
**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): August 1, 2019

Acorda Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-31938

(Commission File Number)

13-3831168
(IRS 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 (see General Instructions A.2. below):

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock (Par Value \$0.01)	ACOR	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company 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 August 1, 2019, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 2019. 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 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 1, 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.

Acorda Therapeutics, Inc.

August 1, 2019

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 Update for Second Quarter Ended June 30, 2019

- INBRIJA™ (levodopa inhalation powder) 2Q 2019 net sales of \$3.0 million
- CHMP issues positive opinion on INBRIJA
- AMPYRA® (dalfampridine) 2Q 2019 net sales of \$44.0 million

ARDSLEY, NY – August 1, 2019 – Acorda Therapeutics, Inc. (NASDAQ: ACOR) provided a financial and pipeline update for the quarter ended June 30, 2019.

“We made significant progress on the launch of Inbrija during the second quarter. Effective May 24, 2019, Inbrija became preferred on the Express Scripts National Preferred, Basic, and High Performance commercial national formularies, and we expect to reach agreements with other key payers in the near future,” said Ron Cohen, M.D., Acorda's President and CEO. “We have also been receiving encouraging feedback on Inbrija from both people with Parkinson’s and health care professionals. This is consistent with our market research and supports our expectation that Inbrija will become a standard of care.”

Second Quarter 2019 Financial Results

For the quarter ended June 30, 2019, the Company reported INBRIJA net revenue of \$3.0 million. INBRIJA became commercially available on February 28, 2019.

For the quarter ended June 30, 2019, the Company reported AMPYRA net revenue of \$44.2 million compared to \$150.3 million for the same quarter in 2018. In September 2018, AMPYRA lost its exclusivity and generics entered the market. Consequently, the Company expects AMPYRA revenue to continue to decline.

Research and development (R&D) expenses for the quarter ended June 30, 2019 were \$19.0 million, including \$0.8 million of share-based compensation compared to \$25.9 million, including \$1.5 million of share-based compensation for the same quarter in 2018.

Sales, general and administrative (SG&A) expenses for the quarter ended June 30, 2019 were \$50.2 million, including \$3.5 million of share-based compensation compared to \$44.3 million, including \$3.7 million of share-based compensation for the same quarter in 2018.

Provision for income taxes for the quarter ended June 30, 2019 was \$0.2 million compared to a provision for income taxes of \$8.4 million for the same quarter in 2018.

The Company reported a GAAP net loss of \$27.5 million for the quarter ended June 30, 2019, or \$0.58 per diluted share. GAAP net income in the same quarter of 2018 was \$46.2 million, or \$0.98 per diluted share.

Non-GAAP net loss for the quarter ended June 30, 2019 was \$26.3 million, or \$0.55 per diluted share. Non-GAAP net income in the same quarter of 2018 was \$65.9 million, or \$1.40 per diluted share. This quarterly non-GAAP net (loss) income measure, more fully described below under “Non-GAAP Financial Measures,” excludes share-based compensation charges, non-cash interest charges on our debt, changes in the fair value of acquired contingent consideration, and restructuring costs. A reconciliation of the GAAP financial results to non-GAAP financial results is included with the attached financial statements.

At June 30, 2019, the Company had cash, cash equivalents and short-term investments of \$296.9 million. The Company has \$345 million of convertible senior notes due in 2021 with a conversion price of \$42.56.

2019 Financial Guidance

- During INBRIJA’s launch year, the Company does not expect to provide INBRIJA revenue guidance.
- The Company expects AMPYRA net revenue for the full year 2019 to be greater than \$140 million.
- 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.”

Second Quarter 2019 Highlights

- INBRIJA launch metrics through July 2019
 - ~4,500 prescription request forms (PRFs)
 - > 1,900 patients received a first dispense
 - > 6,200 total cartons dispensed
 - > 1,250 unique prescribers; ~50% repeat prescribers
 - Effective May 24, 2019, INBRIJA was made preferred on the Express Scripts National Preferred, Basic, and High Performance commercial national formularies.
 - In July, the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending INBRIJA’s approval by the European Commission (EC). The final EC decision is expected before the end of the year. Acorda is in discussions with potential partners to market INBRIJA in Europe.
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Webcast and Conference Call

The Company will host a conference call 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 2287274. The presentation will be available on the Investors section of www.acorda.com.

