

ACORDA THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 01/09/12 for the Period Ending 01/09/12

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
CIK	0001008848
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 9, 2012**

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.)

15 Skyline Drive, Hawthorne, NY

(Address of principal executive offices)

10532

(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 January 9, 2012, Acorda Therapeutics, Inc. (“Acorda”) issued a press release announcing certain financial information for the fourth fiscal quarter of 2011 as well as for the full 2011 fiscal year, including that AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg unaudited net sales for the fourth quarter of 2011 were \$57 million, and that AMPYRA unaudited net sales for the full 2011 year were \$210 million. Acorda also announced 2012 guidance for AMPYRA net sales of \$255-\$275 million, and combined Zanaflex® franchise and ex-U.S. FAMPYRA® royalty revenue of at least \$25 million. Guidance for 2012 sales, general and administrative expense is \$145-\$160 million and 2012 research and development expense is \$50-\$60 million. Based on this guidance, Acorda expects to be cash flow positive in 2012. Acorda also announced that it is providing a business update today at the 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated January 9, 2012

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 9, 2012

By: /s/ David Lawrence

Name: David Lawrence

Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated January 9, 2012



CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Provides 2012 Corporate Update at 30th Annual J.P. Morgan Healthcare Conference

- AMPYRA 2011 Q4 Net Sales of \$57 Million (unaudited) and 2011 Full-Year Net Sales of \$210 Million (unaudited)
- AMPYRA 2012 Net Sales Guidance of \$255-\$275 Million
- 2012 Zanaflex and ex-U.S. FAMPYRA Royalty Revenue Guidance of at Least \$25 Million
- SG&A 2012 Expense Guidance of \$145-\$160 Million and R&D 2012 Expense Guidance of \$50-\$60 Million

HAWTHORNE, N.Y. – January 9, 2012— Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg unaudited net sales for the fourth quarter of 2011 were \$57 million and unaudited AMPYRA 2011 full year net sales were \$210 million. These results are subject to completion of the Company's year-end audit.

The Company also provided 2012 guidance for AMPYRA net sales of \$255-\$275 million, and combined Zanaflex[®] franchise and ex-U.S. FAMPYRA[®] royalty revenue of at least \$25 million. Guidance for 2012 sales, general and administrative (SG&A) expense is \$145-\$160 million and 2012 research and development (R&D) expense is \$50-\$60 million. Based on this guidance, the Company expects to be cash flow positive in 2012.

President and CEO Ron Cohen, M.D. will provide a business update on AMPYRA and the Company's clinical development strategy at the 30th Annual J.P. Morgan Healthcare Conference today at 10:00 a.m. Pacific Time in San Francisco. The presentation is available via webcast at www.acorda.com.

“We are pleased by AMPYRA's revenue growth throughout 2011, and believe there is still significant opportunity to expand patient awareness of AMPYRA and drive further growth of the brand,” said Dr. Cohen. “Persistency rates for AMPYRA are very high, and the average duration of therapy across all patients who have tried AMPYRA since launch is now 12 months, reflecting the importance of bringing each new patient to therapy. We are encouraged by the positive response to the new

commercial initiatives we launched in 2011, and expect that our investments in 2012 will accrue significant value to the AMPYRA franchise over the next several years. ”

Dr. Cohen continued, “We are also exploring AMPYRA’s efficacy in a range of neurological diseases other than MS and other potential indications within MS. These are relatively small studies that can be executed quickly and cost-effectively, providing ‘go/no-go’ data that will guide further investments. We are particularly excited about the proof-of-concept study in cerebral palsy that we initiated at the end of 2011, and one in chronic stroke that we plan to begin in the second half of this year. We are also funding investigator-initiated studies exploring eight additional disease indications.”

About Acorda Therapeutics

Acorda Therapeutics is a biotechnology company developing therapies for multiple sclerosis, spinal cord injury and related nervous system disorders. The Company is commercializing and marketing AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg, in the United States. AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS); this was demonstrated by an improvement in walking speed. AMPYRA was developed using Alkermes’ Matrix Drug Absorption System (MXDAS[®]) technology and is manufactured by Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, based on a supply agreement with Acorda.

Acorda also markets ZANAFLEX CAPSULES[®] (tizanidine hydrochloride), a short-acting drug for the management of spasticity. The Company's pipeline includes a number of products in development for the treatment, regeneration and repair of the spinal cord and brain.

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 Acorda Therapeutics' ability to successfully market and sell Ampyra in the United States; third party payors (including governmental agencies) may not reimburse for the use of Ampyra 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; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of Ampyra outside of the United States and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of anticipated potential generic competition on Zanaflex Capsules revenues; failure to protect Acorda Therapeutics’ 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; the ability to obtain additional financing to support Acorda Therapeutics' operations; and, unfavorable results from our research and development programs. These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities and Exchange Commission. Acorda Therapeutics 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 Therapeutics disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

