ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 11/05/13 for the Period Ending 11/05/13

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): **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	**10502**
(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 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