

Edgar Filing: ACORDA THERAPEUTICS INC - Form 8-K

ACORDA THERAPEUTICS INC

Form 8-K

March 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): March 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, 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

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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))

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Item 8.01 Other Events

On March 29, 2017, Acorda Therapeutics, Inc. (the “Company”) issued a press release announcing results from two ongoing, long-term safety studies of CVT-301 in people with Parkinson’s that showed no differences in pulmonary function between the group receiving CVT-301 and an observational control group. These results are consistent with previously reported data from Phase 2b and Phase 3 clinical trials. The Company also announced results from separate clinical studies that assessed the safety profile of CVT-301 in people with asthma, smokers and early morning OFF. CVT-301 is an investigational, inhalable formulation of levodopa (L-dopa). It is being studied as a treatment for symptoms of OFF periods in people with Parkinson’s taking an oral carbidopa / levodopa regimen. OFF periods are characterized by the re-emergence of Parkinson’s disease symptoms. The Company plans to file a New Drug Application (NDA) in the United States by the end of the second quarter of 2017 and, pending additional data analyses, plans to file a Marketing Authorization Application (MAA) in Europe by the end of 2017. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1	<u>Press Release dated March 29, 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.

March 29, 2017 By: /s/ Jane Wasman

Name: Jane Wasman

Title: President, International and General Counsel

EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release dated March 29, 2017