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): **February 12, 2015**

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 February 12, 2015, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 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 February 12, 2015

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.

February 12, 2015

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated February 12, 2015

EXHIBIT 99.1

CONTACT:

Jeff Macdonald
Acorda Therapeutics
(914) 326-5232
jmacdonald@acorda.com

FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Fourth Quarter and Full Year 2014 Financial Results

- AMPYRA ® (dalfampridine) Fourth Quarter Net Revenue of $109.9 Million; Full Year Net Revenue of $366.2 Million
- Full Year AMPYRA 2015 Net Revenue Guidance of $405-$420 Million
- Full Year 2015 Guidance for R&D Expense of $150-$160 Million
- Full Year 2015 Guidance for SG&A Expense of $180-$190 Million

ARDSLEY, N.Y. – February 12, 2015 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the fourth quarter and full year ended December 31, 2014.

“During 2014, we made major progress across our three core value drivers: AMPYRA commercial performance, clinical pipeline and business development. We grew AMPYRA net revenue 21% over 2013; AMPYRA is now considered a standard of care in MS. Our acquisition of Civitas Therapeutics added high-potential products and an innovative technology platform, complementing an already robust pipeline,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “In 2015, our focus is on maximizing AMPYRA sales, advancing our late-stage clinical trials and continuing to evaluate business development opportunities.”

FINANCIAL RESULTS
The Company reported GAAP net income of $0.3 million for the quarter ended December 31, 2014, or $0.01 per diluted share. GAAP net income in the same quarter of 2013 was $6.2 million, or $0.15 per diluted share. For the full year ended December 31, 2014, the Company reported GAAP net income of $17.7 million, or $0.42 per diluted share. GAAP net income for the full year 2013 was $16.4 million, or $0.39 per diluted share.

Non-GAAP net income for the quarter ended December 31, 2014 was $19.7 million, or $0.46 per diluted share. Non-GAAP net income in the same quarter of 2013 was $18.9 million, or $0.45 per diluted share. Non-GAAP net income for the full year ended December 31, 2014 was $73.8 million, or $1.74 per diluted share. Non-GAAP net income for the full year ended December 31, 2013 was $52.4 million, or $1.26 per diluted share. Non-GAAP net income excludes share based compensation charges, non-cash convertible debt interest expense, acquisition related expenses, an asset impairment, changes in fair value of acquired contingent consideration and non-cash 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 December 31, 2014, the Company reported AMPYRA net revenue of $109.9 million compared to $84.6 million for the same quarter in 2013. For the full year ended December 31, 2014 net revenue was $366.2 million compared to $302.6 million for full year 2013. Full year 2014 net revenue increased 21% over 2013.

ZANAFLEX CAPSULES ®(tizanidine hydrochloride), ZANAFLEX ®(tizanidine hydrochloride) tablets and authorized generic capsules - For the quarter ended December 31, 2014, the Company reported combined net revenue and royalties from ZANAFLEX and tizanidine of $3.2 million compared to $3.2 million for the same quarter in 2013. For the full year ended December 31, 2014 combined net revenue and royalties from ZANAFLEX and tizanidine were $15.3 million compared to $15.1 million for full year 2013.

FAMPYRA ®(prolonged-release fampridine tablets) - For the quarter ended December 31, 2014, the Company reported FAMPYRA royalties from sales outside of the U.S. of $2.3 million compared to $2.2 million for the same quarter in 2013. For the full year ended December 31, 2014, the Company reported FAMPYRA royalties from sales outside of the U.S. of $10.0 million compared to $9.3 million for the full year 2013.

Research and development (R&D) expenses for the quarter ended December 31, 2014 were $25.9 million, including $1.9 million of share-based compensation, compared to $14.3 million including $1.6 million of share-based compensation for the same quarter in 2013. R&D expenses for the full year ended December 31, 2014 were $73.5 million, including $5.9 million of share-based compensation, compared to $53.9 million including $5.8 million of share-based compensation for the full year 2013.

Sales, general and administrative (SG&A) expenses for the quarter ended December 31, 2014 were $56.5 million, including $6.9 million of share-based compensation, compared to $47.0 million including $5.6 million of share-based compensation for the same quarter in 2013. SG&A expenses for the full year ended December 31, 2014 were $201.8 million, including $23.5 million of share-based compensation, compared to $185.5 million including $19.3 million of share-based compensation for the full year 2013.

