ACORDA THERAPEUTICS INC
Form 8-K
August 29, 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): August 29, 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 (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

On August 29, 2017, Acorda Therapeutics, Inc. (the “Company”) issued a press release announcing that it received a Refusal to File (RTF) letter from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for INBRIJA. INBRIJA is an investigational treatment for symptoms of OFF periods in people with Parkinson’s disease taking a carbidopa/levodopa regimen. Upon its preliminary review, FDA determined that the NDA, submitted on June 26, 2017, was not sufficiently complete to permit a substantive review. FDA specified two reasons for the RTF: first, the date when the manufacturing site would be ready for inspection, and, second, a question regarding the submission of the drug master production record. FDA also requested additional information at resubmission, which was not part of the basis for the RTF. The Company will seek immediate guidance, including a Type A meeting with the FDA, to respond to the issues, which it believes are addressable, and to seek clarification of what additional information will be required. The FDA has not requested or recommended additional clinical efficacy or safety studies. 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 9.01Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1 Press Release dated August 29, 2017

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.

August 29, 2017 By:/s/ David Lawrence
Name: David Lawrence
Title: Chief, Business Operations and Principal Accounting Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated August 29, 2017