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ACORDA THERAPEUTICS INC

Form 8-K

September 13, 2018

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 10, 2018

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

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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.

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Item 8.01 Other Events

On September 10, 2018, Acorda Therapeutics, Inc. (the “Company”) issued a press release announcing that the United States Court of Appeals for the Federal Circuit, by a 2-1 vote, has upheld the United States District Court for the District of Delaware’s decision to invalidate four AMPYRA patents. 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.

On September 13, 2018, the Company issued a press release announcing the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) goal date for its review of the New Drug Application (NDA) of INBRIJA™ (levodopa inhalation powder) from October 5, 2018 to January 5, 2019. This extension is related to recent submissions the Company made in response to requests from FDA for additional information on chemistry, manufacturing and controls (CMC). FDA determined that these submissions constitute a major amendment and will take additional time to review. A copy of the press release is attached as Exhibit 99.2 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

The following exhibits are filed herewith:

Exhibit Number	Description
99.1	<u>Press Release dated September 10, 2018</u>
99.2	<u>Press Release dated September 13, 2018</u>

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SIGNATURE

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 13, 2018 By: /s/ David Lawrence

Name: David Lawrence

Title: Chief, Business Operations and Principal Accounting Officer