

Edgar Filing: ACORDA THERAPEUTICS INC - Form 8-K

ACORDA THERAPEUTICS INC

Form 8-K

December 07, 2017

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): December 7, 2017

Acorda Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	000-50513	13-3831168
(State or other jurisdiction	(Commission	(I.R.S. Employer
of incorporation)	File Number)	Identification No.)
	420 Saw Mill River Road,	10502
	Ardsley, NY	
	(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (914) 347-4300

Not Applicable

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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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events

On December 7, 2017, Acorda Therapeutics, Inc. (the “Company”) issued a press release announcing the resubmission of its New Drug Application (“NDA”) for INBRIJA to the U.S. Food and Drug Administration (“FDA”). INBRIJA is an investigational treatment for symptoms of OFF periods in people with Parkinson’s disease taking a carbidopa/levodopa regimen. The resubmission addressed the two issues raised in the recent Refusal to File (“RTF”) letter and included all additional information requested by the FDA in that letter. The INBRIJA NDA is being submitted as a 505(b)(2) application. The FDA is expected to inform the Company within 74 days if the submission has been deemed complete and permits a full review. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1	<u>Press Release dated December 7, 2017</u>
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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.

December 7, 2017 By: /s/ David Lawrence

Name: David Lawrence

Title: Chief, Business Operations and Principal Accounting Officer