ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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SIC Code	2836 - Biological Products, Except Diagnostic Substances
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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 12, 2009**

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 12, 2009, Acorda Therapeutics, Inc. (the "Registrant") issued a press release announcing that it would be providing an update on the company's business and pipeline on January 12, 2009 at the 27 th Annual JPMorgan Healthcare Conference in San Francisco, CA. In the press release, in describing those updates, the Registrant announced that it plans to submit a New Drug Application (NDA) for its drug Fampridine-SR in the U.S. in the first quarter 2009 and that regulatory approval applications for that drug are expected to be filed in Europe and Canada in 2009. The Registrant also announced that it expects to make an Investigative New Drug (IND) filing for its drug GGF2 in 2009 for a cardiac indication. It further announced that its Zanaflex® franchise commercial operations were cash-flow positive on an operating basis in 2008 and are expected to remain cash-flow positive on an operating basis in 2009. Finally, the Registrant provided an update on enrollment in its ongoing Fampridine-SR open-label extension studies.

A copy of the Registrant's press release is filed as Exhibit 99.1 hereto and incorporated by reference into this item 8.01.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated January 12, 2009

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, 2009

By: /s/ David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated January 12, 2009

Exhibit 99.1

CONTACTS:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Provides 2009 Business and Pipeline Update at 27 th Annual JPMorgan Healthcare Conference

- *Company Plans to Submit New Drug Application in U.S. in First Quarter 2009*
- *Regulatory Approval Applications for Fampridine-SR in Europe and Canada Expected in 2009*
- *IND Filing for GGF2 Expected in 2009 for Cardiac Indication*
- *Zanaflex Franchise Commercial Operations Cash-Flow Positive on an Operating Basis in 2008; Expected to Remain Cash-Flow Positive on Operating Basis in 2009*

HAWTHORNE, NY, January 12, 2009 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) President and CEO Ron Cohen, M.D. will provide an update on the Company's U.S. and European commercialization and regulatory filing strategy for its lead product, Fampridine-SR, today at the JPMorgan Healthcare conference in San Francisco, CA. In addition, Dr. Cohen will discuss timelines for advancing the Company's preclinical pipeline candidates into clinical trials and provide an update on the Zanaflex franchise.

Fampridine-SR Updates

Acorda remains on track to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the first quarter of 2009, as well as a centralized Marketing Authorization Application (MAA) with the European Medicines Agency (EMEA) later this year. Acorda also plans to submit a New Drug Submission (NDS) to Health Canada in 2009.

"In 2008 we made tremendous progress with the clinical development of Fampridine-SR and evaluating the regulatory and commercial landscape for this product in Europe. We expect to follow on that success in 2009 with the submission of regulatory filings in the US, EU and Canada. We are also beginning discussions with potential marketing partners to explore commercialization options in Europe and the rest of world excluding the U.S.," said Dr. Cohen. "Achieving these milestones will bring us closer to our goal of making Fampridine-SR available to the many people with MS who may benefit from it."

The Company has updated retention rates for the Fampridine-SR open-label extension studies. Following the conclusion of the Phase 2 and two Phase 3 trials of Fampridine-SR in MS, all study participants were eligible to enroll in extension studies and receive treatment with Fampridine-SR. In the longest-running study, 52% (92 of 177) of those who enrolled in the study are still participating after 4.2-4.8 years. In the other two studies, 69% (186 of 269) and 86% (185 of 214) remain enrolled after 2.3-3.1 years and 7-17 months, respectively.

Preclinical Pipeline Updates

Acorda plans to submit an Investigational New Drug (IND) application to the FDA by the end of 2009 for GGF2, the lead molecule in the Company's neuregulin program. GGF2 has demonstrated potential in neurologic and cardiovascular therapeutic areas, including multiple sclerosis, stroke and congestive heart failure (CHF). The Company will initially pursue a cardiac indication with a focus on CHF. Acorda may seek a partner with relevant category expertise to collaborate on the development of the neuregulins for cardiovascular indications, while retaining rights for their development in neurology indications.

An IND filing for the remyelinating antibody rHIgM22, previously projected for late 2009, will be delayed due to a bankruptcy filing by its current external manufacturing vendor.

Zanaflex Capsules Updates

Acorda has confirmed that Zanaflex Capsules ® (tizanidine hydrochloride) and Zanaflex ® (tizanidine hydrochloride) tablets commercial operations were cash flow positive in 2008 on an operating basis. The Company projects that the franchise will grow modestly and continue to be cash flow positive on an operating basis in 2009.

Corporate Earnings Schedule

Acorda announced its quarterly earnings reporting schedule for the coming year, as follows:

Period Ending	**Reporting Date**
December 2008	February 24, 2009
March 2009	May 6, 2009
June 2009	August 4, 2009
September 2009	November 3, 2009

Presentation Replay

An archived version of Dr. Cohen's presentation will be available until April 12, 2009 on the Acorda website in the Investor Relations section; to access please use the link: http://phx.corporate-ir.net/phoenix.zhtml?c=194451&p=irol-IRHome.

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. In June 2008, Acorda's lead clinical product, Fampridine-SR, completed a second 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 Statement

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 delays in obtaining or failure to obtain FDA approval of Fampridine-SR, the risk of unfavorable results from future studies of Fampridine-SR, Acorda Therapeutics' ability to successfully market and sell Fampridine-SR, if approved, and Zanaflex Capsules, 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.