ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 01/13/14 for the Period Ending 01/13/14

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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Symbol	ACOR
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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): **January 13, 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 January 13, 2014, Acorda Therapeutics, Inc. ("Company") issued a press release announcing certain financial information for the fourth fiscal quarter of 2013 as well as for the full 2013 fiscal year, including that AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg unaudited net sales for the fourth quarter of 2013 were $84 million, and that AMPYRA unaudited net sales for the full 2013 year were $302 million. These results are preliminary and subject to completion of the Company's year-end audit. The Company also announced 2014 guidance for AMPYRA net sales revenue of $328-$335 million. Guidance for 2014 research and development (R&D) expense is $60-$70 million and for 2014 sales, general and administrative (SG&A) expense is $180-$190 million. The Company also announced 2014 guidance for Zanaflex® (tizanidine hydrochloride) and ex-U.S. FAMPYRA® (prolonged-release fampridine tablets) revenue of $25 million, which includes net sales of branded Zanaflex products, royalties from ex-U.S. FAMPYRA and authorized generic tizanidine hydrochloride capsules sales, and $9.1 million in amortized licensing revenue from the $110 million payment the Company received from Biogen Idec in 2009 for FAMPYRA ex-U.S. development and commercialization rights.

The Company also announced it is providing a corporate overview today at the 32 nd Annual J.P. Morgan Healthcare Conference.

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.

This report and Exhibit 99.1 include certain forward-looking financial measures that were not prepared in accordance with accounting principles generally accepted in the United States (GAAP). 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. The Company believes these non-GAAP financial measures help indicate underlying trends in the company's business and are important in 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.

Item 8.01 Other Events

The information set forth in Item 2.02 above is incorporated by reference into this Item.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	*Description*
99.1	Press Release dated January 13, 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.

January 13, 2014

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated January 13, 2014

CONTACT:

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Acorda Therapeutics
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FOR IMMEDIATE RELEASE

Acorda Therapeutics Provides Corporate Update at 32 nd Annual J.P. Morgan Healthcare Conference

- Unaudited AMPYRA ® (dalfampridine) 2013 Fourth Quarter Net Sales of $84 Million and Unaudited 2013 Full-Year Net Sales of $302 Million
  - Approximate 13% Increase Over Full-Year 2012 Net Sales
- AMPYRA 2014 Net Sales Guidance of $328-$335 Million
- 2014 R&D Expense Guidance of $60-$70 Million and 2014 SG&A Expense Guidance of $180-$190 Million
- 2014 Zanaflex ® and ex-U.S. FAMPYRA ® Revenue Guidance of $25 Million

ARDSLEY, N.Y. – January 13, 2014 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg unaudited net sales for the fourth quarter of 2013 were $84 million, and unaudited AMPYRA 2013 full-year net sales were $302 million. These results are preliminary and subject to completion of the Company's year-end audit.

The Company provided 2014 guidance for AMPYRA net sales revenue of $328-$335 million. In prior years, AMPYRA sales have been variable between quarters, with the first quarter lower than subsequent quarters. AMPYRA has Orphan Drug Status until January 2017, and a broad patent portfolio that extends exclusivity in the United States until 2027.

The Company also provided operating expense guidance for 2014. This guidance excludes share-based compensation and costs associated with expenditures related to the potential acquisition of new products or other business development activities. Guidance for research and development (R&D) expense is $60-$70 million and sales, general and administrative (SG&A) expense is $180-$190 million. R&D expense is increasing based on advances in the Company's pipeline. In 2014, the Company expects to support at least four clinical trial programs for products in various stages of development. SG&A expense in 2014 includes commercialization expenses for Diazepam Nasal Spray.

“More than 85,000 people with multiple sclerosis have tried AMPYRA since launch, and thousands have experienced improvement in their walking. The success of this valuable contribution to the treatment of MS has also supported our investment in developing new neurological therapies. We now have five active clinical programs, including one exploring the use of AMPYRA in a new indication,” said Ron Cohen, M.D., Acorda’s President and CEO. “This year, we plan to initiate a Phase 3 trial of a once-daily formulation of dalfampridine in post-stroke deficits. We are also preparing for the potential commercial launch of Diazepam Nasal Spray, a treatment for people with epilepsy who experience cluster seizures. Our commercial success, together with a deep pipeline and strong balance sheet, are positioning Acorda for long-term growth.”

The Company also provided 2014 guidance for Zanaflex ® (tizanidine hydrochloride) and ex-U.S. FAMPYRA® (prolonged-release fampridine tablets) revenue of $25 million, which includes net sales of branded Zanaflex products, royalties from ex-U.S. FAMPYRA and authorized generic tizanidine hydrochloride capsules sales, and $9.1 million in amortized licensing revenue from the $110 million payment the Company received from Biogen Idec in 2009 for FAMPYRA ex-U.S. development and commercialization rights.

President and CEO Ron Cohen, M.D. will provide a corporate overview today at the 32 nd Annual J.P. Morgan Healthcare Conference at 11:00 a.m. Pacific Time in San Francisco. The presentation is available via webcast at www.acorda.com.

This press release includes certain forward-looking financial measures that were not prepared in accordance with accounting principles generally accepted in the United States (GAAP). 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. The Company believes these non-GAAP financial measures help indicate underlying trends in the company's business and are important in 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.

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 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.

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.

Please see accompanying full Prescribing Information and Patient Medication Guide.

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.

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