

# ACORDA THERAPEUTICS INC

## FORM 8-K

(Current report filing)

Filed 07/31/14 for the Period Ending 07/31/14

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
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**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): **July 31, 2014**

**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))
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**Item 2.02****Results of Operations and Financial Condition**

On July 31, 2014, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 2014. 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

Exhibit No.

Description

99.1

Press Release dated July 31, 2014

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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.**

*July 31, 2014*

By: /s/ Michael Rogers

*Name: Michael Rogers*

*Title: Chief Financial Officer*

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## EXHIBIT INDEX

Exhibit No.

Description

99.1 Press Release dated July 31, 2014

**CONTACT:**

Jeff Macdonald  
Acorda Therapeutics  
(914) 326-5232  
jmacdonald@acorda.com

FOR IMMEDIATE RELEASE

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**Acorda Therapeutics Reports Second Quarter 2014 Financial Results**

- AMPYRA<sup>®</sup> (dalfampridine) Second Quarter Net Revenue of \$87.4 Million
- Reiterating Full Year 2014 Guidance for AMPYRA Net Revenue of \$328-\$335 Million
- Cash, cash equivalents and investments of \$727.7 million as of June 30, 2014

ARDSLEY, N.Y. – July 31, 2014 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the second quarter ended June 30, 2014.

“AMPYRA sales in the second quarter were strong and we are reiterating our net sales guidance for the year,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “With six clinical-stage compounds currently in our pipeline, we are creating a diversified portfolio that addresses significant unmet medical needs and drives shareholder value. Our balance sheet puts us in a more competitive position to add new assets to our pipeline, and we are focusing on opportunities that have the potential to be accretive in the near and intermediate term.”

**FINANCIAL RESULTS**

The Company reported GAAP net income of \$4.7 million for the quarter ended June 30, 2014, or \$0.11 per diluted share. GAAP net income in the same quarter of 2013 was \$3.9 million, or \$0.09 per diluted share.

Non-GAAP net income for the quarter ended June 30, 2014 was \$17.7 million, or \$0.42 per diluted share. Non-GAAP net income in the same quarter of 2013 was \$14.1 million, or \$0.34 per diluted share. Non-GAAP net income excludes share based compensation charges and non-cash convertible debt and tax adjustments. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the attached financial statements.

AMPYRA<sup>®</sup> (dalfampridine) Extended Release Tablets, 10 mg - For the quarter ended June 30, 2014, the Company reported AMPYRA net revenue of \$87.4 million compared to \$77.8 million for the same quarter in 2013.

ZANAFLEX CAPSULES<sup>®</sup> (tizanidine hydrochloride), ZANAFLEX<sup>®</sup> (tizanidine hydrochloride) tablets and authorized generic capsules - For the quarter ended June 30, 2014, the Company reported combined net revenue and royalties from ZANAFLEX and tizanidine of \$4.4 million compared to \$4.8 million for the same quarter in 2013.

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FAMPYRA® (prolonged-release fampridine tablets) - For the quarter ended June 30, 2014, the Company reported FAMPYRA royalties from sales outside of the U.S. of \$2.8 million compared to \$2.2 million for the same quarter in 2013.

Research and development (R&D) expenses for the quarter ended June 30, 2014 were \$16.4 million, including \$1.6 million of share-based compensation, compared to \$13.2 million including \$1.5 million of share-based compensation for the same quarter in 2013.

Sales, general and administrative (SG&A) expenses for the quarter ended June 30, 2014 were \$50.6 million, including \$6.0 million of share-based compensation, compared to \$48.0 million including \$5.0 million of share-based compensation for the same quarter in 2013.

The Company is reiterating its 2014 R&D and SG&A expense guidance of \$60-\$70 million and \$180-\$190 million, respectively. This guidance excludes share-based compensation.

Provision for income taxes for the quarter ended June 30, 2014 was \$6.0 million, including \$0.8 million of cash taxes, compared to \$4.2 million, including \$0.6 million of cash taxes for the same quarter in 2013.

