ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 01/07/13 for the Period Ending 01/07/13

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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Industry	Biotechnology & Drugs
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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): **January 7, 2013**

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 7, 2013, Acorda Therapeutics, Inc. ("Acorda") issued a press release announcing certain financial information for the fourth fiscal quarter of 2012 as well as for the full 2012 fiscal year, including that AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg unaudited net sales for the fourth quarter of 2012 were $73 million, and that AMPYRA unaudited net sales for the full 2012 year were $266 million. These results are subject to completion of Acorda's year-end audit. Acorda also announced 2013 guidance for AMPYRA net sales revenue of $285-$315 million; and for Zanaflex ® (tizanidine hydrochloride) and ex-U.S. FAMPYRA revenue of $25 million, which includes sales of branded Zanaflex products, royalties from ex-U.S. FAMPYRA and authorized generic tizanidine hyrdrochloride capsules sales, and $9.1 million in amortized licensing revenue from the $110 million payment Acorda received from Biogen Idec in 2009 for FAMPYRA ex-U.S. development and commercialization rights. Guidance for 2013 sales, general and administrative expense is $170-$180 million and for 2013 research and development expense is $60-$70 million. Based on this guidance, Acorda expects to be cash flow positive in 2013.

Acorda also announced that it is providing a corporate overview today at the 31 st 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.

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 7, 2013

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 7, 2013

By: /s/ David Lawrence
Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated January 7, 2013

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Provides Corporate Update at 31 st Annual J.P. Morgan Healthcare Conference

- Unaudited AMPYRA ® 2012 Fourth Quarter Net Sales of $73 Million and Unaudited 2012 Full-Year Net Sales of $266 Million
  - Approximate 26% Increase Over Full-Year 2011 Net Sales
- AMPYRA 2013 Net Sales Guidance of $285-$315 Million
- 2013 Zanaflex ® and ex-U.S. FAMPYRA ® Revenue Guidance of $25 Million
- 2013 SG&A Expense Guidance of $170-$180 Million and 2013 R&D Expense Guidance of $60-$70 Million

ARDSLEY, N.Y. – January 7, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg unaudited net sales for the fourth quarter of 2012 were $73 million and unaudited AMPYRA 2012 full-year net sales were $266 million. These results are subject to completion of the Company's year-end audit.

The Company provided 2013 guidance for AMPYRA net sales revenue of $285-$315 million. Guidance for Zanaflex ® (tizanidine hydrochloride) and ex-U.S. FAMPYRA revenue is $25 million, which includes 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.

Guidance for 2013 sales, general and administrative (SG&A) expense is $170-$180 million and 2013 research and development (R&D) expense is $60-$70 million. The increase in SG&A and R&D expenses in 2013 over 2012 is primarily related to research and commercialization expenses for the recently acquired product Diazepam Nasal Spray.

Based on this guidance, the Company expects to be cash flow positive in 2013.

President and CEO Ron Cohen, M.D. will provide a corporate overview, including the Company's recent acquisition of Diazepam Nasal Spray, at the 31 st 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.

"AMPYRA has made a significant contribution to the treatment of people with MS, with more than 73,000 people having tried the drug since its launch in 2010. Our marketing programs won numerous industry-wide awards and helped AMPYRA to grow in 2012. We expect continued growth in 2013. We also initiated proof-of-concept clinical studies of AMPYRA in 2012 in two additional disease states, post-stroke deficits and cerebral palsy. We expect to have results for both studies in the second quarter of this year."

Dr. Cohen continued, “In December, we acquired rights to Diazepam Nasal Spray, which adds an important, potential near-term commercial asset to our pipeline. We are currently preparing a New Drug Application that we expect to submit to the FDA later this year. In addition, we expect to have three compounds in Phase 1 or Phase 2 clinical trials in the first half of 2013 that target significant unmet needs in the areas of heart failure, multiple sclerosis and spinal cord injury. We are also continuing to focus on potential in-licensing opportunities, primarily for approved or near-commercial medicines that can leverage our exceptional specialty commercial organization and other areas of company expertise.”

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with MS, spinal cord injury and other neurological conditions.

Acorda markets AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, in the United States as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an improvement in walking speed. AMPYRA is marketed outside the United States as FAMPYRA ® (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda. AMPYRA and FAMPYRA are manufactured under license from Alkermes Pharma Ireland Limited.

The Company also markets ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity. Acorda also receives sales royalties on tizanidine hydrochloride capsules, an authorized generic version of ZANAFLEX CAPSULES distributed by Watson Pharmaceutics, Inc. under its agreement with Acorda.

Acorda has an industry-leading pipeline of novel neurological therapies. The Company is developing Diazepam Nasal Spray for treatment of certain epileptic seizures. It is also studying AMPYRA to improve a range of functional impairments caused by MS, as well as its potential for use in other neurological conditions, including cerebral palsy and post-stroke deficits. In addition, Acorda is developing clinical stage compounds AC105 for acute treatment of spinal cord injury, GGF2 for treatment of heart failure and rHIgM22, a remyelinating monoclonal antibody, for the treatment of MS. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and spinal cord injury. Chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury, is in preclinical development.

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 (“DZNS”) or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market DZNS 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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