# ACORDA THERAPEUTICS INC

## FORM 8-K
(Current report filing)

Filed 01/28/08 for the Period Ending 01/28/08

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|---|---|
| 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 28, 2008**

# 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.) |

| **15 Skyline Drive, Hawthorne, NY** | **10532** |
|---|---|
| (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 8.01 OTHER EVENTS.**

On January 28, 2008, Acorda Therapeutics, Inc. issued a press release announcing the results from a thorough QT study of Fampridine-SR. A copy of the release is attached hereto as Exhibit 99.1 and incorporated by reference into this Item.

**ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.**

(d) Exhibits

99.1 Press release dated January 28, 2008.

**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.

*By: /s/ David Lawrence*

*Name: David Lawrence, M.B.A.*
*Title: Chief Financial Officer*

Exhibit Index

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release dated January 28, 2008 |

**Exhibit 99.1**

**CONTACTS:**

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FOR IMMEDIATE RELEASE

**Acorda Therapeutics Announces Successful Thorough QT Study of Fampridine-SR**

*- Fampridine-SR Not Associated with QT Changes -*

*- Company to Host Conference Call at 8:30 am Eastern Time Today -*

HAWTHORNE, N.Y., January 28, 2008 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced results from a thorough QT study of Fampridine-SR. This study evaluated the potential to cause an increase in the electrocardiographic QT interval. Fampridine-SR, at both therapeutic and supratherapeutic doses, was found to be no different than placebo. The U.S. Food and Drug Administration requires thorough QT studies for all new drugs seeking regulatory approval, as increases in the QT interval (corrected for changes in heart rate, or QTc) may signify an increased risk of developing malignant cardiac arrhythmias.

This double-blind trial compared the electrocardiographic effects of Fampridine-SR, given at a therapeutic (10 mg twice daily) and supratherapeutic dose (30 mg twice daily), to placebo and moxifloxacin in 208 healthy subjects. Moxifloxacin is a positive control known to increase the QT interval.

T he placebo-corrected QTc mean change from baseline (using the individual correction method for heart rate, or QTci) for the therapeutic and supratherapeutic doses of Fampridine-SR were 0 and 1 milliseconds, respectively. Moxifloxacin demonstrated QT prolongation consistent with previous clinical experience. In addition to no changes in the mean QTci interval, none of the subjects in the Fampridine-SR cohort showed increases in the QTci of greater than 30 milliseconds, nor did any of the Fampridine-SR subjects display a QTci interval that exceeded 480 milliseconds at any time.

Ron Cohen, Acorda's President and Chief Executive Officer, commented, "We are delighted with the results of this QT study, and are looking forward to completing our second Phase 3 trial of Fampridine-SR in multiple sclerosis patients in the second quarter of this year."

The company will host a conference call Monday, January 28, 2008 at 8:30 a.m. Eastern Time. To participate, please dial 866-800-8652 (domestic) or 617-614-2705 (international) and reference the access code 87165145. A replay of the call will be available from 11:00 a.m. Eastern Time on January 28, 2008 until February 28, 2008. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 18388394. The archived teleconference will be available for 30 days in the Investor Relations section of the Acorda website at http://www.acorda.com.

**About Fampridine-SR**

Fampridine-SR is a sustained-release tablet formulation of the investigational drug fampridine (4-aminopyridine or 4-AP). Laboratory studies have shown that fampridine can improve the communication between damaged nerves, which may result in increased neurological function. Fampridine-SR is currently being studied in a Phase 3 clinical trial to evaluate its safety and efficacy in improving walking ability in people with multiple sclerosis (MS).

**About Acorda Therapeutics**

Acorda Therapeutics is a biotechnology company developing therapies for spinal cord injury, multiple sclerosis and related nervous system disorders. The Company's marketed products include Zanaflex Capsules ® (tizanidine hydrochloride), a short-acting drug for the management of spasticity. Acorda's lead clinical product, Fampridine-SR, is in a Phase 3 clinical trial to evaluate its safety and efficacy in improving walking ability in people with MS. 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 Zanaflex Capsules, the risk of unfavorable results from future studies of Fampridine-SR, delays in obtaining or failure to obtain FDA approval of Fampridine-SR, competition, failure to protect its intellectual property or to defend against the intellectual property claims of others, the ability to obtain additional financing to support Acorda Therapeutics' operations, and unfavorable results from its preclinical 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. 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.