

**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): **February 14, 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 February 14, 2019 Acorda Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2018. 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 2.02.

Item 8.01 Other Events

The Company is reporting that the Wholesale Acquisition Cost (WAC) of Inbrija will be \$950.00 per carton, each of which contains 30 doses and one inhaler device.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 14, 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.

February 14, 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 Financial and Pipeline Update for Fourth Quarter and Year End 2018

- 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 commercially available in 1Q19
- AMPYRA® (dalfampridine) 4Q18 net revenue of \$64.2 million
- 2018 year-end cash, cash equivalents and investments of \$445 million

ARDSLEY, NY – February 14, 2019 – Acorda Therapeutics, Inc. (NASDAQ: ACOR) provided financial and pipeline updates for the fourth quarter and full year ended December 31, 2018.

“Our top priority for 2019 is to ensure a successful launch of INBRIJA,” said Ron Cohen, M.D., Acorda’s President and CEO. “Our field sales and medical teams have been meeting with Movement Disorder specialists and their office staffs to educate them about INBRIJA’s clinical profile, proper use of the inhaler and our comprehensive patient support services. We are finding strong receptiveness to this novel on-demand treatment for OFF periods.”

“The approval of INBRIJA has now validated the innovative ARCUS technology, which allows relatively large doses of drug to be delivered through inhalation. We plan to apply the ARCUS platform to develop therapies for additional indications, including acute migraine, and we look forward to discussing future development milestones later this year.”

Fourth Quarter 2018 Financial Results

For the quarter ended December 31, 2018, the Company reported AMPYRA net revenue of \$64.2 million compared to \$167.2 million for the same quarter in 2017. In September 2018, AMPYRA lost its exclusivity and generics entered the market. Acorda has stated that there would be a significant decline in AMPYRA revenue as a result.

Research and development (R&D) expenses for the quarter ended December 31, 2018 were \$27.1 million, including \$1.2 million of share-based compensation compared to \$35.1 million, including \$2.2 million of share-based compensation for the same quarter in 2017.

Sales, general and administrative (SG&A) expenses for the quarter ended December 31, 2018 were \$36.8 million, including \$3.8 million of share-based compensation compared to \$39.5 million, including \$5.4 million of share-based compensation for the same quarter in 2017.

Benefit from income taxes for the quarter ended December 31, 2018 was \$63.1 million, compared to a benefit from income taxes of \$51.9 million for the same quarter in 2017.

The Company reported GAAP net income of \$9.6 million for the quarter ended December 31, 2018, or \$0.20 per diluted share. GAAP net loss in the same quarter of 2017 was \$(171.1) million, or \$(3.70) per diluted share.

Non-GAAP net income for the quarter ended December 31, 2018 was \$21.5 million, or \$0.45 per diluted share. Non-GAAP net income in the same quarter of 2017 was \$28.5 million, or \$0.61 per diluted share. This quarterly non-GAAP net income measure, more fully described below under "Non-GAAP Financial Measures," excludes share-based compensation charges, non-cash interest charges on our debt, restructuring expenses, changes in the fair value of acquired contingent consideration, asset impairment charges and gain on sale of assets. A reconciliation of the GAAP financial results to non-GAAP financial results is included with the attached financial statements.

Financial Results - Full Year Ended December 31, 2018

For the full year ended December 31, 2018, the Company reported Ampyra net revenue of \$455.1 million compared to \$543.3 million for the full year 2017. In September 2018, AMPYRA lost its exclusivity and generics entered the market. Acorda has stated that there would be a significant decline in AMPYRA revenue as a result.

Research and development (R&D) expenses for the full year ended December 31, 2018 were \$106.4 million, including \$5.6 million of share-based compensation, compared to \$166.1 million, including \$9.7 million of share-based compensation for the full year 2017.

Sales, general and administrative (SG&A) expenses for the full year ended December 31, 2018 were \$172.3 million, including \$15.7 million of share-based compensation, compared to \$181.6 million, including \$23.1 million of share-based compensation for the full year 2017.

Benefit from income taxes for the full year ended December 31, 2018 was \$13.3 million, compared to a benefit from income taxes of \$28.5 million for the full year 2017.

For the full year ended December 31, 2018, the Company reported GAAP net income of \$33.7 million, or \$0.71 per diluted share. GAAP net loss for the full year 2017 was \$(223.4) million, or \$(4.86) per diluted share.