At June 30, 2014 the Company had cash, cash equivalents and short-term and long-term investments of \$727.7 million.

#### **AMPYRA UPDATE**

- The Company has received eight Paragraph IV Certification Notice Letters advising that companies have submitted Abbreviated New Drug Applications (ANDA) to the U.S. Food and Drug Administration (FDA) requesting permission to manufacture and market a generic version of AMPYRA.
- The Company has filed patent infringement suits against all ANDA filers to date, triggering a 30-month statutory stay period that restricts FDA from approving an ANDA until July 2017 at the earliest, unless a district court issues a decision adverse to all of Acorda's asserted Orange Book patents prior to that date. The 30-month stay starts from January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period. AMPYRA is currently protected by five Orange Book-listed patents, four of which extend into 2025, 2026 and 2027, respectively. Acorda will vigorously defend its intellectual property rights.

#### **PIPELINE UPDATE**

- In June, the Company announced it expects to initiate a Phase 3 clinical trial by the end of this year studying the use of dalfampridine administered twice-daily (BID) to improve walking in people who have experienced a stroke. The Company is working with external partners to develop a new once-daily (QD) formulation that could be included in future post-stroke studies.
  - Enrollment in the second portion of the Phase 1b clinical trial of rHlgM22 for remyelination in MS was completed. The study is evaluating safety, tolerability and efficacy endpoints at the two highest doses achieved in the dose escalation portion of the trial. The Company expects that data from this trial will be available in early 2015.
  - In June, Acorda co-sponsored a conference on remyelination at the New York Academy of Science (NYAS). The program featured leading experts discussing research in this area, including Acorda's clinical development program for rHlgM22.
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## **Corporate Update**

- In June, the Company completed a public offering of \$345 million principal amount of convertible senior notes, including exercise of the underwriter's over-allotment option.
- In May, the Company appointed Andrew Hindman as Chief Business Development Officer and Soon Lee as Vice President of Business Development.
- For the fourth consecutive year, the Company was named one of the Best Places to Work in New York based on an independent survey by Best Companies Group. Acorda was ranked third among large employers, defined as employing more than 250 people. The rankings are determined by feedback from employees about company culture, benefits and overall job satisfaction.

## **WEBCAST AND CONFERENCE CALL**

Ron Cohen, President and Chief Executive Officer, and Michael Rogers, Chief Financial Officer, will host a conference call today at 8:30 a.m. ET to review the Company's second quarter 2014 results.

To participate in the conference call, please dial 877-546-5020 (domestic) or 857-244-7552 (international) and reference the access code 41331388. The presentation will be available via a live webcast on the Investors section of [www.acorda.com](http://www.acorda.com).

A replay of the call will be available from 1:30 p.m. ET on July 31, 2014 until midnight on August 7, 2014. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 97847634. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at [www.acorda.com](http://www.acorda.com).

## **Important Safety Information**

Do not take AMPYRA if you:

- have ever had a seizure,
- have certain types of kidney problems, or
- are allergic to dalfampridine (4-aminopyridine), the active ingredient in AMPYRA.

Take AMPYRA exactly as prescribed by your doctor.

Before taking AMPYRA, tell your doctor if you:

- have kidney problems or any other medical conditions;
- are taking compounded 4-aminopyridine;
- are pregnant or plan to become pregnant. It is not known if AMPYRA will harm your unborn baby;
- are breast-feeding or plan to breast-feed. It is not known if AMPYRA passes into your breast milk. You and your doctor should decide if you will take AMPYRA or breast-feed. You should not do both;
- are taking any other medicines.

Stop taking AMPYRA and call your doctor right away if you have a seizure while taking AMPYRA. You could have a seizure even if you never had a seizure before. Your chance of having a seizure is higher if you take too much AMPYRA or if your kidneys have a mild decrease of function, which is common after age 50. Your doctor may do a blood test to check how well your kidneys are working before you start AMPYRA.

