

ACORDA THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 09/07/11 for the Period Ending 09/07/11

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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): **September 7, 2011**

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 8.01 Other Events

On September 7, 2011, Acorda Therapeutics, Inc. (the “Company”) issued a press release announcing that the U.S. District Court for the District of New Jersey has ruled against it in its patent litigation against Apotex Corporation and Apotex, Inc. The Court held that the claims of U.S. Patent No. 6,455,557 covering use of multiparticulate tizanidine compositions are invalid and not infringed by Apotex Corporation and Apotex, Inc. The litigation began in 2007, based on Apotex, Inc.’s submission of an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) seeking marketing approval for generic versions of three dosage strengths of ZANAFLEX CAPSULES® (tizanidine hydrochloride). The Company is evaluating its options, including a potential appeal of the decision. 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 9.01 Financial Statements and Exhibits

(d) Exhibits

| <i>Exhibit No.</i> | <i>Description</i> |
|------------------------|--|
| 99.1 | Press Release dated September 7, 2011 |

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.

September 7, 2011

**Acorda
Therapeutics, Inc.**

By: /s/ David Lawrence

Name: David

Lawrence

*Title: Chief Financial
Officer*

EXHIBIT INDEX

| <i>Exhibit No.</i> | <i>Description</i> |
|------------------------|--|
| 99.1 | Press Release dated September 7, 2011 |

**CONTACT:**

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jmacdonald@acorda.com

FOR IMMEDIATE RELEASE**Acorda Therapeutics Statement on ZANAFLEX CAPSULES[®] Patent Litigation**

HAWTHORNE, NY, September 7, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the U.S. District Court for the District of New Jersey has ruled against it in its patent litigation against Apotex Corporation and Apotex, Inc. The Court held that the claims of U.S. Patent No. 6,455,557 covering use of multiparticulate tizanidine compositions are invalid and not infringed by Apotex Corporation and Apotex, Inc. The litigation began in 2007, based on Apotex, Inc.'s submission of an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) seeking marketing approval for generic versions of three dosage strengths of ZANAFLEX CAPSULES[®] (tizanidine hydrochloride). The Company is evaluating its options, including a potential appeal of the decision.

“While we are disappointed with the ruling from the Court and will consider our options, it’s important to recall that our acquisition of the ZANAFLEX franchise in 2004 was intended to help fund the development of our commercial capabilities in the specialty neurology space,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “We not only achieved this, but were able to grow the franchise well beyond even the most optimistic expectations at the time. Thanks in part to this strategy, in 2010 we were able to launch AMPYRA[®] successfully in the U.S. Since then, the key value drivers for Acorda have been, and continue to be, growing AMPYRA, advancing our existing product pipeline and potentially acquiring additional clinical and commercial products .”

Net sales of ZANAFLEX CAPSULES[®] and ZANAFLEX[®] (tizanidine hydrochloride) tablets were \$23.3 for the first half of 2011 and \$48.5 million in 2010.

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 Elan's Matrix Drug Absorption System (MXDAS[®]) technology and is manufactured by Elan 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 and to successfully market Zanaflex Capsules; 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; 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.

