ACORDA THERAPEUTICS INC
Form 8-K
November 05, 2013

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): November 5, 2013

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 November 5, 2013, Acorda Therapeutics, Inc. (the "Company") announced that it had submitted a New Drug Application (NDA) filing for Diazepam Nasal Spray to the U.S. Food and Drug Administration (FDA). The Company expects the filing to be reviewed under the criteria established by the Prescription Drug User Fee Act (PDUFA-4), which provides for a standard 10-month review timeframe or expedited 6-month review timeframe. The Company anticipates a standard review for Diazepam Nasal Spray.

Diazepam Nasal Spray was filed under section 505(b)2 of the Food Drug and Cosmetic Act, referencing data from a therapy previously approved by the FDA (DIASTAT® Rectal Gel) and providing pharmacokinetic data comparing the reference product to Diazepam Nasal Spray. The Company is initially seeking an indication for Diazepam Nasal Spray in adults with epilepsy who experience cluster seizures, also known as acute repetitive seizures. It also plans to pursue a pediatric indication.

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.

November 5, 2013 By: /s/ Michael Rogers
Name: Michael Rogers
Title: Chief Financial Officer