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Acura Pharmaceuticals Announces Third Quarter 2015 Financial Results

PALATINE, IL -- (Marketwired) -- 11/04/15 --

Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, announced today financial results for the three and nine months ended September 30, 2015.

The Company reported a net loss of $2.6 million for the third quarter of 2015 or $0.23 per diluted share, compared to net loss of $2.9 million or $0.30 per diluted share for the same period in 2014. Revenues for the quarter were $210 thousand compared to $145 thousand in the third quarter of 2014.

Research and development expenses associated with product candidates utilizing the Company's LIMITX™, and IMPEDE® Technologies were $0.4 million in the third quarter of 2015, compared to $1.0 million for the same period in 2014. Selling, marketing, general and administrative expenses were $2.0 million in the third quarter of 2015, versus $1.7 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 $4.1 million for the nine months ended September 30, 2015 or $0.39 per diluted share, compared to net loss of $10.5 million or $1.08 per diluted share for the same period in 2014. Revenues for the nine months ended September 30, 2015 were $5.9 million compared to $222 thousand 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 (NASDAQ: EGLT) entities.

Research and development expenses associated with product candidates utilizing the Company's LIMITX™, and IMPEDE® Technologies were $1.9 million in the nine months ended September 30, 2015, compared to $3.7 million for the same period in 2014 for the Company's LIMITX™, AVERSION® and IMPEDE® Technologies. Selling, marketing, general and administrative expenses were $6.4 million in the nine months ended September 30, 2015, versus $5.9 million in the same period last year. Selling and marketing expenses primarily consisted of advertising and marketing activities for NEXAFED® and NEXAFED® SINUS.

In October 2015, the Company received a $2.5 million milestone payment from Egalet Corporation triggered by the first commercial shipments of OXAYDO™. As of October 30, 2015, our unrestricted cash, cash equivalents and marketable securities, less our compensating balance requirement of $2.5 million, was approximately $14.0 million, and our outstanding loan balance with Oxford Finance LLC was $8.6 million.

In August 2015, the Company effected a 1-for-5 reverse stock split of its common stock. All share amounts and per share data (other than the par value and number of authorized shares) in this earnings release and the accompanying condensed consolidated financial statements have, where applicable, been adjusted retroactively to reflect this reverse stock split. As a result of the reverse stock split, the Company regained compliance with the minimum bid price requirement for continued listing on the NASDAQ Capital Market in September 2015.

Conference Call Information
Acura Pharmaceuticals, Inc. will host a conference call on Thursday, November 5, 2015 at 8:30 a.m. ET to discuss the results.

To participate in the live conference call, please dial 888-572-7034 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 402784. A replay of the call will be available beginning November 6, 2015 and ending on November 26, 2015 on the company's website, and by dialing 888-203-1112 (U.S. and Canada). The replay participant code is 402784.

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.

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 AVERSION®, IMPEDE® and LIMITX™ 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 IMPEDE license agreement with a multi-national pharmaceutical company;
- 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 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 AVERSION technology 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 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.

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

	(unaudited) September 30, 2015	(audited) December 31, 2014
Current assets	$16,034	$13,231
Property, plant and equipment, net	1,042	957
Other assets	1,865	1,845
Total assets	$18,941	$16,033
Other current liabilities	$1,369	$881
Current deferred revenue	-	353
Current maturities of long-term debt	2,470	1,758
Long-term portion of accrued interest	339	190
Long-term debt, net of discount of $220 and $281,and debt issuance costs of $112 and $162	6,038	7,799
Stockholders' equity	8,725	5,052
Total liabilities and stockholders' equity	$18,941	$16,033

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

	(unaudited) Three Months Ended September 30,		(unaudited) Nine months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
License fee revenue	$ -	$-	$ 5,250	$ -
Collaboration revenue	95	-	95	-
Royalty revenue	-	-	-	4
Product sales, net	115	145	563	218
Total revenues, net	210	145	5,908	222
Cost and expenses:				
Cost of sales (excluding inventory write-down)	132	108	554	188
Inventory write-down	27	-	334	201
Research and development	432	955	1,907	3,674
Selling, marketing, general and administrative	2,024	1,728	6,404	5,903
Total operating expenses	2,615	2,791	9,199	9,966
Operating loss	(2,405)	(2,646)	(3,291)	(9,744)
Non-operating income (expense):				
Investment income	39	46	110	143
Interest expense	(283)	(304)	(892)	(907)
Other expense	-	-	-	(5)
Total other expense, net	(244)	(258)	(782)	(769)
Loss before income taxes	(2,649)	(2,904)	(4,073)	(10,513)
Provision for income taxes	-	-	-	-
Net loss	$ (2,649)	$ (2,904)	$ (4,073)	$ (10,513)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities	2	(44)	2	6
Total other comprehensive (loss) income	2	(44)	2	6
Comprehensive loss	$ (2,647)	$ (2,948)	$ (4,071)	$ (10,507)
Loss per share:				
Basic	$ (0.23)	$ (0.30)	$ (0.39)	$ (1.08)
Diluted	$ (0.23)	$ (0.30)	$ (0.39)	$ (1.08)
Weighted average shares outstanding:				
Basic	11,677	9,784	10,446	9,774
Diluted	11,677	9,784	10,446	9,774

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Source: Acura Pharmaceuticals, Inc.