

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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Sector	Healthcare
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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 6, 2014**

Acorda Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-50513
(Commission
File Number)

13-3831168
(I.R.S. Employer
Identification No.)

420 Saw Mill River Road, Ardsley, NY
(Address of principal executive offices)

10502
(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))
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Item 2.02 Results of Operations and Financial Condition

On May 6, 2014, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 6, 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.

May 6, 2014

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

EXHIBIT INDEX

Exhibit No.

Description

99.1

Press Release dated May 6, 2014

**CONTACT:**

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

FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports First Quarter 2014 Financial Results

- AMPYRA[®] (dalfampridine) First Quarter Net Revenue of \$72.5 Million
- Reiterating Full Year 2014 Guidance for AMPYRA Net Revenue of \$328-\$335 Million
- Cash, cash equivalents and investments of \$372.2 million as of March 31, 2014

ARDSLEY, N.Y. – May 6, 2014 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the first quarter ended March 31, 2014.

“The AMPYRA franchise remains strong, and we are reiterating our 2014 net sales guidance,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “During the quarter, a fifth AMPYRA patent was issued and listed in the Orange Book. AMPYRA’s commercial success is supporting the development of an exciting pipeline of novel therapies. As previously announced, we are planning to initiate a Phase 3 trial for dalfampridine in post-stroke walking deficits in the second half of the year. While we were disappointed to receive a Complete Response Letter on PLUMIAZ[™], we are working to address the FDA’s requests and refile our NDA. We were pleased to resume enrollment of our second clinical trial of GGF2 in chronic heart failure and to have completed the dose escalation phase of our Phase 1 rHlgM22 trial for remyelination in MS, with no serious or limiting adverse events.”

FINANCIAL RESULTS

The Company reported GAAP net income of \$0.7 million for the quarter ended March 31, 2014, or \$0.02 per diluted share, compared to a GAAP net loss in the same quarter of 2013 of \$1.1 million, or \$0.03 per diluted share.

Non-GAAP net income for the quarter ended March 31, 2014 was \$8.8 million, or \$0.21 per diluted share. Non-GAAP net income in the same quarter of 2013 was \$1.3 million, or \$0.03 per diluted share. Non-GAAP net income excludes share based compensation charges 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 March 31, 2014, the Company reported AMPYRA net revenue of \$72.5 million compared to \$62.3 million for the same quarter in 2013.

ZANAFLEX CAPSULES[®] (tizanidine hydrochloride), ZANAFLEX[®] (tizanidine hydrochloride) tablets and authorized generic capsules - For the quarter ended March 31, 2014, the Company

reported combined net revenue and royalties from ZANAFLEX and tizanidine of \$3.1 million compared to \$4.4 million for the same quarter in 2013.

FAMPYRA® (prolonged-release fampridine tablets) - For the quarter ended March 31, 2014, the Company reported FAMPYRA royalties from sales outside of the U.S. of \$2.4 million, compared to \$2.9 million for the same quarter in 2013. Royalties in 2013 included a favorable adjustment of \$1.0 million from the establishment of pricing in Germany.

Research and development (R&D) expenses for the quarter ended March 31, 2014 were \$14.5 million, including \$1.1 million of share-based compensation, compared to \$12.5 million including \$1.2 million of share-based compensation for the same quarter in 2013.

Sales, general and administrative (SG&A) expenses for the quarter ended March 31, 2014 were \$46.9 million, including \$4.7 million of share-based compensation, compared to \$48.2 million including \$3.8 million of share-based compensation for the same quarter in 2013.

The Company is reiterating its 2014 R&D and SG&A expense guidance, and is evaluating the impact of recent events on both R&D and SG&A expenses for 2014. The Company will provide an update on its next earnings call if there are any changes to guidance.

Provision for income taxes for the quarter ended March 31, 2014 was \$2.8 million, including \$0.4 million of cash taxes, compared to a tax benefit of \$1.8 million, including \$0.7 million of cash taxes for the same quarter in 2013.

At March 31, 2014 the Company had cash, cash equivalents and short-term and long-term investments of \$372.2 million.

AMPYRA UPDATE

- A new U.S. AMPYRA patent was issued by the U.S. Patent and Trademark Office (USPTO) in early 2014. The Company now has five Orange Book patents providing protection up to 2027.

