

**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
(State or other jurisdiction
of incorporation)

000-50513
(Commission
File Number)

13-3831168
(I.R.S. Employer
Identification No.)

**420 Saw Mill River Road,
Ardsley, NY**
(Address of principal executive offices)

10502
(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 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.

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated January 7, 2019

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.

January 7, 2019

Acorda Therapeutics, Inc.

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

**CONTACT:**

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FOR IMMEDIATE RELEASE

Acorda Provides 2018 Highlights and 2019 Guidance at J.P. Morgan Healthcare Conference

- INBRIJA™ (levodopa inhalation powder) approved December 21, 2018 – first and only FDA-approved inhaled levodopa for intermittent treatment of OFF episodes in people with Parkinson’s taking carbidopa/levodopa
- INBRIJA expected to be available in Q1 2019
- AMPYRA® (dalfampridine) full year 2018 net revenue greater than \$430 million (unaudited)
- 2018 year-end cash and cash equivalents approximately \$445 million (unaudited)

ARDSLEY, N.Y. – January 7, 2019 – Acorda Therapeutics, Inc. (NASDAQ: ACOR) today provided 2018 highlights, 2019 guidance and commercialization plans for INBRIJA at the 37th Annual J.P. Morgan Healthcare Conference in San Francisco.

“The approval of INBRIJA is a major milestone for Acorda. We are eager to bring this much-needed therapy to the Parkinson’s community,” said Ron Cohen, M.D., Acorda’s President and CEO. “Acorda has one of the pre-eminent specialty neurology sales forces in the industry. Our team will immediately begin visiting key movement disorder centers to begin demonstrations and training on the appropriate use of INBRIJA. We expect INBRIJA to be available in the first quarter of 2019.”

Burkhard Blank, M.D., Acorda’s Chief Medical Officer, added, “INBRIJA represents the first FDA approval of a treatment using the ARCUS® technology, a platform that allows delivery of relatively large doses of medication through inhalation. ARCUS has the potential to be used in the development of a variety of inhaled medicines. In 2019, we will continue our development of an ARCUS-based treatment for migraine.”

2018 Financials

- 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 of R&D \$100-\$110 million and SG&A \$170-\$180 million. This guidance is a non-GAAP projection that excludes share-based compensation as more fully described below under “Non-GAAP Financial Measures.”
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- 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.

2019 Guidance

- 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. This guidance is a non-GAAP projection that excludes share-based compensation as more fully described below under "Non-GAAP Financial Measures."

Presentation/Webcast Details

Dr. Cohen will provide a corporate overview at the 37th Annual J.P. Morgan Healthcare Conference on Wednesday, January 9 at 8:00 a.m. Pacific/11:00 a.m. Eastern. The presentation is available via webcast at <https://jpmorgan.metameetings.net/events/healthcare19/sessions/23912-acorda-therapeutics-inc/webcast> or at www.acorda.com.

Non-GAAP Financial Measures

This press release includes financial measures that were not prepared in accordance with accounting principles generally accepted in the United States (GAAP). In particular, Acorda 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.

About Acorda Therapeutics

Acorda Therapeutics develops therapies to restore function and improve the lives of people with neurological disorders. INBRIJA™ (levodopa inhalation powder) is approved for intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa. INBRIJA is not to be used by patients who take or have taken a nonselective monoamine oxidase inhibitor such as phenelzine or tranylcypromine within the last two weeks. INBRIJA utilizes Acorda's innovative ARCUS® pulmonary delivery system, a technology platform designed to deliver medication through inhalation. Acorda also markets the branded AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg.

Forward-Looking Statement

This press release includes forward-looking statements. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or prospects should be considered forward-looking. These statements are subject to risks and uncertainties that could cause actual results to differ materially, including: we may not be able to successfully market Inbrija or any other products under development; risks associated with complex, regulated manufacturing processes for pharmaceuticals, which could affect whether we have sufficient commercial supply of Inbrija to meet market demand; third party payers (including governmental agencies) may not reimburse for the use of Inbrija or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; competition for Inbrija, Ampyra and other products we may develop and market in the future, including increasing competition and accompanying loss of revenues in the U.S. from generic versions of Ampyra (dalfampridine) following our loss of patent exclusivity; the ability to realize the benefits anticipated from acquisitions, among other reasons because acquired development programs are generally subject to all the risks inherent in the drug development process and our knowledge of the risks specifically relevant to acquired programs generally improves over time; we may need to raise additional funds to finance our operations and may not be able to do so on acceptable terms; the risk of unfavorable results from future studies of Inbrija (levodopa inhalation powder) or from our other research and development programs, or any other acquired or in-licensed programs ; the occurrence of adverse safety events with our products; the outcome (by judgment or settlement) and costs of legal, administrative or regulatory proceedings, investigations or inspections, including, without limitation, collective, representative or class action litigation; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; and failure to comply with regulatory requirements could result in adverse action by regulatory agencies.

These and other risks are described in greater detail in our filings with the Securities and Exchange Commission. We may not actually achieve the goals or plans described in our forward-looking statements, and investors should not place undue reliance on these statements. Forward-looking statements made in this press release are made only as of the date hereof, and we disclaim any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

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