ACORDA THERAPEUTICS INC
Form 8-K
September 27, 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): September 27, 2017

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, | 10502 |
| | Ardsley, NY<br>(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))

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 8.01Other Events

Acorda Therapeutics, Inc. (the “Company”) announced today an update on the Refusal to File (RTF) letter that it received from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for INBRIJA™ (CVT-301, levodopa inhalation powder). The Company has engaged in a constructive dialogue with the FDA to determine the most efficient path forward to resubmitting the INBRIJA NDA. Based on these interactions, Acorda believes it can resubmit without a Type A meeting, and therefore will not request such a meeting.

The Company reiterated that the issues raised in the RTF are addressable and that the FDA has not requested or recommended additional clinical efficacy or safety studies. Acorda plans to resubmit the NDA as soon as possible.

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.

September 27, 2017 By: /s/ David Lawrence
Name: David Lawrence
Title: Chief, Business Operations and Principal Accounting Officer