ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
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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): **April 30, 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 April 30, 2015, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2015. 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 April 30, 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.

April 30, 2015

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated April 30, 2015

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Reports First Quarter 2015 Financial Results

- AMPYRA ® (dalfampridine) First Quarter Net Revenue of $92.4 Million; 27% Increase from 1Q 2014

ARDSLEY, N.Y. – April 30, 2015 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the first quarter ended March 31, 2015.

“AMPYRA’s 27% increase in sales this quarter over the same period last year reflects the continued strong growth of the brand, which is increasingly considered a standard of care to improve walking in people with MS,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO.

“We also continued to advance our clinical stage pipeline. We are enrolling participants in Phase 3 trials for CVT-301 in Parkinson’s disease and for dalfampridine in chronic post-stroke walking deficits. Earlier this month, we presented data from our first Phase 1 clinical trial of rHIgM22 for remyelination in MS at the American Academy of Neurology meeting. In addition to being well-tolerated, the antibody was detected in the cerebrospinal fluid, an encouraging and important step indicating that it enters the central nervous system. During the second quarter, we expect to initiate a second Phase 1 study of rHIgM22 in MS patients experiencing an active relapse.”

FINANCIAL RESULTS
The Company reported a GAAP net loss of $3.1 million for the quarter ended March 31, 2015, or $0.07 per diluted share. GAAP net income in the same quarter of 2014 was $0.7 million, or $0.02 per diluted share.

Non-GAAP net income for the quarter ended March 31, 2015 was $6.5 million, or $0.15 per diluted share. Non-GAAP net income in the same quarter of 2014 was $8.8 million, or $0.21 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 March 31, 2015, the Company reported AMPYRA net revenue of $92.4 million compared to $72.5 million for the same quarter in 2014.

The Company is reiterating 2015 AMPYRA net sales guidance of $405-$420 million.

ZANAFLEX CAPSULES ®(tizanidine hydrochloride), ZANAFLEX ®(tizanidine hydrochloride) tablets and authorized generic capsules - For the quarter ended March 31, 2015, the Company reported combined net revenue and royalties from ZANAFLEX and tizanidine of $2.6 million compared to $3.1 million for the same quarter in 2014.

FAMPYRA ®(prolonged-release fampridine tablets) - For the quarter ended March 31, 2015, the Company reported FAMPYRA royalties from sales outside of the U.S. of $2.3 million compared to $2.4 million for the same quarter in 2014.

Research and development (R&D) expenses for the quarter ended March 31, 2015 were $30.6 million, including $1.8 million of share-based compensation, compared to $14.5 million including $1.1 million of share-based compensation for the same quarter in 2014.

The Company is reiterating 2015 R&D guidance of $150-$160 million.

Sales, general and administrative (SG&A) expenses for the quarter ended March 31, 2015 were $48.8 million, including $5.3 million of share-based compensation, compared to $46.9 million including $4.7 million of share-based compensation for the same quarter in 2014.

The Company is reiterating 2015 SG&A guidance of $180-$190 million.

Provision for income taxes for the quarter ended March 31, 2015 was $(2.0) million, including $0.7 million of cash taxes, compared to $2.8 million, including $0.5 million of cash taxes for the same quarter in 2014.

At March 31, 2015 the Company had cash, cash equivalents and investments of $299.7 million. The Company expects to be cash flow positive in 2015.

AMPYRA Update

- The U.S. District Court in Delaware, which is adjudicating Abbreviated New Drug Application (ANDA) challenges to certain AMPYRA patents, has scheduled a Markman hearing for March 2016 and set a trial date for September 2016.
- Petitions for Inter Partes Review (IPR) of two AMPYRA patents have been submitted to the United States Patent and Trademark Office (USPTO). The Company is responding to these filings.
- The Company has five Orange Book-listed patents on AMPYRA, and will vigorously defend its intellectual property rights.

Pipeline Update

- In March, the Company presented new analyses of data from the first Phase 1 clinical trial of cimaglermin alfa, an investigational drug for heart failure, at the America College of Cardiology (ACC) 64 th Annual Scientific Session and Expo. The poster contained new analyses of ejection fraction measures, which found that cimaglermin produced a dose-dependent benefit at multiple time points for up to three months following a single infusion. Additional information on adverse events, demographics, and analysis of hemodynamic and echo parameters were also reported. Data from the second clinical trial of cimaglermin in people with heart failure is expected in the second half of 2015.