Non-GAAP net income for the full year ended December 31, 2018 was \$103.4 million, or \$2.18 per diluted share. Non-GAAP net income for the full year ended December 31, 2017 was \$80.7 million, or \$1.75 per diluted share. This full year non-GAAP net income measure, more fully described below under "Non-GAAP Financial Measures," excludes share-based compensation charges, non-cash

interest charges on our debt, restructuring expenses, changes in the fair value of acquired contingent consideration, asset impairment charges, gain on sale of assets, realized foreign currency loss and acquisition related expenses. A reconciliation of the GAAP financial results to non-GAAP financial results is included with the attached financial statements.

At December 31, 2018, the Company had cash, cash equivalents and investments of \$445 million.

2019 Financial Guidance

- During INBRIJA's launch year, the Company does not expect to provide INBRIJA revenue guidance.
- 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."

Fourth Quarter 2018 Highlights

- **INBRIJA™ (levodopa inhalation powder)**
 - On December 21, 2018, INBRIJA was approved by the FDA for intermittent treatment of OFF episodes in people with Parkinson's taking carbidopa/levodopa. It is not known if INBRIJA is safe or effective in children.
 - The Company's Marketing Authorization Application (MAA) for INBRIJA is currently under review by the European Medicines Agency (EMA). After the adoption of a CHMP (Committee for Medicinal Products for Human Use) opinion, the Company expects a final decision from the European Commission before the end of 2019.
 - In January 2019, *The Lancet Neurology* published results from SPANSM-PD, the Phase 3 pivotal trial of INBRIJA.
- **AMPYRA (dalfampridine) Patent Appeal**
 - In January 2019, the Federal Circuit denied Acorda's petition for an en banc hearing in the AMPYRA patent appeal process. The Company intends to file a petition for certiorari appealing the case to the U.S. Supreme Court.

Webcast and Conference Call

The Company will host a conference call and webcast in conjunction with its fourth quarter/year end 2018 update and financial results today at 4:30 p.m. ET. To participate in the conference call, please dial (866) 393-4306 (domestic) or (734) 385-2616 (international) and reference the access code 2726179. The presentation will be available on the Investors section of www.acorda.com.

A replay of the call will be available from 5:30 p.m. ET on February 14, 2019 until 11:59 p.m. ET on March 16, 2019. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406

(international); reference code 2726179. The archived webcast will be available in the Investor Relations section of the Acorda website at www.acorda.com .

Non-GAAP Financial Measures

This press release includes financial results prepared in accordance with accounting principles generally accepted in the United States (GAAP), and also certain historical and forward-looking non-GAAP financial measures. In particular, Acorda has provided non-GAAP net income, adjusted to exclude the items below, and has provided 2019 guidance for R&D and SG&A expenses on a non-GAAP basis. Non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, the Company believes the presentation of non-GAAP net income, when viewed in conjunction with our GAAP results, provides investors with a more meaningful understanding of our ongoing and projected operating performance because this measure excludes (i) non-cash compensation charges and benefits that are substantially dependent on changes in the market price of our common stock, (ii) non-cash interest charges related to the accounting for our outstanding convertible debt which are in excess of the actual interest expense owing on such convertible debt, as well as non-cash interest related to the Fampyra monetization, the asset based loan which was terminated in 2017 and acquired Biotie debt, (iii) changes in the fair value of acquired contingent consideration which do not correlate to our actual cash payment obligations in the relevant periods, (iv) acquisition related expenses and related foreign currency losses that pertain to a non-recurring event, (v) expenses that pertain to non-routine restructuring events, (vi) asset impairments which are non-cash charges that relate to program terminations that are not routine to the operation of the business, and (vii) gain on sale of assets that pertains to non-routine events. The Company believes its non-GAAP net income measure helps indicate underlying trends in the Company's business and is important in comparing current results with prior period results and understanding projected operating performance. Also, management uses this non-GAAP financial measure to establish budgets and operational goals, and to manage the Company's business and to evaluate its performance.

In addition to non-GAAP net income, we have provided 2019 guidance for R&D and SG&A expenses on a non-GAAP basis. Due to the forward looking nature of this information, 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 and is not available at this time. The Company believes that these non-GAAP measures, when viewed in conjunction with our GAAP results, provide investors with a more meaningful understanding of our ongoing and projected R&D and SG&A expenses. 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 adults 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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Financial Statements