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AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

AMPYRA may cause serious side effects, including:

- severe allergic reactions. Stop taking AMPYRA and call your doctor right away or get emergency medical help if you have shortness of breath or trouble breathing, swelling of your throat or tongue, or hives;
- kidney or bladder infections.

The most common adverse events for AMPYRA in MS patients were urinary tract infection, trouble sleeping, dizziness, headache, nausea, weakness, back pain, and problems with balance.

Please see Patient Medication Guide for full safety information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

### **About AMPYRA (dalfampridine)**

AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed. AMPYRA, which was previously referred to as Fampridine-SR, is an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), and is known as prolonged-, modified-, or sustained-release fampridine (FAMPYRA<sup>®</sup>) in some countries outside the United States (U.S).

In laboratory studies, dalfampridine extended release tablets has been found to improve impulse conduction in nerve fibers in which the insulating layer, called myelin, has been damaged. AMPYRA is being developed and commercialized in the U.S. by Acorda Therapeutics; FAMPYRA is being developed and commercialized by Biogen Idec in markets outside the U.S. based on a licensing agreement with Acorda. AMPYRA and FAMPYRA are manufactured globally by Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, based on a supply agreement with Acorda.

AMPYRA is available by prescription in the United States. For more information about AMPYRA, including patient assistance and co-pay programs, healthcare professionals and people with MS can contact AMPYRA Patient Support Services at 888-881-1918. AMPYRA Patient Support Services is available Monday through Friday, from 8:00 a.m. to 8:00 p.m. Eastern Time.

For full U.S. Prescribing Information and Medication Guide, please visit: [www.AMPYRA.com](http://www.AMPYRA.com).

### **About Acorda Therapeutics**

Founded in 1995, Acorda Therapeutics is a biotechnology company focused on developing therapies that improve the lives of people with neurological disorders.

Acorda markets three FDA-approved therapies including: AMPYRA<sup>®</sup> (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in patients with multiple sclerosis (MS); ZANAFLEX CAPSULES<sup>®</sup> (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity; and QUTENZA<sup>®</sup> (capsaicin) 8% Patch, for the management of neuropathic pain associated with postherpetic neuralgia. AMPYRA is marketed outside the

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United States as FAMPYRA<sup>®</sup> (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda.

Acorda has one of the leading pipelines in the industry of novel neurological therapies. The Company is currently developing six clinical-stage therapies and one preclinical stage therapy that address a range of disorders including post-stroke deficits, epilepsy, stroke, peripheral nerve damage, spinal cord injury, neuropathic pain, and heart failure. For more information, please visit the Company's website at: [www.acorda.com](http://www.acorda.com).

### **Forward-Looking Statements**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 our ability to successfully market and sell Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra or from our other research and development programs, including Plumiaz (our trade name for Diazepam Nasal Spray), or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market Plumiaz or other products under development; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of generic competition on Zanaflex Capsules revenues; 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; failure to comply with regulatory requirements could result in adverse action by regulatory agencies; and the ability to obtain additional financing to support our operations. These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities & Exchange Commission. Acorda may not actually achieve the goals or plans described in its forward-looking statements, and investors should not place undue reliance on these statements. Forward-looking statements made in this release are made only as of the date hereof, and Acorda disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this release.

### **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 income, adjusted to exclude share-based compensation charges and certain non-cash debt and tax charges. These 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 our GAAP results, provide investors with a more meaningful understanding of our ongoing and projected operating performance because they exclude (i) non-cash 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 or (iii) non-cash tax expenses related to our tax accounting which do not correlate to our actual tax payment obligations. The Company believes these non-GAAP

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financial measures help indicate underlying trends in the company's business and are important in comparing current results with prior period results and understanding projected 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. A reconciliation of the historical non-GAAP financial results presented in this release to our GAAP financial results is included in the attached financial statements.

