

# ACORDA THERAPEUTICS INC

## FORM 8-K (Current report filing)

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Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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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 7, 2007**

**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.)

**15 Skyline Drive, Hawthorne, NY**  
(Address of principal executive offices)

**10532**  
(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 August 7, 2007, Acorda Therapeutics, Inc. (the “registrant”) issued a press release announcing its financial results for the quarter ended June 30, 2007. 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.

The information in this Item 2.02 of Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

## Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated August 7, 2007

### 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 7, 2007*

By: /s/ David Lawrence

*Name: David Lawrence, M.B.A.*

*Title: Chief Financial Officer*

Exhibit Index

<b>Exhibit No</b>	<b>Description</b>
99.1	Press Release dated August 7, 2007

**CONTACTS:**

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FOR IMMEDIATE RELEASE

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**Acorda Therapeutics Reports Second Quarter 2007 Financial Results**

HAWTHORNE, N.Y, August 7, 2007—Acorda Therapeutics, Inc. (Nasdaq:ACOR) today announced its financial results for the second quarter 2007.

**Financial Results**

Corporate Financing — Acorda's recent secondary offering raised \$72.3 million, net of issuance costs, from the sale of approximately 4.2 million shares of the Company's common stock.

"I am gratified by the confidence shown in Acorda by the capital markets in this recent financing," said Ron Cohen, M.D., President and CEO of Acorda Therapeutics. "The proceeds will allow us to move forward aggressively with the Fampridine-SR clinical and commercialization agendas, as well as to continue to develop our pipeline of potential therapies for CNS disorders."

Zanaflex Gross Sales - For the quarter ended June 30, 2007, the Company reported gross sales of Zanaflex Capsules of \$9.4 million and gross sales of Zanaflex tablets of \$1.1 million providing combined gross sales of \$10.5 million, compared to \$3.9 million in Zanaflex Capsules and \$4.0 million in Zanaflex tablets providing combined gross sales of \$7.9 million for the same quarter in 2006. Included in the \$7.9 million of gross sales recorded in the second quarter of 2006 was \$2.2 million of recognized revenue from tablet inventory acquired from Elan by the Company as part of the 2004 Zanaflex acquisition. This inventory was shipped by the Company during the period from July 2004 through March 2005. Revenue specific to this inventory was deferred until the right of return expired, since the Company was unable to distinguish this specific product from product sold by Elan prior to July 2004. In June 2006 the right to return this product expired and the Company recognized the \$2.2 million deferred revenue as gross sales.

Zanaflex Shipments - Zanaflex Capsules shipments for the quarter ended June 30, 2007 were \$10.9 million and Zanaflex tablet shipments were \$1.2 million, providing total shipments of \$12.1 million compared to \$4.3 million of Zanaflex Capsules shipments and \$1.6 million of tablet shipments for total shipments of \$5.9 million for the same quarter in 2006.

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Discounts and allowances for the quarter ended June 30, 2007 were \$1.0 million as compared to negative \$1.5 million for the same quarter in 2006. As part of the 2004 Zanaflex acquisition, the Company agreed to accept Zanaflex tablet returns that were received subsequent to January 2005, including the return of product originally sold by Elan. As a result of this agreement, the Company recorded an estimated returns liability of \$4.1 million in December 2004. Based on the returns the Company accepted through June 30, 2006, the net balance remaining on this estimated liability was approximately \$1.8 million. The Company's obligation to accept these returns ended in June 2006 at which time the remaining estimated liability of \$1.8 million was reversed which resulted in a reduction in discounts and allowances and a corresponding reduction of the product return liability on the Company's balance sheet.

Research and development expenses for the quarter ended June 30, 2007 were \$4.0 million, including \$0.3 million of share-based compensation, compared to \$3.0 million, including \$0.1 million of share-based compensation, for the same quarter in 2006.

Sales, general and administrative expenses for the quarter ended June 30, 2007 were \$11.6 million, including \$1.6 million of share-based compensation, compared to \$7.8 million, including \$0.8 million of share-based compensation for the same quarter in 2006.

