

Acura Pharmaceuticals Announces Fourth Quarter and Full Year 2015 Financial Results

PALATINE, IL -- (Marketwired) -- 02/29/16 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, announced today financial results for the year and three months ended December 31, 2015.

The Company reported a net loss of \$5.0 million or \$0.46 per diluted share for 2015 compared to a net loss of \$13.2 million or \$1.35 per diluted share for 2014. For the fourth quarter ended December 31, 2015 the Company reported a net loss of \$0.9 million or \$0.08 per diluted share, compared to net loss of \$2.7 million or \$0.30 per diluted share for the same period in 2014.

For the twelve months ended December 31, 2015, the Company recorded \$5.0 million and \$2.5 million in license fee revenue and milestone revenue, respectively, derived from the January 7, 2015 Collaboration and License Agreement with Egalet Corporation, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize OXAYDO®. We recorded \$0.2 million in collaboration revenue, some of which arises from the June 15, 2015 License and Development Agreement with Bayer Healthcare pursuant to which we granted Bayer an exclusive worldwide license to our IMPEDE® Technology for use in an undisclosed methamphetamine resistant pseudoephedrine -- containing product and providing for the joint development of such product using our IMPEDE® Technology for the U.S. market. We also recorded other license fee revenue of \$0.25 million and \$0.7 million in NEXAFED® product line net sales as compared with \$0.5 million in license fee revenue and \$0.2 million in NEXAFED® product line net sales in the same period in 2014.

Research and development expenses associated with product candidates utilizing the Company's LIMITX[™], AVERSION® and IMPEDE® Technologies were \$2.6 million in the twelve months ended December 31, 2015, compared to \$4.6 million in the same period in 2014, although much of the expense associated with LIMITX was offset by a grant by the National Institute on Drug Abuse of the National Institutes of Health. These expenses were \$0.7 million in the fourth quarter 2015, compared to \$0.9 million for the same period in 2014.

Selling, marketing, general and administrative expenses were \$9.0 million in the twelve months ended December 31, 2015, versus \$7.9 million in the same period last year. These expenses were \$2.6 million in the fourth quarter 2015, versus \$2.0 million in the same period last year. The increases in these expenses in 2015 were primarily associated with additional NEXAFED selling and marketing expenses as well as certain patent litigation costs.

At December 31, 2015, the Company had cash, cash equivalents and marketable securities totaling \$13.3 million and \$8.0 million in term debt financing (excluding debt discount and debt issuance costs).

Conference Call Information

Acura Pharmaceuticals, Inc. will host a conference call on Tuesday, March 1, 2016 at 8:30 a.m. ET to discuss the results.

To participate in the live conference call, please dial 888-430-8694 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 7143401. A replay of the call will be available beginning March 2, 2016 and ending on March 22, 2016 on the company's website, and by dialing 888-203-1112 (U.S. and Canada). The replay participant code is 7143401.

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 LIMITX[™], 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 designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

In June 2011, the U.S. Food and Drug Administration approved OXAYDO (oxycodone HCl immediate-release tablets) which incorporates the AVERSION technology. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet Corporation pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize OXAYDO. Acura markets NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products that utilize the

IMPEDE Technology.

Forward-Looking Statements

Certain statements in this Report 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;
- 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," "estimates," "indicates", "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.

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

	(audited) December 31, 2015	(audited) December 31, 2014		
Current assets	\$ 14,135 \$	13,231		
Property, plant and equipment, net	1,013	957		
Other assets	1,813	1,845		
Total assets	\$ 16,961 \$	16,033		

Accounts payable and other current liabilities Current deferred revenue Current maturities of long-term debt	\$ 924 \$ - 2,320	881 353 1,758
Long-term debt, net of discount of \$193 and \$281, and debt issuance costs of		
\$97 and \$162	5,430	7,799
Long-term portion of accrued interest	387	190
Stockholders' equity	7,900	5,052
Total liabilities and stockholders' equity	\$ 16,961 \$	16,033

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

		(audited) Twelve Months Ended December 31, 2015 2014				(unaudited) Three Months Ended December 31, 2015 2014		
Revenues:								
License fee revenue	\$	5,250	\$	500	\$	-	\$	500
Milestone revenue		2,500		-		2,500		-
Collaboration revenue		170		-		75		-
Royalty revenue		5		4		5		-
Product sales, net		662		247		99		29
Total revenues, net		8,587		751		2,679	\$	529
Operating expenses:		,						
Cost of sales (excluding inventory write-down)		656		227		102		39
Inventory write-down (write-up)		330		201		(4)		-
Research and development		2,608		4,582		701		908
Selling, marketing, general and administrative		8,994		7,940		2,590		2,037
Total operating expenses		12,588		12,950		3,389		2,984
Operating loss		(4,001)		(12,199)		(710)		(2,455)
Non-operating income (expense):		. ,		. ,		. ,		. ,
Investment income		166		198		56		55
Interest expense		(1,157)		(1,212)		(265)		(305)
Other income		3		4		3		9
Total other expense, net		(988)		(1,010)		(206)		(241)
Loss before income taxes		(4,989)		(13,209)		(916)		(2,696)
Provision for income taxes		-		-		-		
Net loss	\$	(4,989)	\$	(13,209)	\$	(916)	\$	(2,696)
Other comprehensive income (loss):								
Unrealized losses on marketable securities		(52)		(32)		(54)		(38)
Total other comprehensive loss		(52)		(32)		(54)		(38)
Comprehensive loss	\$	(5,041)	\$	(13,241)	\$	(970)	\$	(2,734)
Loss per share:								
Basic	\$	(0.46)	\$	(1.35)	\$	(0.08)	\$	(0.30)
Diluted	у \$	(0.46)	\$	(1.35)	φ \$	(0.08)		(0.30)
Weighted average shares outstanding:	Ψ	(0.+0)	_Ψ	(1.55)	Ψ	(0.00)	_Ψ	(0.00)
Basic		10,796		9,779		11,836		9,792
Diluted		10,796		9,779		11,836		9,792
Dilatoa		10,100		5,115		11,000		0,102

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