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

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
<b>Assets</b>		
Cash, cash equivalents, short-term and long-term investments	\$ 727,708	\$ 367,227
Trade receivable, net	27,027	30,784
Other current assets	18,396	17,135
Finished goods inventory	31,401	26,172
Property and equipment, net	15,823	16,525
Deferred tax asset	95,337	127,299
Intangible assets, net	17,281	17,459
Other assets	10,344	4,526
Total assets	<u>\$ 943,317</u>	<u>\$ 607,127</u>
<b>Liabilities and stockholders' equity</b>		
Accounts payable, accrued expenses and other liabilities	\$ 54,724	\$ 53,491
Deferred product revenue	29,462	32,090
Current portion of deferred license revenue	9,057	9,057
Current portion of notes payable	1,144	1,144
Current portion of revenue interest liability	225	861
Convertible senior notes	283,948	-
Other long-term liabilities	8,854	9,863
Non-current portion of revenue interest liability	425	640
Non-current portion of deferred license revenue	55,099	59,628
Stockholders' equity	500,379	440,353
Total liabilities and stockholders' equity	<u>\$ 943,317</u>	<u>\$ 607,127</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
<b>Revenues:</b>				
Net product revenues	\$ 89,719	\$ 80,125	\$ 164,182	\$ 144,209
Royalty revenues	5,146	4,664	8,937	10,180
License revenue	2,264	2,264	4,529	4,529
Total revenues	<u>97,129</u>	<u>87,053</u>	<u>177,648</u>	<u>158,918</u>
<b>Costs and expenses:</b>				
Cost of sales	18,899	16,935	34,428	30,418
Cost of license revenue	159	159	317	317
Research and development	16,448	13,216	30,970	25,736
Selling, general and administrative	50,644	48,003	97,537	96,202
Total operating expenses	<u>86,150</u>	<u>78,313</u>	<u>163,252</u>	<u>152,673</u>
Operating income	<u>\$ 10,979</u>	<u>\$ 8,740</u>	<u>\$ 14,396</u>	<u>\$ 6,245</u>
Other expense, net	(261)	(583)	(181)	(1,001)
Income before income taxes	10,718	8,157	14,215	5,244
Provision for income taxes	(6,033)	(4,247)	(8,825)	(2,472)
Net income	<u>\$ 4,685</u>	<u>\$ 3,910</u>	<u>\$ 5,390</u>	<u>\$ 2,772</u>
Net income per common share - basic	\$ 0.11	\$ 0.10	\$ 0.13	\$ 0.07
Net income per common share - diluted	\$ 0.11	\$ 0.09	\$ 0.13	\$ 0.07
Weighted average per common share - basic	41,032	39,960	40,985	39,896
Weighted average per common share - diluted	42,432	41,583	42,336	41,311

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
GAAP net income	\$ 4,685	\$ 3,910	\$ 5,390	\$ 2,772
Pro forma adjustments:				
Non-cash interest expense (1)	157	-	157	-
Non-cash taxes (2)	5,279	3,641	7,611	1,135
Share-based compensation expenses included in R&D	1,562	1,544	2,666	2,695
Share-based compensation expenses included in SG&A	6,054	4,995	10,707	8,776
Total share-based compensation expenses	7,616	6,539	13,373	11,471
Total pro forma adjustments	13,052	10,180	21,141	12,606
Non-GAAP net income	<u>\$ 17,737</u>	<u>\$ 14,090</u>	<u>\$ 26,531</u>	<u>\$ 15,378</u>
Net income per common share - basic	\$ 0.43	\$ 0.35	\$ 0.65	\$ 0.39
Net income per common share - diluted	\$ 0.42	\$ 0.34	\$ 0.63	\$ 0.37
Weighted average per common share - basic	41,032	39,960	40,985	39,896
Weighted average per common share - diluted	42,432	41,583	42,336	41,311

(1) Non-cash interest expense related to convertible senior notes.

(2) \$0.8 million and \$0.6 million paid in cash taxes in the three months ended 2014 and 2013, respectively, and \$1.2 million and \$1.3 million paid in cash taxes in the six months ended 2014 and 2013, respectively. 2013 revised to include non-cash tax adjustments to conform with current year presentation.