- In April, the Company presented data from a Phase 1 clinical trial of rHIgM22, a remyelinating antibody being studied for the treatment of multiple sclerosis (MS). Safety data showed rHIgM22 was well-tolerated in each of the five tested doses, supporting additional clinical development. In addition, testing detected rHIgM22 in cerebrospinal fluid (CSF), indicating the drug's access to the central nervous system. These data were presented at the 67th American Academy of Neurology Annual Meeting. The Company expects to begin a second Phase 1 trial in relapsing MS patients in the second quarter of 2015.

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 first quarter 2015 results.

To participate in the conference call, please dial 800-638-4817 (domestic) or 617-614-3943 (international) and reference the access code 13484356. 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 April 30, 2015 until midnight on May 7, 2015. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 42536532. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at www.acorda.com.

AMPYRA ® (dalfampridine) 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 at www.ampyra.com/medication-guide.pdf for additional 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. The mechanism by which dalfampridine exerts its therapeutic effect has not been fully elucidated. 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 additional information, including U.S. Full 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) changes in the 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)

	March 31, 2015	December 31, 2014
Assets		
Cash, cash equivalents, short-term and long-term investments	$ 299,697	$ 307,618
Trade receivable, net	30,551	32,211
Other current assets	27,288	24,052
Finished goods inventory	45,831	26,837
Deferred tax asset	20,469	18,420
Property and equipment, net	45,919	46,090
Goodwill	182,952	182,952
Intangible assets, net	432,155	432,822
Other assets	14,120	9,677
Total assets	$ 1,098,982	$ 1,080,679
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 82,094	$ 73,869
Deferred product revenue	29,121	29,420
Current portion of deferred license revenue	9,057	9,057
Current portion of revenue interest liability	749	893
Current portion of notes payable	1,144	1,144
Convertible senior notes	289,607	287,699
Contingent consideration	55,700	52,600
Non-current portion of deferred license revenue	48,306	50,570
Deferred tax liability	23,885	23,885
Other long-term liabilities	10,299	11,287
Stockholders' equity	549,020	540,255
Total liabilities and stockholders' equity	$ 1,098,982	$ 1,080,679

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

	Three Months Ended March 31,	
	2015	**2014**
Revenues:		
Net product revenues	$ 93,500	$ 74,463
Royalty revenues	4,087	3,791
License revenue	2,264	2,264
Total revenues	99,851	80,518
Costs and expenses:		
Cost of sales	18,446	15,529
Cost of license revenue	159	159
Research and development	30,636	14,522
Selling, general and administrative	48,769	46,892
Change in fair value of acquired contingent consideration	3,100	-
Total operating expenses	101,110	77,102
Operating (loss) income	$ (1,259)	$ 3,416
Other (expense) income, net	(3,864)	80
(Loss) income before income taxes	(5,123)	3,496
Benefit from (provision for) income taxes	2,038	(2,793)
Net (loss) income	$ (3,085)	$ 703
Net (loss) income per common share - basic	$ (0.07)	$ 0.02
Net (loss) income per common share - diluted	$ (0.07)	$ 0.02
Weighted average per common share - basic	42,031	40,934
Weighted average per common share - diluted	42,031	42,235

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

	Three Months Ended March 31,	
	2015	**2014**
GAAP net (loss) income	$ (3,085)	$ 703
Pro forma adjustments:		
Non-cash interest expense (1)	2,103	-
Non-cash taxes (2)	(2,781)	2,333
Change in fair value of acquired contingent consideration (3)	3,100	-
Share-based compensation expenses included in R&D	1,822	1,104
Share-based compensation expenses included in SG&A	5,304	4,653
Total share-based compensation expenses	7,126	5,757
Total pro forma adjustments	9,548	8,090
Non-GAAP net income	$ 6,463	$ 8,793
Net income per common share - basic	$ 0.15	$ 0.21
Net income per common share - diluted	$ 0.15	$ 0.21
Weighted average per common share - basic	42,031	40,934
Weighted average per common share - diluted	43,585	42,235

(1) Non-cash interest expense related to convertible senior notes.
(2) $0.7 million and $0.5 million paid in cash taxes in the three months ended 2015 and 2014, respectively.
(3) Changes in fair value of acquired contingent consideration related to Civitas transaction.