ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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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): **August 1, 2013**

Acorda Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-50513**	**13-3831168**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

420 Saw Mill River Road, Ardsley, NY	**10502**
(Address of principal executive offices)	(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))

Item 2.02 Results of Operations and Financial Condition

On August 1, 2013, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 2013. 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 August 1, 2013

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, 2013

By: /s/ David Lawrence
Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated August 1, 2013

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Second Quarter 2013 Financial Results

- AMPYRA ® (dalfampridine) Second Quarter Net Revenue of $77.8 Million
- Reiterating 2013 AMPYRA Net Revenue Guidance of $285-$315 Million
- Completed Acquisition of Neuropathic Pain Management Products Qutenza ® (capsaicin) 8% Patch and NP-1998

ARDSLEY, N.Y. – August 1, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the second quarter ended June 30, 2013.

“AMPYRA sales rebounded strongly in the second quarter, as expected, based on underlying product demand and a return to normal inventory levels by the end of the first quarter. Quarterly sales patterns are uneven, and we do not expect to see the same rate of quarter-over-quarter growth for the rest of the year. We are reiterating our full-year AMPYRA net revenue guidance of $285-$315 million,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “We were also pleased with our acquisition of two promising products, Qutenza and NP-1998. These will allow us to expand into the area of neuropathic pain management.”

FINANCIAL RESULTS
The Company reported GAAP net income of $3.9 million for the quarter ended June 30, 2013, or $0.09 per diluted EPS, including share-based compensation charges totaling $6.5 million. GAAP net income in the same quarter of 2012 was $4.5 million, or $0.11 per diluted EPS, including share-based compensation charges totaling $5.6 million.

Non-GAAP net income for the quarter ended June 30, 2013 was $10.4 million, or $0.25 per diluted EPS. Non-GAAP net income in the same quarter of 2012 was $10.8 million or $0.27 per diluted EPS.

AMPYRA ®(dalfampridine) Extended Release Tablets, 10 mg net revenue - For the quarter ended June 30, 2013, the Company reported AMPYRA net revenue of $77.8 million, compared to $66.3 million in net revenue for the same quarter in 2012. AMPYRA revenue is recognized following shipment of the product from the Company’s distribution facility to its network of specialty pharmacies.

ZANAFLEX CAPSULES ® (tizanidine hydrochloride), ZANAFLEX ® (tizanidine hydrochloride) tablets and authorized generic capsules net revenue and royalties - For the quarter ended June 30, 2013, the Company reported combined net revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales of $1.2 million; revenue from the sale of authorized generic tizanidine hydrochloride capsules to Actavis, Inc. totaled $1.1 million and royalties from Actavis for the sale of authorized generic tizanidine hydrochloride capsules were $2.5 million, for combined total net revenue of $4.8 million. Combined net revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales were $4.6 million for the same quarter in 2012.

ZANAFLEX revenue is recognized using a deferred revenue recognition model, meaning ZANAFLEX CAPSULES and ZANAFLEX tablets shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of ZANAFLEX CAPSULES and ZANAFLEX tablets are reported. Authorized generic product sold to Actavis is recorded as sales when shipped.

FAMPYRA ® (prolonged-release fampridine tablets) royalties - For the quarter ended June 30, 2013, the Company reported FAMPYRA royalties from sales outside of the U.S. of $2.2 million, compared to $2.5 million for the same quarter in 2012.

Cost of sales for the quarter ended June 30, 2013 were $16.9 million, compared to $13.6 million for the same quarter in 2012. Included in cost of sales for the quarter ended June 30, 2013 was $1.1 million in cost of authorized generic tizanidine hydrochloride capsules sold to Actavis.

Research and development (R&D) expenses for the quarter ended June 30, 2013 were $13.2 million, including $1.5 million of share-based compensation, compared to $12.6 million including $1.3 million of share-based compensation for the same quarter in 2012. R&D expenses for the quarter ended June 30, 2013 included AMPYRA proof-of-concept post-stroke deficits and cerebral palsy studies, and development of the Company's pipeline products, including expenses for Glial Growth Factor 2 (GGF2), rHIgM22 and Diazepam Nasal Spray.

