

Acorda Provides Financial and Pipeline Update for Third Quarter 2016

10/27/2016

- AMPYRA® (dalfampridine) 3Q 2016 Net Revenue of \$128.8 Million; 10% Increase over 3Q 2015 Net Revenue of \$117.0 Million
- Data for Dalfampridine in Post-Stroke Walking Difficulties by Year End 2016 and Phase 3 data for CVT-301 for OFF Periods in Parkinson's Disease in Q1 2017

ARDSLEY, N.Y.--(BUSINESS WIRE)-- Acorda Therapeutics, Inc. (Nasdaq: **ACOR**) provided a financial and pipeline update for the third quarter ended September 30, 2016.

"Over the next 12 months, we expect multiple, potentially transformative clinical and corporate milestones," said Ron Cohen, M.D. "By year end we plan to announce topline data from our dalfampridine post-stroke walking difficulties and QD formulation studies and, in the first quarter of 2017, data from our Phase 3 CVT-301 program. Our clinical programs for tozadenant in Parkinson's disease and CVT-427 in acute migraine are also progressing well. Regarding our defense of AMPYRA patents, we are preparing to file our post-trial brief and continuing to defend our patents vigorously."

Financial Results

The Company reported a GAAP net loss attributable to Acorda of \$(12.7) million for the quarter ended September 30, 2016, or \$(0.28) per diluted share. GAAP net income in the same quarter of 2015 was \$3.9 million, or \$0.09 per diluted share.

Non-GAAP net loss for the quarter ended September 30, 2016 was \$(1.9) million, or \$(0.04) per diluted share. Non-GAAP net income in the same quarter of 2015 was \$3.3 million, or \$0.08 per diluted share. Non-GAAP net income (loss) excludes share based compensation charges, non-cash interest expense, expenses associated with changes in

the fair value of acquired contingent consideration, foreign currency gains, acquisition-related costs, and the impact of a change in accounting policy for ZANAFLEX revenue recognition. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the attached financial statements.

AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg - For the quarter ended September 30, 2016, the Company reported AMPYRA net revenue of \$128.8 million compared to \$117.0 million for the same quarter in 2015.

The Company is reiterating 2016 AMPYRA net sales guidance of \$475-\$485 million.

ZANAFLEX CAPSULES® (tizanidine hydrochloride), ZANAFLEX® (tizanidine hydrochloride) tablets and authorized generic capsules - For the quarter ended September 30, 2016, the Company reported combined net revenue and royalties from ZANAFLEX and tizanidine of \$0.5 million compared to \$26.0 million for the same quarter in 2015. Net revenue for Zanaflex for the quarter ended September 30, 2015 includes the impact of a one-time net adjustment of \$22.2 million, representing the cumulative impact of the Company's conversion from the sell-through to the sell-in method of revenue recognition.

FAMPYRA® (prolonged-release fampridine tablets) - For the quarter ended September 30, 2016, the Company reported FAMPYRA royalties from sales outside of the U.S. of \$2.6 million compared to \$2.5 million for the same quarter in 2015.

Research and development (R&D) expenses for the quarter ended September 30, 2016 were \$54.8 million, including \$2.9 million of share-based compensation, compared to \$43.4 million, including \$2.3 million of share-based compensation, for the same quarter in 2015. R&D expenses increased due to investment in our late-stage programs, as well as the addition of Biotie R&D expenses.

The Company is reiterating 2016 R&D guidance of \$195-\$205 million. This guidance is a non-GAAP projection which excludes share-based compensation, as more fully described below under "Non-GAAP Financial Measures."

Sales, general and administrative (SG&A) expenses for the quarter ended September 30, 2016 were \$54.4 million, including \$7.1 million of share-based compensation, compared to \$51.1 million, including \$6.7 million of share-based compensation, for the same quarter in 2015. SG&A expenses exclude transaction expenses related to the Biotie acquisition and include Biotie expenses for the quarter ended September 30, 2016.

The Company is reiterating 2016 SG&A guidance of \$195-\$205 million. This guidance is a non-GAAP projection which excludes share-based compensation for the Company and transaction expenses related to the Biotie acquisition, as more fully described below under "Non-GAAP Financial Measures."

Provision for income taxes for the quarter ended September 30, 2016 was \$3.0 million compared to a provision for income taxes of \$17.8 million for the same quarter in 2015.

At September 30, 2016, the Company had cash, cash equivalents and investments of \$127.9 million.