The Company reported a net loss of \$8.2 million for the quarter ended June 30, 2007, or \$0.33 per diluted common share, compared to a net loss of \$2.9 million, or \$0.15 per diluted common share, for the same quarter in 2006. The net loss in the second quarter of 2006 was favorably impacted by the \$2.2 million adjustment to gross sales and the \$1.8 million adjustment to discounts and allowances, as described above.

As of June 30, 2007, Acorda held cash, cash equivalents, and short-term investments of \$104.7 million.

### **Fampridine-SR Clinical Trials Updates**

On May 22, Acorda announced that it reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for a second Phase 3 trial of Fampridine-SR in MS, the MS-F204 study, and began enrolling study participants in June. The study is expected to enroll approximately 200 patients at 35 leading MS clinical centers in the United States and Canada.

- As of the August 3, 2007, 33 clinical centers had been initiated and were screening patients and 58 individuals were participating in the trial.
  - Data from the study is expected approximately mid-year 2008.
  - As of August 3, 2007 115 of the 177 individuals enrolled in its MS-F202 Open-Label Extension Study, or 65%, were still participating, with an average of 3.1 years in the study.
  - As of August 3, 2007, in the MS-F203 Open-Label Extension Study, 216 of the 268 individuals enrolled, or 81%, were still participating, with an average of 1.3 years in the study.
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- There are now over 800 patient-years clinical experience at the 10mg twice a day dose of Fampridine-SR.

A protocol for a Thorough QT cardiac study has been submitted to the FDA and is under discussion. Subject to the timing of the FDA's response, the Company expects to complete this study by the end of 2007.

- Acorda provided the following detail on its earlier preclinical and clinical cardiac safety studies:
  - In *in vitro* studies, Fampridine, the active component of Fampridine-SR, produced a 50% block of human ether-a-go-go related gene (hERG) channels at a concentration approximately 10,000 times higher than average peak levels measured in human blood during treatment with Fampridine-SR.
  - In isolated canine heart cells (Purkinje fibers) a 500 micromolar concentration of fampridine (approximately 1,000 times higher than average peak blood levels) increased action potential duration (a measure of partial hERG channel block and potential for QT prolongation), but a concentration approximately 100 times higher did not show such an effect.
  - Fampridine did not produce any effect on cardiac electrical parameters in dogs up to a maximum tested dose of 1.5 mg/kg, which is more than 10 times the clinical dose.
  - Routine electrocardiograms (ECGs) recorded during clinical trials in people with spinal cord injury or multiple sclerosis have shown no signal of concern, though these studies were not powered sufficiently to evaluate thoroughly all potential effects on QT interval. This will be the role of the Thorough QT study.

### **Fampridine-SR Data Presentations at Medical Meetings**

Dr. Andrew Goodman, M.D., Director of the Multiple Sclerosis Center at the University of Rochester, presented data from Acorda's MS-F203 Phase 3 clinical trial of Fampridine-SR in multiple sclerosis at the American Academy of Neurology (AAN) Meeting in Boston, MA. A separate meta-analysis comparing the data from the MS-F202 and MS-F203 trials of Fampridine-SR in MS was presented as a poster presentation at the Americas Committee on Treatment and Research in Multiple Sclerosis (ACTRIMS) Meeting in Washington, D.C.

### **Webcast and Conference Call**

Ron Cohen, M.D., President and Chief Executive Officer, Andrew Blight, Ph.D., Chief Scientific Officer and David Lawrence, Chief Financial Officer will host a webcast and conference call today at 8:30 am ET to review the Company's second quarter 2007 results.

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The live webcast and accompanying slides may be accessed on Acorda's website at <http://phx.corporate-ir.net/phoenix.zhtml?c=194451&p=irol-IRHome>. To access the call only, please dial 866-700-5192 (domestic) or 617-213-8833 (international) and provide the access code 87776505 five minutes prior to the start time.