The Company continues to expect R&D expenses for the full year 2013 to be $60-$70 million , excluding share-based compensation. This guidance is not affected by the acquisition of assets from NeurogesX, Inc., but excludes costs associated with expenditures related to the potential acquisition of new products or other business development activities.

Sales, general and administrative (SG&A) expenses for the quarter ended June 30, 2013 were $48.0 million, including $5.0 million of share-based compensation, compared to $44.2 million including $4.3 million of share-based compensation for the same quarter in 2012. The increase was primarily due to increases in expenses related to the overall growth of the organization to support AMPYRA, to support the possible commercialization of Diazepam Nasal Spray, if approved, and to support the development of our pipeline products.

The Company continues to expect SG&A expenses for the full year 2013 to be $170-$180 million , excluding share-based compensation. This guidance is not affected by the acquisition of assets from NeurogesX, Inc., but excludes costs associated with expenditures related to the potential acquisition of new products or other business development activities.

For the quarter ended June 30, 2013, the Company closed in a strong financial position with cash, cash equivalents and short-term and long-term investments of $332.4 million.

AMPYRA UPDATE

- In May, the Company presented data on the effect of AMPYRA on gait and balance in people with multiple sclerosis at the 5 th Cooperative Meeting of the Consortium of Multiple Sclerosis Centers (CMSC) and Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS).
- In May, the United States Patent and Trademark Office (USPTO) issued a patent which includes claims directed to methods of improving lower extremity function and walking and increasing walking speed in patients with MS by administering less than 15 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent is set to expire in 2025. This patent is in addition to the two AMPYRA method of use patents issued by the USPTO in 2011 and 2013 that are set to expire in 2027 and 2026, respectively.
- Since launch in March 2010, more than 80,000 people with MS have tried AMPYRA.

PIPELINE UPDATE

- The Company is planning to move forward with a Phase 2b/3 study that will assess the use of a once-daily formulation of dalfampridine (AMPYRA) as a treatment for post-stroke deficits,

primarily focusing on walking improvement. The Company plans to begin the trial in the second quarter of 2014.

- In May, data from preclinical models showing dalfampridine improves motor function in post-stroke deficits was published in the peer-reviewed journal *Stroke* .
- In June, the Company presented results of the first clinical study to assess pharmacokinetics, safety and tolerability of Diazepam Nasal Spray in people with epilepsy. Results showed that diazepam was well absorbed from the nasal cavity of people with epilepsy, had a similar pharmacokinetic profile regardless of when administered relative to the seizure episode and was well tolerated. The data were presented at the biennial International Congress of the International League Against Epilepsy (ILAE) and International Bureau for Epilepsy (IBE).
- A joint study by the Company and University of Connecticut on the impact of MS on work productivity and self-reported health assessments was published in the peer-reviewed journal PLoS ONE.

CORPORATE UPDATE

- In July, the Company completed the acquisition of two neuropathic pain management products from NeurogesX, Inc. The Company acquired rights in the United States, Canada, Latin America and certain other markets to the FDA-approved therapy Qutenza ® (capsaicin) 8% patch and Phase 3-ready product NP-1998 (formerly referred to as NGX-1998).
- For the third consecutive year, the Company was recognized as one of the Best Places to Work in New York by the Best Companies Group. This year, Acorda was ranked 2 nd among large companies, defined as employing more than 250 people. The rankings are determined by feedback from employees about company culture, benefits and overall job satisfaction.
- The Company's legal team was selected by *Corporate Counsel* magazine as one of four "Best Legal Departments 2013."
- Anthony Caggiano, M.D., Ph.D., Vice President of Research & Development, was named one of 15 Emerging Pharmaceutical Industry Leaders for 2013 by *Pharmaceutical Executive* magazine.

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 the payments associated with Neuronex in 2012. These non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, we believe 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 non-cash charges that are substantially dependent on changes in the market price of our common stock and expenses that do not arise from the ordinary course of our business. We believe 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 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.

WEBCAST AND CONFERENCE CALL

Ron Cohen, President and Chief Executive Officer, and David Lawrence, Chief Financial Officer, will host a conference call today at 8:30 a.m. ET to review the Company's second quarter 2013 results.