Third Quarter 2016 Highlights

- AMPYRA® (dalfampridine)
 - AMPYRA revenue for the third quarter of 2016 was \$128.8 million, up 10% from the third quarter of 2015. This represents the 14th consecutive quarter of double-digit, year-over-year growth for AMPYRA, which was launched in 2010.
 - A District Court trial for the Company's litigation against four generic companies seeking ANDA approvals concluded in September 2016. Post-trial briefing by the parties is expected to be completed in November.
- Dalfampridine in Post-Stroke Walking Difficulties (PSWD)
 - The Company expects to announce topline data from an unblinded analysis of the twice-daily (BID) clinical trial in the fourth quarter of 2016. Results from multi-dose testing of a once-daily (QD) formulation of dalfampridine will be disclosed concurrently.
- CVT-301 in Parkinson's Disease
 - The Company expects last patient out (LPO) in the Phase 3 CVT-301 efficacy and safety study by the end of 2016.
 - Topline data from the Phase 3 efficacy and safety study is expected in the first quarter of 2017.
- CVT-427 in Migraine
 - Upon successful completion of its ongoing Phase 1 special population studies, the Company is planning to begin a Phase 2 study in the first half of 2017.
- Corporate
 - On September 30, Acorda acquired the remaining approximately 3% of Biotie's fully diluted capital stock pursuant to Finnish redemption proceedings, and with 100% of the shares, completed the acquisition of Biotie. Under Finnish law, the purchase price for the 3% of the shares will be determined in accordance with the redemption proceedings.
 - In October, Michael Rogers, CFO, left the Company. David Lawrence, Chief of Business Operations, has assumed the role of Chief, Business Operations and Principal Accounting Officer. Andrew Hindman, Chief Business Development Officer, has assumed responsibility for Financial Planning and Analysis and Investor Relations.

Webcast and Conference Call

The Company will host a conference call today at 8:30 a.m. ET to review its third quarter 2016 results.

To participate in the conference call, dial (855) 542-4209 (domestic) or (412) 455-6054 (international) and reference the access code 83356384. The presentation will be available on the Investors section of www.acorda.com. A replay of the call will be available from 11:30 a.m. ET on October 27, 2016 until 11:59 p.m. ET on November 3, 2016. To access the replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and reference the access code 83356384.

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 disorders.

Acorda has an pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease, post-stroke walking difficulties, migraine, and multiple sclerosis. Acorda markets three FDA-approved therapies, including AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg.

For more information, please visit the Company's website at: www.acorda.com.

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: the ability to realize the benefits anticipated from the Biotie and Civitas transactions, 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; the ability to successfully integrate Biotie's operations and Civitas' operations, respectively, into our operations; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; our ability to successfully market and sell Ampyra (dalfampridine) Extended Release Tablets, 10 mg 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 CVT-301 or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, any other products under development, or the products that we acquired with the Biotie transaction; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain and maintain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaborator Biogen in connection therewith; competition; 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 presentation 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 presentation.

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 income, adjusted to exclude the items below, and has provided 2016 guidance for R&D and SG&A 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 income when viewed in conjunction with our GAAP results, provide investors with a more meaningful understanding of our ongoing and projected operating performance because this measure excludes (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 as well as non-cash interest charges related to our asset based loan and acquired Biotie debt, (iii) changes in the fair value of acquired contingent consideration which do not correlate to our actual cash payment obligations in the relevant period, (iv) realized foreign currency transaction gain (v) acquisition related expenses that pertain to a non-recurring event, and (vi) the impact of a one-time change in accounting policy for Zanaflex revenue recognition due to a one-time, non-recurring event. The Company believes its non-GAAP net 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 income, we have provided 2016 guidance for R&D and SG&A 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 range of SG&A expenditures for 2016 also excludes expenses related to the acquisition of Biotie because of the extraordinary nature of these expenses. The Company believes that this non-GAAP measure provides investors with a more meaningful understanding of our ongoing and projected SG&A expenses.

A reconciliation of the historical non-GAAP financial results presented in this release to our GAAP financial results (but not the 2016 guidance for R&D and SG&A) is included in the attached financial statements.