Benefit from (provision for) income taxes for the quarter ended December 31, 2014 was $3.0 million of a benefit, including $2.5 million of cash taxes, compared to $6.4 million of a provision, including $0.9 million of cash taxes for the same quarter in 2013. Provision for income taxes for the full year ended December 31, 2014 was $10.3 million, including $4.4 million of cash taxes, compared to $12.4 million, including $2.6 million of cash taxes for the full year 2013.

At December 31, 2014 the Company had cash, cash equivalents and investments of $307.6 million.

Guidance for 2015
The following guidance does not include potential expenditures related to the acquisition of new products or other business development activities.

- The Company expects AMPYRA 2015 full year net revenue of $405-$420 million.
- In 2015, the Company expects ZANAFLEX franchise and ex-U.S. FAMPYRA revenue of approximately $25 million, which includes sales of branded ZANAFLEX products and royalties from ex-U.S. FAMPYRA and authorized generic tizanidine hydrochloride capsules sales.

- R&D expenses for the full year 2015 are expected to be $150-$160 million, excluding share-based compensation. The increase in R&D expenses in 2015 is primarily related to Phase 3 studies of dalfampridine and CVT-301. Additional expenses include continued development of PLUMIAZ ™ (diazepam) Nasal Spray, clinical trials for cimaglermin and rHIgM22, as well as ongoing preclinical studies.
- SG&A expenses for the full year 2015 are expected to be $180-$190 million, excluding share-based compensation.

AMPYRA Update

- More than 65% of new AMPYRA patients currently 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.
- More than 100,000 people with multiple sclerosis in the United States have tried AMPYRA since its launch in 2010.

- The Company received eight Paragraph IV Certification Notice Letters advising that companies have submitted Abbreviated New Drug Applications (ANDA) to the U.S. Food and Drug Administration (FDA) requesting permission to manufacture and market a generic version of AMPYRA. Acorda has filed patent infringement suits against all ANDA filers to date, triggering a 30-month statutory stay period that restricts FDA from approving an ANDA until July 2017 at the earliest, unless a district court issues a decision adverse to all of Acorda's asserted Orange Book patents prior to that date.
- In February 2015, a hedge fund filed an *inter partes* review (IPR) petition with the U.S. Patent and Trademark Office, challenging one of the five AMPYRA Orange Book-listed patents. The Company will oppose the request to institute the IPR, and if it is allowed to proceed, the Company will oppose the full proceeding. The 30-month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by this filing, and remains in effect.

Pipeline Update

- In February 2015, the Company announced safety and tolerability data from the first Phase 1 clinical trial of rHIgM22, a remyelinating antibody for treatment of multiple sclerosis. The trial, which followed participants for up to six months after receiving a single dose of rHIgM22, found no dose-limiting toxicities at any of the five dose levels studied. Based on these data, the Company plans to initiate a second Phase 1 trial of rHIgM22 in 2015.
- In December 2014, the Company initiated 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.
- The Company initiated a Phase 3 clinical trial studying the use of CVT-301 to treat OFF episodes in Parkinson's disease in December 2014.
- The Company announced it is deferring further development of NP-1998 for neuropathic pain in 2015. The Company is continuing to work with the FDA to define the additional clinical work necessary for the approval of PLUMIAZ .

Corporate Update

- In October, the Company completed the acquisition of Civitas Therapeutics, a privately-held biotechnology company, obtaining global rights to CVT-301, CVT-427 and 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 fourth quarter and full year 2014 results.

To participate in the conference call, please dial 877-280-4956 (domestic) or 857-244-7313 (international) and reference the access code 67493058. 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 12:30 p.m. ET on February 12, 2015 until midnight on February 19, 2015. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 15118889. 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, problems with balance,
multiple sclerosis relapse, burning, tingling, or itching of your skin, irritation in your nose and throat, constipation, indigestion, and pain in your throat.

