA.

WEBCAST AND CONFERENCE CALL

Ron Cohen, 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 2014 results.

To participate in the conference call, please dial 866-515-2912 (domestic) or 617-399-5126 (international) and reference the access code 35452540. The presentation will be available via a live webcast on the Investors section of www.acorda.com.

A replay of the call will be available from 1:30 p.m. ET on October 30, 2014 until midnight on November 6, 2014. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 92700720. 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

Do not take AMPYRA if you:

- have ever had a seizure,
- 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.

Before taking AMPYRA, tell your doctor if you:

- have kidney problems or any other medical conditions;
- are taking compounded 4-aminopyridine;
- are pregnant or plan to become pregnant. It is not known if AMPYRA will harm your unborn baby;
- 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;
- are taking any other medicines.

Stop taking AMPYRA and call your doctor right away if you have a seizure while taking AMPYRA. 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 before you start AMPYRA.

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

AMPYRA may cause serious side effects, including:

- severe 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;
- kidney or bladder infections.

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.

Please see Patient Medication Guide for full safety information.

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 ®) 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.

For full U.S. Prescribing Information and Medication Guide, please visit: www.AMPYRA.com.

About Acorda Therapeutics
Founded in 1995, Acorda Therapeutics is a biotechnology company focused on developing therapies that improve the lives of people with neurological disorders.

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), as demonstrated by an increase in walking speed. The Company has one of the leading pipelines in the industry of novel neurological therapies. Acorda is currently developing a number of clinical and preclinical stage therapies. This pipeline addresses a range of disorders including post-stroke walking deficits, Parkinson’s disease, epilepsy, neuropathic pain, heart failure, MS, and spinal cord injury.

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 the ability to realize the benefits anticipated from the Civitas transaction and to successfully integrate Civitas' operations into our operations; 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 CVT-301, Plumiaz, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, Plumiaz, or any other products under development; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; 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; 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, failure to comply with regulatory requirements could result in adverse action by regulatory agencies.

These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities and 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.

Non-GAAP Financial Measures
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 the items below. 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 (i) non-cash charges and benefits that are substantially dependent on changes in the market price of our common stock, (ii) non-cash interest charges related to the accounting for our outstanding convertible debt which are in excess of the actual interest expense owing on such convertible debt, (iii) payments associated with acquisitions that are expenses that do not arise from the ordinary course of our business or (iv) non-cash tax expenses related to our tax accounting which do not correlate to our actual tax payment obligations. 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.

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Financial Statements

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

	September 30, 2014	December 31, 2013
Assets		
Cash, cash equivalents, short-term and long-term investments	$ 766,441	$ 367,227
Trade receivable, net	24,792	30,784
Other current assets	19,568	17,135
Finished goods inventory	27,215	26,172
Property and equipment, net	17,089	16,525
Deferred tax asset	90,758	127,299
Intangible assets, net	16,865	17,459
Other assets	10,039	4,526
Total assets	$ 972,767	$ 607,127
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 60,292	$ 53,491
Deferred product revenue	29,515	32,090
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	913	861
Convertible senior notes	285,825	-
Other long-term liabilities	10,259	9,863
Non-current portion of revenue interest liability	14	640
Non-current portion of deferred license revenue	52,835	59,628
Stockholders' equity	522,913	440,353
Total liabilities and stockholders' equity	$ 972,767	$ 607,127

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	**2013**	**2014**	**2013**
Revenues:				
Net product revenues	$ 98,481	$ 79,760	$ 262,662	$ 223,969
Royalty revenues	5,216	2,895	14,153	13,076
License revenue	2,264	2,264	6,793	6,793
Total revenues	105,961	84,919	283,608	243,838
Costs and expenses:				
Cost of sales	20,575	17,213	55,004	47,631
Cost of license revenue	159	159	476	476
Research and development	16,578	13,839	47,548	39,575
Selling, general and administrative	47,820	42,336	145,357	138,538
Total operating expenses	85,132	73,547	248,385	226,220
Operating income	$ 20,829	$ 11,372	$ 35,223	$ 17,618
Other expense, net	(4,340)	(382)	(4,520)	(1,383)
Income before income taxes	16,489	10,990	30,703	16,235
Provision for income taxes	(4,536)	(3,513)	(13,361)	(5,985)
Net income	$ 11,953	$ 7,477	$ 17,342	$ 10,250
Net income per common share - basic	$ 0.29	$ 0.19	$ 0.42	$ 0.26
Net income per common share - diluted	$ 0.28	$ 0.18	$ 0.41	$ 0.25
Weighted average per common share - basic	41,094	40,315	41,022	40,037
Weighted average per common share - diluted	42,365	41,996	42,346	41,541

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,	
	2014	2013	2014	2013
GAAP net income	$ 11,953	$ 7,477	$ 17,342	$ 10,250
Pro forma adjustments:				
Non-cash interest expense (1)	2,069	-	2,226	-
Non-cash taxes (2)	3,921	3,108	11,532	4,243
Acquisition related expenses (3)	2,355	-	2,355	-
Product related payments included in R&D (4)	-	1,000	-	1,000
Share-based compensation expenses included in R&D	1,423	1,550	4,089	4,245
Share-based compensation expenses included in SG&A	5,848	4,980	16,555	13,756
Total share-based compensation expenses	7,271	6,530	20,644	18,001
Total pro forma adjustments	15,616	10,638	36,757	23,244
Non-GAAP net income	$ 27,569	$ 18,115	$ 54,099	$ 33,494
Net income per common share - basic	$ 0.67	$ 0.45	$ 1.32	$ 0.84
Net income per common share - diluted	$ 0.65	$ 0.43	$ 1.28	$ 0.81
Weighted average per common share - basic	41,094	40,315	41,022	40,037
Weighted average per common share - diluted	42,365	41,996	42,346	41,541

(1) Non-cash interest expense related to convertible senior notes.

(2) $0.6 million and $0.4 million paid in cash taxes in the three months ended 2014 and 2013, respectively, and $1.8 million and $1.7 million paid in cash taxes in the nine months ended 2014 and 2013, respectively. 2013 revised to include non-cash tax adjustments to conform with current year presentation.

(3) Deal related expenses for Civitas acquisition.

(4) $1.0M milestone upon the FDA’s acceptance for review of the first NDA for Plumiaz pursuant to the SK license.