PIPELINE UPDATE

- In May, the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) for the New Drug Application (NDA) for PLUMIAZ™ (diazepam) Nasal Spray for the treatment of people with epilepsy who experience cluster seizures. The Company is evaluating the CRL and expects to work closely with the FDA to address the items outlined in the letter, which will include additional clinical work, and refile the NDA. Based on the requirements noted in the letter, the Company does not expect PLUMIAZ to receive FDA approval in 2014.
 - In April, the Company announced that additional data on QD (once-daily) dalfampridine extended release tablets are needed before starting a Phase 3 trial in post-stroke walking deficits, and now expects to begin the trial in the second half of 2014. Previously the Company had projected study initiation in the second quarter of 2014. The developer of the once-daily formulation informed the Company of an alcohol dose dumping finding in vitro and the Company will need to perform a short clinical study to determine whether this also exists in vivo. The clinical study will be conducted in healthy volunteers and is expected to be completed in the third quarter of 2014.
 - In April, the Company announced that it has completed its review of certain preclinical data and that the Phase 1b clinical trial of GGF2 in chronic heart failure will resume recruitment.
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The single-intravenous infusion trial is assessing tolerability of three dose levels of GGF2 and also includes several exploratory efficacy measures. The Company expects that the trial will be completed in 2015.

- The Company has completed the dose escalation portion of the Phase 1b rHlgM22 clinical trial, with no serious or limiting adverse events reported. The second portion of this study will explore safety, tolerability and efficacy endpoints for six months in additional patients at the two highest doses achieved in the dose escalation portion of the trial. Enrollment in the second part of the trial is almost complete.

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 2014 results.

To participate in the conference call, please dial 800-706-7745 (domestic) or 617-614-3472 (international) and reference the access code 66119945. 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 12:30 p.m. ET on May 6, 2014 until midnight on June 3, 2014. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 83511569. 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 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

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); 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 Plumiaz (our trade name for 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.

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 share-based compensation charges and non-cash taxes. 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 and benefits that are substantially dependent on changes in the market price of our common stock or relate to tax accounting, 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.

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

(Unaudited)

	March 31, 2014	December 31, 2013
Assets		
Cash, cash equivalents, short-term and long-term investments	\$ 372,152	\$ 367,227
Trade receivable, net	29,265	30,784
Other current assets	16,087	17,135
Finished goods inventory	31,154	26,172
Property and equipment, net	16,440	16,525
Deferred tax asset	124,478	127,299
Intangible assets, net	17,959	17,459
Other assets	4,352	4,526
Total assets	<u>\$ 611,887</u>	<u>\$ 607,127</u>
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	\$ 52,837	\$ 53,491
Deferred product revenue	31,217	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	450	861
Long-term liabilities	8,788	9,863
Non-current portion of revenue interest liability	511	640
Non-current portion of deferred license revenue	57,363	59,628
Stockholders' equity	450,520	440,353
Total liabilities and stockholders' equity	<u>\$ 611,887</u>	<u>\$ 607,127</u>

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

	Three Months Ended March 31,	
	2014	2013
Revenues:		
Net product revenues	\$ 74,463	\$ 64,084
Royalty revenues	3,791	5,516
License revenue	2,264	2,265
Total revenues	80,518	71,865
Costs and expenses:		
Cost of sales	15,529	13,484
Cost of license revenue	159	159
Research and development	14,522	12,520
Selling, general and administrative	46,892	48,198
Total operating expenses	77,102	74,361
Operating income (loss)	\$ 3,416	\$ (2,496)
Other income (expense), net	80	(418)
Income (loss) before income taxes	3,496	(2,914)
(Provision for) benefit from income taxes	(2,793)	1,775
Net income (loss)	\$ 703	\$ (1,139)
Net income (loss) per common share - basic	\$ 0.02	\$ (0.03)
Net income (loss) per common share - diluted	\$ 0.02	\$ (0.03)
Weighted average per common share - basic	40,934	39,832
Weighted average per common share - diluted	42,235	39,832

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

	Three Months Ended March 31,	
	2014	2013
GAAP net income (loss)	\$ 703	\$ (1,139)
Pro forma adjustments:		
Non-cash taxes (1)	2,333	(2,506)
Share-based compensation expenses included in R&D	1,104	1,151
Share-based compensation expenses included in SG&A	4,653	3,782
Total share-based compensation expenses	<u>5,757</u>	<u>4,933</u>
Total pro forma adjustments	<u>8,090</u>	<u>2,427</u>
Non-GAAP net income	<u>\$ 8,793</u>	<u>\$ 1,288</u>
Net income per common share - basic	\$ 0.21	\$ 0.03
Net income per common share - diluted	\$ 0.21	\$ 0.03
Weighted average per common share - basic	40,934	39,832
Weighted average per common share - diluted	42,235	41,038

(1) \$460,000 and \$731,000 paid in cash taxes in 2014 and 2013, respectively. 2013 revised to include a non-cash tax adjustment to conform with current year presentation.