ACORDA THERAPEUTICS INC Form 10-Q May 09, 2011

#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

## FORM 10-Q

Х

0

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended March 31, 2011 OR TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from to Commission File Number 000-50513

# ACORDA THERAPEUTICS, INC. (Exact name of registrant as specified in its charter)

Delaware (State of Incorporation) 13-3831168 (I.R.S. Employer Identification Number)

15 Skyline Drive Hawthorne, New York 10532 (914) 347-4300 (Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (\$232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer x Accelerated filer o Non-accelerated filer o Smaller Reporting Company o (Do not check if a

# Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-Q

smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class Common Stock, \$0.001 par value per share Outstanding at April 30, 2011 39,461,985 shares

## ACORDA THERAPEUTICS, INC. TABLE OF CONTENTS

	PART I—FINANCIAL INFORMATION	Page
Item 1.	Financial Statements	1 uge
	Consolidated Balance Sheets March 31, 2011 (unaudited) and	-
	December 31, 2010	1
	Consolidated Statements of Operations (unaudited) Three-month periods	
	ended March 31, 2011 and 2010	2
	Consolidated Statements of Cash Flows (unaudited) Three-month periods	
	ended March 31, 2011 and 2010	3
	Notes to Consolidated Financial Statements (unaudited)	4
	Management's Discussion and Analysis of Financial Condition and Result	5
<u>Item 2.</u>	of Operations	14
<u>Item 3.</u>	Quantitative and Qualitative Disclosures About Market Risk	26
<u>Item 4.</u>	Controls and Procedures	26
	<u>PART II—OTHER INFORMATIO</u> N	
<u>Item 1.</u>	Legal Proceedings	28
<u>Item 1A.</u>	Risk Factors	28
<u>Item 5</u>	Other Information	30
<u>Item 6.</u>	<u>Exhibits</u>	30

This Quarterly Report on Form 10-Q contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties, including our ability to successfully market and sell Ampyra in the U.S. and to successfully market Zanaflex Capsules, third party payers (including governmental agencies) may not reimburse for the use of Ampyra 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, the occurrence of adverse safety events with our products, delays in obtaining or failure to obtain regulatory approval of Ampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith, competition, failure to protect our intellectual property or to defend against the intellectual property claims of others, the ability to obtain additional financing to support our operations, and unfavorable results from our preclinical programs. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and investors should not place undue reliance on these statements. In addition to the risks and uncertainties described above, we have included important factors in the cautionary statements included in this report and in our Annual Report on Form 10-K for the year ended December 31, 2010, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. Forward-looking statements in this report are made only as of the date hereof, and we do not assume any obligation to publicly update any forward-looking statements as a result of developments occurring after the date of this report.

We own several registered trademarks in the U.S. and in other countries. These registered trademarks include, in the U.S., the marks "Acorda Therapeutics," our stylized Acorda Therapeutics logo, "Ampyra," "Zanaflex," and "Zanaflex Capsules." Also, our mark "Fampyra" is a registered mark in the European Community Trademark Office and we have registrations or pending applications for this mark in other jurisdictions. Our trademark portfolio also includes several registered trademarks and pending trademark applications in the U.S. and worldwide for potential product names or for disease awareness activities. Third party trademarks, trade names, and service marks used in this report are the property of their respective owners.

# PART I

## Item 1. Financial Statements

# ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

#### **Consolidated Balance Sheets**

(In thousands, except share data) Assets	March 31, 2011 (unaudited)	December 31, 2010
Current assets:		
Cash and cash equivalents	\$78,457	\$34,641
Restricted cash	302	302
Short-term investments	146,890	205,389
Trade accounts receivable, net	23,795	203,589
Prepaid expenses	7,098	6,413
Finished goods inventory held by the Company	42,595	36,232
Finished goods inventory held by others	2,200	2,186
Other current assets	4,343	3,734
Total current assets	305,680	311,169
Property and equipment, net of accumulated depreciation	3,594	3,203
Intangible assets, net of accumulated amortization	20,707	21,336
Non-current portion of deferred cost of license revenue	5,917	6,050
Other assets	309	343
Total assets	\$336,207	\$342,101
Liabilities and Stockholders' Equity	ψ550,207	ψ542,101
Current liabilities:		
Accounts payable	\$19,184	\$16,961
Accrued expenses and other current liabilities	25,774	34,122
Deferred product revenue—Zanaflex tablets	9,694	9,526
Deferred product revenue—Zanaflex Capsules	21,242	21,770
Current portion of deferred license revenue	9,057	9,429
Current portion of revenue interest liability	1,979	1,297
Current portion of convertible notes payable	1,144	1,144
Total current liabilities	88,074	94,249
Non-current portion of deferred license revenue	84,535	86,429
Put/call liability	391	391
Non-current portion of revenue interest liability	3,329	3,586
Non-current portion of convertible notes payable	5,090	6,185
Commitments and contingencies	- ,	-,
Stockholders' equity:		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at March 31,		
2011 and December 31, 2010; issued and outstanding 38,808,217 and 38,779,370		
shares as of March 31, 2011 and December 31, 2010, respectively	39	39
Treasury stock at cost (12,420 shares at March 31, 2011 and December 31, 2010)	(329)	(329)
Additional paid-in capital	595,796	591,650
Accumulated deficit	(440,758)	(440,086)

# Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-Q

Accumulated other comprehensive income	40	(13)
Total stockholders' equity	154,788	151,261
Total liabilities and stockholders' equity	\$336,207	\$342,101

See accompanying Unaudited Notes to Consolidated Financial Statements

# ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

# Consolidated Statements of Operations

# (unaudited)

(In the second case of each data)	Three-month period ended March 31, 2011	Three-month period ended March 31, 2010
(In thousands, except per share data)	2011	2010
Revenues:	¢ ( 5, 007	¢17.054
Gross product sales	\$65,207	\$17,254
Less: discounts and allowances	(6,282)	(1,864)
Net sales	58,925	15,390
License and royalty revenue	2,361	2,357
Total net revenues	61,286	17,747
Costs and expenses:		
Cost of sales	12,050	3,076
Research and development	10,708	8,062
Selling, general and administrative	38,087	26,714
Total operating expenses	60,845	37,852
Operating income (loss)	441	(20,105)
Other expense (net):		
Interest and amortization of debt discount expense	(1,136)	(1,214)
Interest income	140	204
Total other expense (net)	(996)	(1,010)
Loss before taxes	(555)	(21,115)
Provision for income taxes	(117)	
Net loss	\$(672)	\$(21,115)
Net loss per share—basic	\$(0.02)	\$(0.56)
Net loss per share—diluted	\$(0.02)	\$(0.56)
Weighted average common shares outstanding used in computing net loss per		
share—basic	38,781	38,021
Weighted average common shares outstanding used in computing net loss per		,-=-
share—diluted	38,781	38,021

See accompanying Unaudited Notes to Consolidated Financial Statements

# ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

# (unaudited)

(In thousands)	Three-month period ended March 31, 2011	Three-month period ended March 31, 2010
Cash flows from operating activities:		
Net loss	\$(672)	\$(21,115)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Share-based compensation expense	3,755	3,186
Amortization of net premiums and discounts on short-term investments	1,863	1,219
Amortization of revenue interest issuance cost	36	30
Depreciation and amortization expense	1,139	838
Changes in assets and liabilities:		
Increase in accounts receivable	(1,523)	(2,205)
Increase in prepaid expenses and other current assets	(1,294)	(2,291)
Increase in inventory held by the Company	(6,363)	(16,808)
(Increase) decrease in inventory held by others	(14)	88
Decrease in non-current portion of deferred cost of license revenue	133	165
(Decrease) increase in accounts payable, accrued expenses, other current liabilities	(7,216)	15,605
Increase in revenue interest liability interest payable	659	615
Decrease in current portion of deferred license revenue	(371)	
Decrease in non-current portion of deferred license revenue	(1,893)	(2,357)
Increase (decrease) in deferred product revenue-Zanaflex tablets	168	(457)
Decrease in deferred product revenue—Zanaflex Capsules	(529)	(540)
Net cash used in operating activities	(12,122)	(24,027)
Cash flows from investing activities:		
Purchases of property and equipment	(743)	(456)
Purchases of intangible assets	(164)	(6,612)
Purchases of short-term investments	(42,812)	(31,113)
Proceeds from maturities of short-term investments	99,500	96,750
Net cash provided by investing activities	55,781	58,569
Cash flows from financing activities:		
Proceeds from issuance of common stock and option exercises	392	4,108
Repayments of revenue interest liability	(235)	(232)
Net cash provided by financing activities	157	3,876
Net increase in cash and cash equivalents	43,816	38,418
Cash and cash equivalents at beginning of period	34,641	47,314
Cash and cash equivalents at end of period	\$78,457	\$85,732
Supplemental disclosure:		
Cash paid for interest	429	541

See accompanying Unaudited Notes to Consolidated Financial Statements

#### Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-Q

#### table of contents

### ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

#### Notes to Consolidated Financial Statements

#### (unaudited)

(1) Organization and Business Activities

Acorda Therapeutics, Inc. ("Acorda" or the "Company") is a commercial stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis (MS), spinal cord injury (SCI) and other disorders of the central nervous system (CNS).

The management of the Company is responsible for the accompanying unaudited interim consolidated financial statements and the related information included in the notes to the consolidated financial statements. In the opinion of management, the unaudited interim consolidate