An archived webcast of the call can also be accessed from the Company's website, at <http://www.acorda.com>, for the next 30 days. A replay of the call will be available from 10:30 a.m. Eastern Time on August 7, 2007 until 11:59 p.m. Eastern Time on September 7, 2007. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international), and provide the access code 11403273.

### **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 Acorda Therapeutics' ability to successfully market and sell Zanaflex Capsules, the risk of unfavorable results from future studies of Fampridine-SR, delays in obtaining or failure to obtain FDA approval of Fampridine-SR, competition, the ability to obtain additional financing to support Acorda Therapeutics' operations, unfavorable results from its preclinical programs, and failure to protect its intellectual property or to defend against the intellectual property claims of others. These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities and Exchange Commission. Acorda Therapeutics may not actually achieve the goals or plans described in its forward-looking statements, and investors should not place undue reliance on these statements. Acorda Therapeutics disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

### **About Acorda Therapeutics**

Acorda Therapeutics is a biotechnology company developing therapies for SCI, MS and related nervous system disorders. The Company's marketed products include Zanaflex Capsules<sup>TM</sup> (tizanidine hydrochloride), a short-acting drug for the management of spasticity. For full prescribing information, please go to [www.zanaflexcapsules.com](http://www.zanaflexcapsules.com). Acorda is currently conducting a second Phase 3 clinical trial of its lead clinical stage product, Fampridine-SR, in people with MS. The Company's pipeline includes a number of products in development for the treatment, regeneration and repair of the spinal cord and brain.

### **Interim Financial Statements**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Gross sales - Zanaflex	\$ 10,499	\$ 7,892	\$ 19,304	\$ 11,766
Less: discounts and allowances	(1,014)	1,532	(1,509)	1,336
Net sales	9,484	9,424	17,795	13,102
Grant revenue	10	179	16	301
Total net revenue	9,494	9,603	17,811	13,403
Cost of sales	(2,011)	(1,344)	(3,565)	(2,385)
Gross profit	7,484	8,259	14,246	11,018
Operating expenses:				
Research and development	4,008	3,021	7,251	6,298
Sales and marketing	7,118	4,282	14,088	8,845
General and administrative	4,476	3,560	8,830	5,838
Total operating expenses	15,602	10,863	30,169	20,981
Operating loss	\$ (8,118)	\$ (2,604)	\$ (15,923)	\$ (9,963)
Other income (expense), net	(46)	(292)	211	(331)
Cumulative effect of change in accounting principle	—	—	—	454
Net loss	(8,164)	(2,896)	(15,712)	(9,840)
Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders	—	—	—	(36,007)
Net loss	\$ (8,164)	\$ (2,896)	\$ (15,712)	\$ (45,847)
Net loss per common share - basic and diluted	\$ (0.33)	\$ (0.15)	\$ (0.65)	\$ (3.00)
Weighted average per common share - basic and diluted	24,450	19,629	24,074	15,278

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

	<u>June 30,</u> <u>2007</u>	<u>December 31,</u> <u>2006</u>
<b>Assets</b>		
Cash, cash equivalents and short-term investments	\$ 104,681	\$ 53,756
Trade and grant receivable, net	3,638	4,389
Other current assets	2,738	7,867
Finished goods inventory	5,996	6,221
Property and equipment, net	1,427	1,223
Intangible assets, net	14,723	10,178
Other assets	705	734
Total assets	<u>\$ 133,908</u>	<u>\$ 84,368</u>
<b>Liabilities and stockholders' equity</b>		
Accounts payable, accrued expenses and other liabilities	\$ 14,948	\$ 14,033
Deferred product revenue	19,035	20,441
Current liabilities	4,246	4,436
Long term notes payable	6,606	6,695
Non-current portion of revenue interest liability	18,393	20,094
Stockholders' equity	70,680	18,669
Total liabilities and stockholders' equity	<u>\$ 133,908</u>	<u>\$ 84,368</u>