ACORDA THERAPEUTICS INC
Form 8-K
November 15, 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): November 15, 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 November 15, 2017, Acorda Therapeutics, Inc. (the “Company”) issued a press release announcing that it has increased the frequency of blood cell count monitoring for participants to weekly in its Phase 3 program of tozadenant for Parkinson’s disease. The Company took this action in response to cases of agranulocytosis, possibly drug-related, and in some cases associated with sepsis and death. Agranulocytosis is the absence of white blood cells, which fight infection. The Company also has paused new enrollment in the long-term safety studies, pending further discussion with the independent Data Safety Monitoring Board (DSMB) and the United States Food and Drug Administration (FDA). Including the previously conducted Phase 2b study, approximately 890 patients have been exposed to tozadenant and 234 have been exposed to placebo. This corresponds to approximately 300 patient years of tozadenant exposure and 75 patient-years of placebo. There have been seven cases of sepsis, all in the tozadenant groups, five of which were fatal. Four of the sepsis cases were associated with agranulocytosis, two had no white blood cell counts available at the time of the event and one had a high white blood cell count. 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 November 15, 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.

November 15, 2017 By: /s/ David Lawrence
Name: David Lawrence
Title: Chief, Business Operations and Principal Accounting Officer