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 restore function and 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, (iv) asset impairment charges that do not arise from the ordinary course of our business, (v) changes in fair value of acquired contingent consideration which do not correlate to our actual cash payment obligations in the current period or (vi) 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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Acorda Therapeutics, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	December 31, 2014	December 31, 2013
Assets		
Cash, cash equivalents, short-term and long-term investments	$ 307,618	$ 367,227
Trade receivable, net	32,211	30,784
Other current assets	24,052	17,135
Finished goods inventory	26,837	26,172
Deferred tax asset	18,420	127,299
Property and equipment, net	46,090	16,525
Goodwill	182,952	-
Intangible assets, net	432,822	17,459
Other assets	9,677	4,526
Total assets	$ 1,080,679	$ 607,127
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 73,869	$ 53,491
Deferred product revenue	29,420	32,090
Current portion of deferred license revenue	9,057	9,057
Current portion of revenue interest liability	893	861
Current portion of notes payable	1,144	1,144
Convertible senior notes	287,699	-
Contingent consideration	52,600	-
Non-current portion of deferred license revenue	50,570	59,628
Deferred tax liability	23,885	-
Other long-term liabilities	11,287	10,503
Stockholders' equity	540,255	440,353
Total liabilities and stockholders' equity	$ 1,080,679	$ 607,127

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Revenues:				
Net product revenues	$ 110,630	$ 86,348	$ 373,292	$ 310,317
Royalty revenues	4,978	3,981	19,131	17,056
License revenue	2,264	2,264	9,057	9,057
Total revenues	117,872	92,593	401,480	336,430
Costs and expenses:				
Cost of sales	24,977	18,377	79,981	66,009
Cost of license revenue	158	158	634	634
Research and development	25,921	14,302	73,470	53,877
Selling, general and administrative	56,456	47,007	201,813	185,545
Asset Impairment	6,991	-	6,991	-
Change in fair value of acquired contingent consideration	2,200	-	2,200	-
Total operating expenses	116,703	79,844	365,089	306,065
Operating income	$ 1,169	$ 12,749	$ 36,391	$ 30,365
Other expense, net	(3,862)	(119)	(8,382)	(1,502)
Income (loss) before income taxes	(2,693)	12,630	28,009	28,863
Benefit from (provision for) income taxes	3,024	(6,437)	(10,337)	(12,422)
Net income	$ 331	$ 6,193	$ 17,672	$ 16,441
Net income per common share - basic	$ 0.01	$ 0.15	$ 0.43	$ 0.41
Net income per common share - diluted	$ 0.01	$ 0.15	$ 0.42	$ 0.39
Weighted average per common share - basic	41,532	40,713	41,150	40,208
Weighted average per common share - diluted	43,135	42,102	42,544	41,682

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
GAAP net income	$ 331	$ 6,193	$ 17,672	$ 16,441
Pro forma adjustments:				
Non-cash interest expense (1)	2,065	-	4,291	-
Non-cash taxes (2)	(5,551)	5,549	5,981	9,792
Acquisition related expenses in SG&A (3)	4,893	-	7,248	-
Asset Impairment (4)	6,991	-	6,991	-
Change in fair value of acquired contingent consideration (5)	2,200	-	2,200	-
Product related payments included in R&D (6)	-	-	-	1,000
Share-based compensation expenses included in R&D	1,851	1,559	5,939	5,804
Share-based compensation expenses included in SG&A	6,943	5,577	23,498	19,334
Total share-based compensation expenses	8,794	7,136	29,437	25,138
Total pro forma adjustments	19,392	12,685	56,148	35,930
Non-GAAP net income	$ 19,723	$ 18,878	$ 73,820	$ 52,371
Net income per common share - basic	$ 0.47	$ 0.46	$ 1.79	$ 1.30
Net income per common share - diluted	$ 0.46	$ 0.45	$ 1.74	$ 1.26
Weighted average per common share - basic	41,532	40,713	41,150	40,208
Weighted average per common share - diluted	43,135	42,102	42,544	41,682

(1) Non-cash interest expense related to convertible senior notes.
(2) $2.5 million and $0.9 million paid in cash taxes in the three months ended 2014 and 2013, respectively, and $4.4 million and $2.6 million paid in cash taxes in the twelve 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) Non-cash charge for NP-1998 impairment due to reprioritization of R&D activities in Q4 2014.
(5) Changes in fair value of acquired contingent consideration related to Civitas transaction.
(6) $1.0M milestone upon the FDA's acceptance for review of the first NDA for Plumiaz pursuant to the SK license.