

Acura Pharmaceuticals Announces Second Quarter 2016 Financial Results

PALATINE, IL -- (Marketwired) -- 08/08/16 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, announced today financial results for the three and six months ended June 30, 2016.

The Company reported a net loss of \$3.3 million for the second quarter of 2016 or \$0.28 per diluted share, compared to net loss of \$2.7 million or \$0.27 per diluted share for the same period in 2015. Revenues for the quarter were \$257 thousand compared to \$341 thousand in the second quarter of 2015.

Research and development expenses were \$1.4 million in the second quarter of 2016, compared to \$0.5 million for the same period in 2015. Research and development expenses were primarily associated with product candidates utilizing the Company's LIMITX™, and IMPEDE® Technologies. Selling, marketing, general and administrative expenses were \$1.8 million in the second quarter of 2016, versus \$2.1 million in the same period last year. Selling and marketing expenses primarily consist of advertising and marketing activities for NEXAFED® and NEXAFED® SINUS.

The Company reported a net loss of \$6.7 million for the six months ended June 30, 2016 or \$0.56 per diluted share, compared to net loss of \$1.4 million or \$0.15 per diluted share for the same period in 2015. Revenues for the six months ended June 30, 2016 were \$0.5 million compared to \$5.7 million in the same period last year. The 2015 results reflect the \$5.0 million payment arising from licensing OXAYDO™ (oxycodone HCI) tablets to Egalet Corporation entities.

Research and development expenses were \$2.4 million in the six months ended June 30, 2016, compared to \$1.5 million for the same period in 2015. Research and development expenses were primarily associated with product candidates utilizing the Company's LIMITXTM, and IMPEDE® Technologies. Selling, marketing, general and administrative expenses were \$4.1 million in the six months ended June 30, 2016, versus \$4.4 million in the same period last year. Selling and marketing expenses primarily consisted of advertising and marketing activities for NEXAFED® and NEXAFED® SINUS.

At August 5, 2016, our unrestricted cash (after deduction of our term loan compensating balance requirement of \$2.5 million), cash equivalents and marketable securities was approximately \$3.4 million, and our outstanding term loan balance with Oxford Finance LLC was \$6.6 million.

Conference Call Information

Acura Pharmaceuticals, Inc. will host a conference call on Tuesday, August 9, 2016 at 8:30 a.m. EDT to discuss the results.

To participate in the live conference call, please dial (888) 240-9345 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 3124614. A digital replay of the call will be available for 30 days following the call by dialing (888) 203-1112 (U.S. and Canada). The replay participant code is 3124614.

About Acura Pharmaceuticals

Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of product candidates intended to address medication abuse and misuse, utilizing its proprietary LIMITXTM, AVERSION® and IMPEDE® Technologies.

- LIMITX contains ingredients that are intended to reduce or limit the rate or extent of opioid release when multiple tablets are ingested.
- AVERSION contains polymers that cause the drug to gel when dissolved; it also contains compounds that irritate the nasal passages if the product is snorted.
- IMPEDE is directed at minimizing the extraction and conversion of pseudoephedrine into methamphetamine.

OXAYDO® (oxycodone HCl immediate-release tablets) which incorporates the AVERSION Technology, is FDA approved and marketed in the U.S. by our partner Egalet Corporation.

Acura markets NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products that utilize the IMPEDE Technology.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to:

- our ability to fund or obtain funding for our continuing operations, including the development of our products utilizing our Limitx[™] and Impede® technologies;
- the expected results of clinical studies relating to LTX-04, the date by which such study results will be available and whether LTX-04 will ultimately receive FDA approval;
- whether LIMITX will retard the release of opioid active ingredients as dose levels increase;
- whether we will be able to reformulate LTX-04 to provide an efficacious level of drug when one or two tablets are taken;
- whether we will be able to reformulate LTX-04 to improve its abuse deterrent performance;
- whether the extent to which products formulated with the Limitx technology deter abuse will be determined sufficient by the FDA to support approval or labeling describing abuse deterrent features;
- whether our LIMITX technology can be expanded into extended-release formulations;
- our and our licensee's ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;
- the pricing and price discounting that may be offered by Egalet for Oxaydo;
- whether we can successfully develop a product under our agreement with Bayer;
- the results of our development of our Limitx technology;
- our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- the market acceptance of, timing of commercial launch and competitive environment for any of our products;
- the willingness of pharmacies to stock our Nexafed products;
- expectations regarding potential market share for our products;
- our ability to develop and enter into additional license agreements for our product candidates using our technologies;
- our exposure to product liability and other lawsuits in connection with the commercialization of our products;
- the increasing cost of insurance and the availability of product liability insurance coverage;
- the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
- the ability of our patents to protect our products from generic competition and our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation;
- the ability to fulfill the FDA requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development process to meet over-the-counter ("OTC") Monograph standards, as applicable;
- the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates;
- changes in regulatory requirements;
- adverse safety findings relating to our commercialized products or product candidates in development;
- whether the FDA will agree with our analysis of our clinical and laboratory studies;
- whether further studies of our product candidates will be required to support FDA approval;
- whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and will be able to promote the features of our abuse discouraging technologies; and
- whether Oxaydo or our Aversion® and Limitx product candidates will ultimately deter abuse in commercial settings and whether our Nexafed products and Impede technology product candidates will disrupt the processing of pseudoephedrine into methamphetamine.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "indicates," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in our filings with the Securities and Exchange Commission. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Accordingly, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

ACURA PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	(unaudited) June 30, 2016	(audited) December 31, 2015	
Current assets	\$ 7,678	\$ 14,135	
Property, plant and equipment, net	1,009	1,013	
Other assets	1,535	1,813	
Total assets	\$ 10,222	\$ 16,961	
Other current liabilities	\$ 1,314	\$ 924	
Debt, current	2,629	2,320	
Debt, non-current portion - net of discount of \$142 and \$193, and debt			
issuance costs of \$70 and \$97	4,165	5,430	
Accrued interest, non-current portion	477	387	
Stockholders' equity	1,637	7,900	
Total liabilities and stockholders' equity	\$ 10,222	\$ 16,961	

ACURA PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited; in thousands, except per share amounts)

	(unaudited) Three Months Ended June 30,		(unaudited) Six months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
License fee revenue	\$ -	\$250	\$ -	\$ 5,250
Collaboration revenue	133	-	233	-
Royalty revenue	30	-	47	-
Product sales, net	94	91	201	448_
Total revenues, net	257	341	481	5,698
Cost and expenses:				
Cost of sales (excluding inventory write-downs)	99	98	201	422
Inventory write-downs	26	47	26	307
Research and development	1,403	511	2,417	1,475
Selling, marketing, general and administrative	1,808	2,083	4,054	4,380
Total costs and expenses	3,336	2,739	6,698	6,584
Operating loss	(3,079)	(2,398)	(6,217)	(886)
Non-operating income (expense):				
Investment income	21	36	48	71
Interest expense	(233)	(301)	(482)	(609)
Other income (expense)	3	-	(21)	
Total other expense, net	(209)	(265)	(455)	(538)
Loss before provision for income taxes	(3,288)	(2,663)	(6,672)	(1,424)
Provision for income taxes	· -	· -	· -	` -
Net loss	\$ (3,288)	\$ (2,663)	\$ (6,672)	\$ (1,424)
Other comprehensive income (loss):		,	, , , , , , , , , , , , , , , , , , , ,	
Unrealized gains (losses) on securities	21	(31)	91	-
Comprehensive loss	\$ (3,267)	\$ (2,694)	\$ (6,581)	\$ (1,424)
Loss per share of common stock:				
Basic	\$ (0.28)	\$ (0.27)	\$ (0.56)	\$ (0.15)
Diluted	\$ (0.28)	\$ (0.27) \$ (0.27)	\$ (0.56) \$ (0.56)	\$ (0.15) \$ (0.15)
Weighted average common shares outstanding:	ψ (0.20)	Ψ (U.∠1)	ψ (0.30)	Ψ (0.13)
Basic	11,858	9,847	11,847	9,820
Diluted	11,858	9,847	11,847	9,820
Diluteu	11,000	3,041	11,041	9,020

Contact:

for Acura Investor Relations Email contact

(847) 705-7709

Renmark Financial Communications Inc.
Robert Thaemlitz
Email contact

(416) 644-2020 or (514) 939-3989 www.renmarkfinancial.com

Source: Acura Pharmaceuticals, Inc.

News Provided by Acquire Media