A replay of the call will be available from 7:30 p.m. ET on August 1, 2019 until 11:59 p.m. ET on August 31, 2019. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international); reference code 2287274. 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 (loss) 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 (loss) 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, and acquired Biotie debt, and (iii) changes in the fair value of acquired contingent consideration which do not correlate to our actual cash payment obligations in the relevant periods, and (iv) expenses that pertain to non-routine restructuring events. The Company believes its non-GAAP net (loss) 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 (loss) 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>June 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets		
Cash, cash equivalents and short-term investments	\$ 296,890	\$ 445,553
Trade receivables, net	21,010	23,430
Other current assets	12,384	30,110
Inventories, net	28,086	29,014
Property and equipment, net	113,455	60,519
Goodwill	281,467	282,059
Intangible assets, net	418,000	428,570
Right of use assets	25,876	—
Other assets	294	411
Total assets	\$ 1,197,462	\$ 1,299,666
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other current liabilities	\$ 71,318	\$ 125,741
Current portion of lease liability	7,644	—
Current portion of royalty liability	9,384	8,985
Current portion of acquired contingent consideration	4,993	4,914
Current portion of loans payable	612	616
Convertible senior notes	323,780	318,670
Non-current portion of acquired contingent consideration	157,544	163,086
Non-current portion of lease liability	25,766	—
Non-current portion of royalty liability	18,491	21,731
Non-current portion of loans payable	25,237	24,470
Deferred tax liability	3,069	7,483
Other long-term liabilities	4,787	11,987
Total stockholders' equity	544,837	611,983
Total liabilities and stockholders' equity	\$ 1,197,462	\$ 1,299,666

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Net product revenues	\$ 47,191	\$ 150,412	\$ 88,525	\$ 253,415
Royalty revenues	2,862	2,890	5,665	6,052
Total revenues	<u>50,053</u>	<u>153,302</u>	<u>94,190</u>	<u>259,467</u>
Costs and expenses:				
Cost of sales	9,397	30,378	18,196	51,012
Research and development	18,959	25,910	34,987	56,470
Selling, general and administrative	50,195	44,263	102,921	91,864
Amortization of Intangible Asset	7,691	716	10,255	1,432
Change in fair value of acquired contingent consideration	<u>(12,800)</u>	<u>(7,000)</u>	<u>(5,400)</u>	<u>(800)</u>
Total operating expenses	<u>73,442</u>	<u>94,267</u>	<u>160,959</u>	<u>199,978</u>
Operating (loss) income	<u>\$ (23,389)</u>	<u>\$ 59,035</u>	<u>\$ (66,769)</u>	<u>\$ 59,489</u>
Other expense, (net)	<u>(3,883)</u>	<u>(4,482)</u>	<u>(8,823)</u>	<u>(9,658)</u>
(Loss) income before income taxes	<u>(27,272)</u>	<u>54,553</u>	<u>(75,592)</u>	<u>49,831</u>
(Provision for) benefit from income taxes	<u>(214)</u>	<u>(8,356)</u>	<u>501</u>	<u>(11,833)</u>
Net (loss) income	<u>\$ (27,486)</u>	<u>\$ 46,197</u>	<u>\$ (75,091)</u>	<u>\$ 37,998</u>
Net (loss) income per common share - basic	\$ (0.58)	\$ 0.99	\$ (1.58)	\$ 0.82
Net (loss) income per common share - diluted	\$ (0.58)	\$ 0.98	\$ (1.58)	\$ 0.81
Weighted average common shares - basic	47,486	46,799	47,480	46,546
Weighted average common shares - diluted	47,486	47,201	47,480	46,974

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
GAAP net (loss) income	\$ (27,486)	\$ 46,197	\$ (75,091)	\$ 37,998
Pro forma adjustments:				
Non-cash interest expense (1)	3,780	3,970	8,497	7,973
Change in fair value of acquired contingent consideration (2)	(12,800)	(7,000)	(5,400)	(800)
Restructuring costs (3)	—	278	—	1,316
Share-based compensation expenses included in Cost of Sales	207	—	357	—
Share-based compensation expenses included in R&D	783	1,519	1,483	3,225
Share-based compensation expenses included in SG&A	3,544	3,725	6,361	7,887
Total share-based compensation expenses	4,534	5,244	8,201	11,112
Total pro forma adjustments	(4,486)	2,492	11,298	19,601
Income tax effect of reconciling items above (4)	(5,680)	(17,233)	(11,023)	(16,156)
Non-GAAP net (loss) income	<u>\$ (26,292)</u>	<u>\$ 65,922</u>	<u>\$ (52,770)</u>	<u>\$ 73,755</u>
Net (loss) income per common share - basic	\$ (0.55)	\$ 1.41	\$ (1.11)	\$ 1.58
Net (loss) income per common share - diluted	\$ (0.55)	\$ 1.40	\$ (1.11)	\$ 1.57
Weighted average common shares - basic	47,486	46,799	47,480	46,546
Weighted average common shares - diluted	47,486	47,201	47,480	46,974

- (1) Non-cash interest expense related to convertible senior notes, Biotie non-convertible and R&D loans and Fampyra royalty monetization.
- (2) Changes in fair value of acquired contingent consideration related to the Civitas acquisition.
- (3) Restructuring costs associated with corporate restructuring initiatives.
- (4) Represents the tax effect of the non-GAAP adjustments.