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ACORDA THERAPEUTICS INC

Form 8-K

January 07, 2019

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): January 7, 2019

Acorda Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

|                              |                                          |                     |
|------------------------------|------------------------------------------|---------------------|
| Delaware                     | 000-50513                                | 13-3831168          |
| (State or other jurisdiction | (Commission                              | (I.R.S. Employer    |
| of incorporation)            | File Number)                             | 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.

Item 2.02 Results of Operations and Financial Condition

On January 7, 2019, Acorda Therapeutics, Inc. (“Company”) issued a press release announcing 2018 highlights, 2019 guidance, and commercialization plans for Inbrija™ (levodopa inhalation powder). Inbrija is the first and only FDA-approved inhaled levodopa for intermittent treatment of OFF episodes in people with Parkinson’s taking carbidopa/levodopa, and is expected to be available in the first quarter of 2019.

The Company announced that Ampyra® (dalfampridine) Extended Release Tablets, 10 mg unaudited net sales for 2018 are expected to be greater than \$430 million, subject to change based on discounts and allowances recorded in the fourth quarter of 2018. The Company is reiterating its 2018 non-GAAP operating expense guidance for research and development (R&D) expense of \$100-\$110 million, and sales, general and administrative (SG&A) expense of \$170-\$180 million. These are non-GAAP projections which exclude share-based compensation, as more fully described below. 2018 year-end cash and cash equivalents were approximately \$445 million (unaudited). Final results are subject to completion of the Company’s year-end audit.

During Inbrija’s 2019 launch year, the Company expects to assess key metrics such as total and new prescriptions, unique prescribers, and managed care access, and does not expect to provide Inbrija revenue projections. The Company will no longer provide revenue guidance for Ampyra, due to the unpredictable trajectory of revenue decline given the entrance of generics. R&D expenses for the full year 2019 are expected to be \$70-\$80 million and SG&A expenses for the full year 2019 are expected to be \$200-\$210 million. These are non-GAAP projections which exclude share-based compensation, as more fully described below.

The Company also announced that it is providing a corporate overview Wednesday, January 9 at the 37th Annual J.P. Morgan Healthcare Conference.

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.

This report and Exhibit 99.1 include financial measures that were not prepared in accordance with accounting principles generally accepted in the United States (GAAP). In particular, the Company has provided 2018 and 2019 expense guidance for R&D and SG&A on a non-GAAP basis. Reconciliations of these measures to the most directly comparable GAAP financial measures are not available at this time because our analysis of 2018 financial performance (including share-based compensation expense) is ongoing, and because the 2019 financial measures are forward looking in nature and the amount of compensation charges and benefits needed to reconcile these measures to the most directly comparable GAAP financial measures is dependent on future changes in the market price of our common stock. Non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, the Company believes the presentation of these non-GAAP financial measures, when viewed

in conjunction with actual GAAP results, provides investors with a more meaningful understanding of our ongoing and projected operating performance because they exclude non-cash charges that are substantially dependent on changes in the market price of our common stock. The Company believes these non-GAAP financial measures help indicate underlying trends in the Company's business and are important in comparing current results with prior period results and understanding expected operating performance. Also, management uses these non-GAAP financial measures to establish budgets and operational goals, and to manage the Company's business and to evaluate its performance.

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Item 8.01 Other Events

The information set forth in Item 2.02 above is incorporated by reference into this Item.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1 Press Release dated January 7, 2019

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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.

January 7, 2019 By: /s/ David Lawrence

Name: David Lawrence

Title: Chief, Business Operations and Principal Accounting Officer