March 2, 2015

Acura Pharmaceuticals Announces Fourth Quarter and Full Year 2014 Financial Results

PALATINE, IL -- (Marketwired) -- 03/02/15 --

Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, announced today financial results for the year and three months ended December 31, 2014.

The Company reported a net loss of $2.7 million for the fourth quarter 2014 or $0.06 per diluted share, compared to net loss of $3.4 million or $0.07 per diluted share for the same period in 2013.

Research and development expenses associated with product candidates utilizing the Company's AVERSION® and IMPEDE® Technologies were $0.9 million in the fourth quarter 2014, compared to $0.8 million for the same period in 2013. Selling, marketing, general and administrative expenses were $2.0 million in the fourth quarter 2014, versus $2.8 million in the same period last year. Selling and marketing expenses for the three months ended December 31, 2014 were primarily for advertising and marketing activities for NEXAFED®.

For the twelve months ended December 31, 2014, Acura recorded $0.5 million in license fee revenue and $0.2 million in net product sales from NEXAFED as compared with $0.1 million in net product sales from NEXAFED in the same period in 2013. In the fourth quarter of 2014, the Company shipped $0.2 million of NEXAFED but has recognized only a portion of those shipments to customers until the right of return no longer exists or adequate history and information becomes available to estimate product returns. At December 31, 2014, the Company has deferred the recognition of $0.4 million in NEXAFED revenue and $0.2 million in related cost of sales.

Research and development expenses were $4.6 million in the twelve months ended December 31, 2014, compared to $4.9 million in the same period in 2013. Selling, marketing, general and administrative expenses were $7.9 million in the twelve months ended December 31, 2014, versus $8.9 million in the same period last year. The Company reported a net loss of $13.2 million or $0.27 per diluted share, for the twelve months ending December 31, 2014, compared to a net loss of $13.9 million or $0.29 per diluted share for the same period in 2013. At December 31, 2014 the Company had cash, cash equivalents and marketable securities totaling $12.1 million and $10.0 million in term debt financing (excluding debt discount).

Conference Call Information

Acura Pharmaceuticals, Inc. will host a conference call on Tuesday, March 3, 2015 at 8:30 a.m. ET to discuss the results.

To participate in the live conference call, please dial 888-468-2440 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 7932939.

A replay of the call will be available beginning March 4, 2015 at 11:30 a.m. ET and ending on March 24, 2015 on the company's website, and by dialing 888-203-1112 (U.S. and Canada). The replay participant code is 7932939.

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 US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize OXAYDO. The Company has a development pipeline of additional AVERSION Technology products containing other opioids.

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 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;
- the results of our development of our LIMITX technology;
- our ability to fund, or obtain funding for, products developed utilizing our AVERSION, IMPEDE and LIMITX technologies;
- the results of our meetings or discussions with the U.S. Food and Drug Administration ("FDA"), or any appeals of prior FDA determinations, relating to our AVERSION hydrocodone/acetaminophen product;
- whether the results of studies AP-ADF-302, AP-ADF-303, and AP-ADF-304 relating to our AVERSION hydrocodone/acetaminophen product will be acceptable to the FDA;
- whether we will conduct an additional intranasal abuse liability study on our AVERSION hydrocodone/acetaminophen product and, if conducted, whether the results of such study will support the filing of a New Drug Application and/or a claim of intranasal abuse deterrence;
- our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- the market acceptance of and competitive environment for any of our products;
- the willingness of wholesalers and pharmacies to stock our NEXAFED products;
- expectations regarding potential market share for our products and the timing of first sales;
- our ability to enter into additional license agreements for our AVERSION Technology product candidates;
- 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 filings with the Securities and Exchange Commission.

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

	(audited) December 31, 2014	(audited) December 31, 2013
Current assets	$ 13,231	$ 27,453
Property, plant and equipment, net	957	941

Other assets	2,007	236
Total assets	$ 16,195	$ 28,630
Current liabilities	$ 881	$ 820
Current deferred revenue	353	287
Current maturities of long-term debt	1,758	-
Long-term debt, net of discount of $281 and $400	7,961	9,600
Long-term portion of accrued interest	190	-
Stockholders' equity	5,052	17,923
Total liabilities and stockholders' equity	$ 16,195	$ 28,630

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

	(audited) Twelve Months Ended December 31,		(unaudited) Three Months Ended December 31,	
	2014	2013	2014	2013
Revenues:				
Royalty revenue	$ 4	$ 10	$ -	$ 2
Product sales, net	247	113	29	33
License fee revenue	500	-	500	-
Total revenues, net	751	123	529	35
Operating expenses:				
Cost of sales (excluding write-down)	227	114	39	36
Inventory write-down (write-up)	201	250	-	(111)
Research and development	4,582	4,923	908	803
Selling, marketing, general and administrative	7,940	8,926	2,037	2,788
Total operating expenses	12,950	14,213	2,984	3,516
Operating loss	(12,199)	(14,090)	(2,455)	(3,481)
Non-operating income (expense):				
Investment income	198	194	55	58
Gain on sales of marketable securities	4	4	9	15
Interest expense	(1,212)	(9)	(305)	(9)
Total other income (expense), net	(1,010)	189	(241)	64
Loss before income taxes	(13,209)	(13,901)	(2,696)	(3,417)
Provision for income taxes	-	-	-	-
Net loss	$ (13,209)	$ (13,901)	$ (2,696)	$ (3,417)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities	(32)	59	(38)	24
Total other comprehensive income (loss)	(32)	59	(38)	24
Comprehensive loss	$ (13,241)	$ (13,842)	$ (2,734)	$ (3,393)
Loss per share:				
Basic	$ (0.27)	$ (0.29)	$ (0.06)	$ (0.07)
Diluted	$ (0.27)	$ (0.29)	$ (0.06)	$ (0.07)
Weighted average shares outstanding:				
Basic	48,893	47,764	48,958	49,152
Diluted	48,893	47,764	48,958	49,152

Contact:

for Acura Investor Relations
Email contact847-705-7709

for Acura Media Relations
Email contact847-705-7709

Source: Acura Pharmaceuticals, Inc.