Financial Statements

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

	September 30, <u>2016</u>	December 31, <u>2015</u>
Assets		
Cash, cash equivalents, short-term and long-term investments	\$ 127,940	\$ 353,305
Trade receivable, net	48,575	31,466
Other current assets	20,502	30,070
Finished goods inventory	40,935	36,476
Deferred tax asset	2,951	2,128
Property and equipment, net	35,777	40,204
Goodwill	284,029	183,636
Intangible assets, net	749,415	430,856
Other assets	8,244	3,153
Total assets	<u>\$ 1,318,368</u>	<u>\$ 1,111,294</u>
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other current liabilities	\$ 107,931	\$ 80,391
Current portion of deferred license revenue	9,057	9,057
Current portion of notes payable	1,134	1,144
Convertible senior notes	297,111	290,420
Contingent consideration	75,400	63,500
Non-current portion of deferred license revenue	34,720	41,513
Deferred tax liability	91,429	12,146
Other long-term liabilities	34,820	10,098
Total stockholder's equity	<u>666,766</u>	<u>603,025</u>
Total liabilities and stockholders' equity	<u>\$ 1,318,368</u>	<u>\$ 1,111,294</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Net product revenues	\$ 128,508	\$ 141,330	\$ 359,350	\$ 342,394
Royalty revenues	4,841	4,605	12,831	12,571
License revenue	2,264	2,264	6,793	6,793
Total revenues	<u>135,613</u>	<u>148,199</u>	<u>378,974</u>	<u>361,758</u>
Costs and expenses:				
Cost of sales	27,644	24,741	77,265	65,896
Cost of license revenue	159	159	476	476
Research and development	54,777	43,356	149,640	105,221
Selling, general and administrative	54,366	51,056	159,203	152,645
Acquisition related expenses	439	-	17,185	-
Change in fair value of acquired contingent consideration	3,700	3,200	11,900	7,400
Total operating expenses	<u>141,085</u>	<u>122,512</u>	<u>415,669</u>	<u>331,638</u>
Operating (loss) income	<u>\$ (5,472)</u>	<u>\$ 25,687</u>	<u>\$ (36,695)</u>	<u>\$ 30,120</u>
Other (expense) income, net	<u>(4,537)</u>	<u>(3,976)</u>	<u>(3,500)</u>	<u>(11,406)</u>
(Loss) income before income taxes	<u>(10,009)</u>	<u>21,711</u>	<u>(40,195)</u>	<u>18,714</u>
(Provision for) benefit from income taxes	<u>(3,023)</u>	<u>(17,770)</u>	<u>7,686</u>	<u>(16,861)</u>
Net (loss) income	<u>\$ (13,032)</u>	<u>\$ 3,941</u>	<u>\$ (32,509)</u>	<u>\$ 1,853</u>
Net loss attributable to noncontrolling interest	<u>307</u>	<u>-</u>	<u>985</u>	<u>-</u>
Net (loss) income attributable to Acorda Therapeutics, Inc.	<u><u>\$ (12,725)</u></u>	<u><u>\$ 3,941</u></u>	<u><u>\$ (31,524)</u></u>	<u><u>\$ 1,853</u></u>
Net (loss) income per common share - basic	\$ (0.28)	\$ 0.09	\$ (0.70)	\$ 0.04
Net (loss) income per common share - diluted	\$ (0.28)	\$ 0.09	\$ (0.70)	\$ 0.04
Weighted average per common share - basic	45,378	42,174	45,178	42,097
Weighted average per common share - diluted	45,378	43,432	45,178	43,434

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
GAAP net (loss) income	\$ (13,032)	\$ 3,941	\$ (32,509)	\$ 1,853
Pro forma adjustments:				
Non-cash interest expense (1)	2,514	2,153	7,078	6,383
Change in fair value of acquired contingent consideration (2)	3,700	3,200	11,900	7,400
Acquisition related expenses (3)	439	-	17,185	-
Realized foreign currency gain (4)	-	-	(7,738)	-
Change in revenue recognition - Zanaflex Capsules & tablets (5)	-	(21,633)	-	(21,633)
Share-based compensation expenses included in R&D	2,925	2,250	7,648	6,231
Share-based compensation expenses included in SG&A	7,051	6,664	19,744	18,517
Total share-based compensation expenses	9,976	8,914	27,392	24,748
Total pro forma adjustments	16,629	(7,366)	55,817	16,898
Income tax effect of reconciling items above (6)	(5,464)	6,761	(15,379)	(204)
Non-GAAP net (loss) income (7)	<u>\$ (1,867)</u>	<u>\$ 3,336</u>	<u>\$ 7,929</u>	<u>\$ 18,547</u>
Net (loss) income per common share - basic	\$ (0.04)	\$ 0.08	\$ 0.18	\$ 0.44
Net (loss) income per common share - diluted	\$ (0.04)	\$ 0.08	\$ 0.17	\$ 0.43
Weighted average per common share - basic	45,378	42,174	45,178	42,097
Weighted average per common share - diluted	45,378	43,432	45,983	43,434

- (1) Non-cash interest expense related to convertible senior notes, asset based loan, and Biotie debt.
(2) Changes in fair value of acquired contingent consideration related to Civitas transaction.
(3) Transaction expenses related to the Biotie acquisition.
(4) Realized foreign currency gain related to the Biotie acquisition.
(5) Change from "sell-through" (deferred) revenue recognition to "sell-in" (traditional) revenue recognition.
(6) Represents the tax effect of the non-GAAP adjustments.
(7) Prior to the quarter ended September 30, 2016, non-GAAP adjustments included a separate income tax expense adjustment from GAAP tax expense to the amount of cash taxes paid or payable for the respective period. As of September 30, 2016, the presentation includes the tax effect of the non-GAAP adjustments as prescribed by the updated Compliance and Disclosure Interpretations issued by the SEC in May, 2016. In the three months ended September 30, 2016 and 2015, cash taxes paid were \$1.0M and \$0.8M, respectively. In the nine months ended September 30, 2016 and 2015, cash taxes paid were \$3.6M and \$2.1M, respectively. A reconciliation to the previously reported non-GAAP results is presented below.

	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2015
Non-GAAP net income - as revised (see above)	\$ 3,336	\$ 18,547
Income tax effect of the reconciling items (see above)	(6,761)	204
Non-cash income taxes (as previously reported)	16,941	14,709
Non-GAAP net income (as previously reported)	<u>\$ 13,516</u>	<u>\$ 33,460</u>

Note: Non-GAAP net income per share basic and diluted as presented above were also revised as a result of the changes to the income tax effect of the non-GAAP adjustments as noted above.

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Source: Acorda Therapeutics, Inc.

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