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Acura Pharmaceuticals Announces First Quarter 2015 Financial Results

PALATINE, IL -- (Marketwired) -- 05/04/15 --

Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, announced today financial results for the first quarter ended March 31, 2015.

The Company reported net income of $1.2 million for the first quarter 2015 or $0.03 per diluted share, compared to net loss of $4.1 million or $0.08 per diluted share for the same period in 2014.

Revenues for the quarter were $5.4 million compared to only $42 thousand in the first quarter of 2014 reflecting the $5.0 million payment arising from licensing Oxaydo to Egalet Corporation entities.

Research and development expenses associated with product candidates utilizing the Company's LIMITX™, AVERSION® and IMPEDE® Technologies were $1.0 million in the first quarter 2015, compared to $1.4 million for the same period in 2014. Selling, marketing, general and administrative expenses were $2.3 million in each of the first quarters of 2015 and 2014. Selling expenses primarily consisted of advertising and marketing activities for NEXAFED® and NEXAFED® SINUS.

As of April 30, 2015, our unrestricted cash, cash equivalents and marketable securities less our compensating balance requirement of $2.5 million was $11.0 million. We have $10.0 million in term debt financing.

Conference Call Information

Acura Pharmaceuticals, Inc. will host a conference call on Tuesday, May 5, 2015 at 8:30 a.m. ET to discuss the results.

To participate in the live conference call, please dial 888-389-5988 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 6133222. A replay of the call will be available beginning May 5, 2015 and ending on May 26, 2015 on the company's website, and by dialing 888-203-1112 (U.S. and Canada). The replay participant code is 6133222.

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 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 LIMITX, AVERSION and IMPEDE Technologies;
- 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 develop and 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 our filings with the Securities and Exchange Commission.

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

	(unaudited) March 31, 2015	(audited) December 31, 2014
Current assets	$ 14,956	$ 13,231
Property, plant and equipment, net	973	957
Other assets	1,938	2,007
Total assets	$ 17,867	$ 16,195
Other current liabilities	$ 1,393	$ 881
Current deferred revenue	-	353
Current maturities of long-term debt	2,369	1,758
Long-term debt, net of discount of $283 and $281	7,348	7,961
Long-term portion of accrued interest	241	190
Stockholders' equity	6,516	5,052
Total liabilities and stockholders' equity	$ 17,867	$ 16,195

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

	(unaudited) Three Months Ended March 31,	
	2015	2014
Revenues:		
Royalty revenue	$ -	$ 3
Product sales, net	357	39
License fee revenue	5,000	-
Total revenues, net	5,357	42
Operating expenses:		
Cost of sales (excluding inventory write-down)	324	38
Inventory write-down	260	133
Research and development	964	1,438
Selling, marketing, general and administrative	2,297	2,259
Total operating expenses	3,845	3,868
Operating income (loss)	1,512	(3,826)
Non-operating income (expense):		
Investment income	35	44
Loss on sales of marketable securities	-	(5)
Interest expense	(308)	(301)
Total other expense	(273)	(262)
Income (loss) before income taxes	1,239	(4,088)
Provision for income taxes	-	-
Net income (loss)	$ 1,239	$ (4,088)
Other comprehensive income:		
Unrealized gains on securities	31	29
Total other comprehensive income	31	29
Comprehensive income	$ 1,270	$ (4,059)
Income (loss) per share:		
Basic	$ 0.03	$ (0.08)
Diluted	$ 0.03	$ (0.08)
Weighted average shares outstanding:		
Basic	48,965	48,842
Diluted	49,347	48,842

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Source: Acura Pharmaceuticals, Inc.