To participate in the conference call, please dial 866-953-6860 (domestic) or 617-399-3484 (international) and reference the access code 76844097. The presentation will be available via a live webcast on the Investor section of www.acorda.com.

A replay of the call will be available from 10:30 a.m. ET on August 1, 2013 until midnight on August 29, 2013. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and

reference the access code 84613445. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at www.acorda.com.

Important New Safety Information
Do not take AMPYRA if you are allergic to dalfampridine (4-aminopyridine), the active ingredient in AMPYRA.

Important Safety Information
Do not take AMPYRA if you have ever had a seizure, or 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.

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, if that is not known before you start taking AMPYRA.

AMPYRA may cause serious allergic reactions, including rare occurrence of anaphylaxis. 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.

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

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.

Before taking AMPYRA tell your doctor if you are pregnant or plan to become pregnant. It is not known if AMPYRA will harm your unborn baby.

Tell your doctor if you 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit 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 ®) 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.

About Acorda Therapeutics
Founded in 1995, Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with neurological conditions.

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

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 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 Diazepam Nasal Spray 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.

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

(Unaudited)

	June 30, 2013	December 31, 2012
Assets		
Cash, cash equivalents, short-term and long-term investments	$ 332,379	$ 333,188
Trade receivable, net	27,055	26,327
Other current assets	17,896	16,863
Finished goods inventory	31,690	20,957
Property and equipment, net	17,740	16,706
Deferred tax asset	134,388	136,727
Intangible assets, net	9,875	9,319
Other assets	4,883	5,245
Total assets	$ 575,906	$ 565,332
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 55,400	$ 58,261
Deferred product revenue	30,085	29,275
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	1,174	1,134
Long-term liabilities	9,339	10,415
Non-current portion of revenue interest liability	753	1,440
Non-current portion of deferred license revenue	64,156	68,685
Stockholders' equity	404,798	385,921
Total liabilities and stockholders' equity	$ 575,906	$ 565,332

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	**2012**	**2013**	**2012**
Revenues:				
Net product revenues	$ 80,125	$ 69,112	$ 144,209	$ 134,785
Royalty revenues	4,664	4,280	10,180	7,590
License revenue	2,264	2,264	4,529	4,529
Total revenues	87,053	75,656	158,918	146,904
Costs and expenses:				
Cost of sales	16,935	13,576	30,418	26,040
Cost of license revenue	159	158	317	317
Research and development	13,216	12,634	25,736	23,659
Selling, general and administrative	48,003	44,230	96,202	82,975
Total operating expenses	78,313	70,598	152,673	132,991
Operating income	$ 8,740	$ 5,058	$ 6,245	$ 13,913
Other expense, net	(583)	(233)	(1,001)	(870)
Income before income taxes	8,157	4,825	5,244	13,043
Provision for income taxes	(4,247)	(280)	(2,472)	(652)
Net income	$ 3,910	$ 4,545	$ 2,772	$ 12,391
Net income per common share - basic	$ 0.10	$ 0.12	$ 0.07	$ 0.31
Net income per common share - diluted	$ 0.09	$ 0.11	$ 0.07	$ 0.31
Weighted average per common share - basic	39,960	39,433	39,896	39,387
Weighted average per common share - diluted	41,583	40,099	41,311	40,253

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,	
	2013	**2012**	**2013**	**2012**
GAAP net income	$ 3,910	$ 4,545	$ 2,772	$ 12,391
Pro forma adjustments:				
Neuronex payments included in R&D	-	700	-	3,200
Share-based compensation expenses included in R&D	1,544	1,339	2,695	2,328
Share-based compensation expenses included in SG&A	4,995	4,254	8,776	7,456
Total share-based compensation expenses	6,539	5,593	11,471	9,784
Total pro forma adjustments	6,539	6,293	11,471	12,984
Non-GAAP net income	$ 10,449	$ 10,838	$ 14,243	$ 25,375
Net income per common share - basic	$ 0.26	$ 0.27	$ 0.36	$ 0.64
Net income per common share - diluted	$ 0.25	$ 0.27	$ 0.34	$ 0.63
Weighted average per common share - basic	39,960	39,433	39,896	39,387
Weighted average per common share - diluted	41,583	40,099	41,311	40,253