ACORDA THERAPEUTICS INC
Form 8-K
May 27, 2015

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): May 27, 2015

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 (Address of principal executive offices)	10502 (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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 May 27, 2015, Acorda Therapeutics, Inc. (the "Company") provided an update on the status of its PLUMIAZTM (diazepam) Nasal Spray program. The Company has completed discussions with the U.S. Food and Drug Administration (FDA), and is advancing the development of PLUMIAZ.

Based on interactions with the FDA, the Company plans to conduct three clinical trials prior to resubmitting the New Drug Application (NDA) for PLUMIAZ.

- The first trial, a long-term open-label study assessing safety and tolerability of PLUMIAZ over 52 weeks, was initiated in December 2014. This study will enroll approximately100 participants ages 12-65 and is expected to be completed in the second half of 2016. Details of this study are available at www.clinicaltrials.gov.
- The Company will also conduct a pharmacokinetic dose proportionality study in healthy adults; this study is expected to be initiated in the third quarter of 2015 and completed in first half of 2016.
- The third study will assess the bioavailability, safety and tolerability of PLUMIAZ compared to diazepam rectal gel (Diastat®). This open-label, randomized, crossover study will enroll approximately 120 people with refractory epilepsy ages 12-65 who experience seizure clusters. This study is expected to be initiated in the second quarter of 2015 and completed in the fourth quarter of 2016.

Pending the successful completion of these studies, the Company is planning to resubmit its NDA for PLUMIAZ in the first quarter of 2017. Based on FDA guidelines, the expected review period of the resubmitted NDA would be six months.

If approved, the Company projects peak U.S. net sales revenue of more than $200 million. Previously, the Company estimated peak sales of more than $100 million; the increase is based on the unmet need in this market and expanding the clinical trial program to include adolescents. PLUMIAZ has orphan-drug designation.

PLUMIAZ is being studied as a potential treatment for the management of selected, refractory patients with epilepsy currently on stable regimens of antiepileptic drugs (AEDs) who experience bouts of increased seizure activity. These bouts of increased seizure activity are also known as seizure clusters or acute repetitive seizures (ARS).

Forward Looking Statements

This filing 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 the ability to realize the benefits anticipated from the Civitas transaction and to successfully integrate Civitas' operations into our operations; 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 CVT-301, Plumiaz, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, Plumiaz, or any other products under development; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; 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 in connection therewith; competition; 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; and, failure to comply with regulatory requirements could result in adverse action by regulatory agencies.

These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities and 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 filing 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 filing.

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.

May 27, 2015 By: /s/ Michael Rogers
Name: Michael Rogers
Title: Chief Financial Officer