Acorda Therapeutics, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Assets		
Cash, cash equivalents and short-term investments	\$ 445,553	\$ 307,068
Trade receivable, net	23,430	81,403
Other current assets	30,110	15,726
Finished goods inventory	29,014	37,501
Property and equipment, net	60,519	36,669
Goodwill	282,059	286,611
Intangible assets, net	428,570	430,603
Other assets	411	2,388
Total assets	<u>\$ 1,299,666</u>	<u>\$ 1,197,969</u>
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other current liabilities	\$ 125,741	\$ 127,217
Current portion of deferred license revenue	—	9,057
Current portion of royalty liability	8,985	6,763
Current portion of contingent consideration	4,914	278
Current portion of loans payable	616	645
Convertible senior notes	318,670	308,805
Non-current portion of contingent consideration	163,086	112,722
Non-current portion of deferred license revenue	—	23,398
Non-current portion of royalty liability	21,731	29,025
Non-current portion of loans payable	24,470	25,670
Deferred tax liability	7,483	22,459
Other long-term liabilities	11,987	11,943
Total stockholder's equity	611,983	519,987
Total liabilities and stockholders' equity	<u>\$ 1,299,666</u>	<u>\$ 1,197,969</u>

Acorda Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Revenues:				
Net product revenues	\$ 66,351	\$ 170,044	\$ 459,739	\$ 549,749
Royalty revenues	2,801	16,090	11,694	29,481
License revenue	—	2,264	—	9,057
Total revenues	69,152	188,398	471,433	588,287
Costs and expenses:				
Cost of sales	21,476	50,240	99,310	135,080
Cost of license revenue	—	159	—	634
Research and development	27,058	35,142	106,383	166,105
Selling, general and administrative	36,819	39,518	172,254	181,299
Asset impairment	—	257,318	—	296,763
Acquisition related expenses	—	—	—	320
Change in fair value of acquired contingent consideration	33,100	24,100	55,000	40,900
Total operating expenses	118,453	406,477	432,947	821,101
Operating (loss) income	\$ (49,301)	\$ (218,079)	\$ 38,486	\$ (232,814)
Other expense, (net)	(4,166)	(4,932)	(18,063)	(19,071)
(Loss) income before income taxes	(53,467)	(223,011)	20,423	(251,885)
Benefit from income taxes	63,062	51,947	13,259	28,526
Net income (loss)	\$ 9,595	\$ (171,064)	\$ 33,682	\$ (223,359)
Net income (loss) per common share - basic	\$ 0.20	\$ (3.70)	\$ 0.72	\$ (4.86)
Net income (loss) per common share - diluted	\$ 0.20	\$ (3.70)	\$ 0.71	\$ (4.86)
Weighted average common shares - basic	47,515	46,239	47,010	45,999
Weighted average common shares - diluted	47,606	46,239	47,341	45,999

Acorda Therapeutics, Inc.
Non-GAAP Net Income and Net Income per Common Share Reconciliation
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
GAAP net income (loss)	\$ 9,595	\$ (171,064)	\$ 33,682	\$ (223,359)
Pro forma adjustments:				
Non-cash interest expense (1)	3,905	3,338	15,822	12,256
Change in fair value of acquired contingent consideration (2)	33,100	24,100	55,000	40,900
Restructuring costs (3)	(4)	22	1,316	7,647
Acquisition related expenses (4)	—	—	—	320
Realized foreign currency loss (5)	—	—	—	247
Asset impairment charge (6)	—	257,318	—	296,763
Gain on sale of assets (7)	(7,837)	(3,534)	(7,837)	(3,534)
Share-based compensation expenses included in R&D	1,224	2,154	5,560	9,683
Share-based compensation expenses included in SG&A	3,782	5,396	15,692	23,131
Total share-based compensation expenses	5,006	7,550	21,252	32,814
Total pro forma adjustments	34,170	288,794	85,553	387,413
Income tax effect of reconciling items above (8)	22,241	89,196	15,814	83,346
Non-GAAP net income	<u>\$ 21,524</u>	<u>\$ 28,534</u>	<u>\$ 103,421</u>	<u>\$ 80,708</u>
Net income per common share - basic	\$ 0.45	\$ 0.62	\$ 2.20	\$ 1.75
Net income per common share - diluted	\$ 0.45	\$ 0.61	\$ 2.18	\$ 1.75
Weighted average common shares - basic	47,515	46,239	47,010	45,999
Weighted average common shares - diluted	47,606	46,540	47,341	46,173

(1) Non-cash interest expense related to convertible senior notes, asset based loan (which was terminated in Q2 2017), Biotie non-convertible and R&D loans and Fampyra royalty monetization.

(2) Changes in fair value of acquired contingent consideration related to the Civitas transaction.

(3) Restructuring costs associated with corporate restructuring initiatives.

(4) Transaction expenses related to the Biotie acquisition.

(5) Realized foreign currency transaction loss related to the Biotie acquisition.

(6) Asset impairment charges related to Tozadenant, Selincro and SYN 120 acquired in the Biotie acquisition.

(7) Gain on the sales of Qutenza and Zanaflex assets.

(8) Represents the tax effect of the non-GAAP adjustments.