ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 01/12/15 for the Period Ending 01/12/15

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 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 January 12, 2015, Acorda Therapeutics, Inc. (the "Company") issued a press release announcing certain financial information for the fourth fiscal quarter of 2014 as well as for the full 2014 fiscal year, including that Ampyra (dalfampridine) Extended Release Tablets, 10 mg unaudited net sales for the fourth quarter of 2014 were $109 million, and that Ampyra unaudited net sales for the full 2014 year were $366 million. Final results are subject to completion of the Company's year-end audit. The Company provided 2015 guidance for Ampyra net sales of $405-$420 million.

The Company also provided 2015 operating expense guidance of $150-$160 million for research and development expenses and $180-$190 million for sales, general and administrative expenses. This guidance excludes share-based compensation and certain non-cash expenses related to the Civitas Therapeutics, Inc. acquisition.

Following the acquisition of Civitas Therapeutics, the Company announced that it was evaluating and prioritizing its clinical stage pipeline. As a result, the Company 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 (diazepam) Nasal Spray.

The Company also announced that it is providing a corporate overview today at the 33 rd 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. 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.

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 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.

January 12, 2015

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

EXHIBIT INDEX

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

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Provides Corporate Update at J.P. Morgan Healthcare Conference

- AMPYRA ® 2014 Fourth Quarter Net Sales of $109 Million; Full-Year Net Sales of $366 Million
- AMPYRA 2015 Net Sales Guidance of $405-$420 Million
- 2015 Operating Expense Guidance for R&D of $150-$160 Million and SG&A of $180-$190 Million

ARDSLEY, N.Y. – January 12, 2015 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg unaudited net sales for the fourth quarter of 2014 were $109 million, and unaudited AMPYRA 2014 full-year net sales were $366 million, an increase of approximately 21% from 2013. Final results are subject to completion of the Company's year-end audit.

"We were very pleased with AMPYRA's 2014 net sales, and our 2015 guidance of $405-$420 million reflects our confidence in the continued growth of the brand," said Ron Cohen, M.D., Acorda's President and CEO. "We believe the strength of the franchise demonstrates outstanding execution by our commercial, sales and medical education teams, and the growing acceptance of AMPYRA as a standard of care in MS."

Dr. Cohen added, "We added substantial value to our pipeline and capabilities in 2014 with the acquisition of CVT-301 and the ARCUS technology. We are now entering 2015 with two active Phase 3 programs. CVT-301 is being developed for people with Parkinson's disease who experience OFF episodes, which include impaired ability to move, muscle stiffness and tremor. Dalfampridine is being developed for people with chronic post-stroke walking deficits, which affect approximately 3.5 million people in the U.S. alone."

The Company provided 2015 operating expense guidance of $150-$160 million for R&D expense and $180-$190 million for SG&A expense. This guidance excludes share-based compensation and certain non-cash expenses related to the Civitas acquisition.

Michael Rogers, Acorda's Chief Financial Officer, said, "Our increased R&D budget for 2015 is primarily related to our two Phase 3 programs, as well as the advancement of our earlier stage clinical programs. It also includes the manufacturing plant and R&D operations of our new Chelsea, Massachusetts location. Given our increasing R&D investment needs, we are setting a high priority on managing SG&A costs in 2015. Despite the added infrastructure accompanying our acquisition of Civitas, SG&A guidance for 2015 remains the same as for 2014. We expect to remain cash flow positive in 2015."

Following the acquisition of Civitas Therapeutics, the Company announced that it was evaluating and prioritizing its clinical stage pipeline. As a result, Acorda 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™ (diazepam) Nasal Spray.

Dr. Cohen will provide a corporate overview at the 33 rd Annual J.P. Morgan Healthcare Conference today 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. 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.

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.

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