May 2, 2013

Acura Pharmaceuticals Announces First Quarter 2013 Financial Results

PALATINE, IL -- (Marketwired) -- 05/02/13 -- 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 months ended March 31, 2013.

The Company reported a net loss of $4.2 million for the first quarter 2013 or $0.9 per diluted share, compared to net loss of $2.3 million or $0.05 per diluted share for the same period in 2012. In connection with our Pfizer Agreement, we began to earn royalties starting in February 2013. These royalties are based on net sales of Oxecta by Pfizer and are paid to Acura within 45 days after the end of each calendar quarter. We have previously indicated that Oxecta sales were expected to be nominal until Pfizer commences physician promotional efforts. The Company recorded royalties of approximately $4 thousand for the first quarter 2013 based on sales of approximately $77 thousand.

Research and development expenses associated with product candidates utilizing the company's AVERSION® and IMPEDE® Technologies were $2.2 million in the first quarter 2013, compared to $0.9 million for the same period in 2012. Selling, general and administrative expenses were $2.2 million in the first quarter 2013, versus $1.4 million in the same period last year. Selling expenses for the first quarter 2013 primarily consisted of advertising and marketing activities for NEXAFED®.

As of April 30, 2013, the Company had cash, cash equivalents and marketable securities of $21.5 million and no long term debt.

During the first quarter 2013 the Company's submitted an Investigational New Drug application ("IND") with the FDA to allow clinical testing of Acura's hydrocodone bitartrate with acetaminophen product formulated with AVERSION Technology (hydrocodone/acetaminophen product). The Company commenced and completed enrollment in an intranasal abuse liability study in recreational drug users of the crushed hydrocodone/acetaminophen product ("study AP- ADF-301"). We are awaiting comments from the FDA regarding our statistical analysis plan for this study before analyzing the results. We have initiated technical transfer for our Aversion hydrocodone/acetaminophen product to the proposed commercial manufacturer to commence scale-up activities. Based on the development program, we anticipate preparing and submitting a 505(b)(2) NDA for our hydrocodone/acetaminophen product in the first half of 2014.

In December, 2012 the Company launched in the United States NEXAFED [pseudoephedrine hydrochloride (HCl)], a 30 mg immediate-release next generation pseudoephedrine product, combining effective nasal-congestion relief with a unique technology that disrupts the conversion of pseudoephedrine into the dangerous drug, methamphetamine. NEXAFED is available through several regional and national drug wholesalers for redistribution to pharmacies, including the three largest U.S. drug wholesalers: McKesson, Cardinal Health and AmerisourceBergen. In March 2013, we completed our first shipment of Nexafed directly to the warehouse of a regional drug chain who, we understand, would further stock all of their pharmacies with Nexafed. We also have gained support from three additional chain customers, including one operating food/drug combination stores that ranks in the top ten based on retail pharmacy outlets and one that plans to exclusively stock NEXAFED as its only 30mg tablet. We continue to work to expand the wholesale and retail distribution network for NEXAFED. We have shipped nearly 8 thousand cartons of NEXAFED representing approximately $31 thousand in product gross sales during the first quarter 2013.

Conference Call Information
Acura Pharmaceuticals, Inc. will host a conference call on Friday, May 3, 2013 at 8:30 a.m. ET to discuss the quarterly results.

To participate in the live conference call, please dial 888-427-9417 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 1259095.

A replay of the call will be available beginning May 6, 2013 and ending on May 27, 2013 on the company's website, and by dialing 888-203-1112 (U.S. and Canada). The replay participant code is 1259095.

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 AVERSION® and IMPEDE® Technologies. AVERSION contains polymers that cause the drug to gel when dissolved; it also contains compounds that irritate the nasal passages. IMPEDE is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

In June 2011, the U.S. Food and Drug Administration approved OXECTA® (oxycodone HC1 tablets) which incorporates the AVERSION® technology. The Company has a development pipeline of additional AVERSION® technology products containing other opioids.

The trademark OXECTA® is owned by Pfizer Inc.

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 Oxecta Tablets and Nexafed Tablets, the price discounting that may be offered by Pfizer for Oxecta, our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, the willingness of wholesalers and pharmacies to stock Nexafed Tablets, 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, and the ability of our patents to protect our products from generic competition, our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation, and 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 to meet 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 product candidates, whether the FDA will agree with our analysis of our clinical and laboratory studies and how it may evaluate the results of these studies or 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, whether our product candidates will ultimately deter abuse in commercial settings and whether our Impede technology 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.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in thousands)

	March 31, 2013	December 31, 2012
Current assets	$ 24,218	$ 27,991
Property, plant and equipment, net	1,018	1,052
Other assets	9	11
Total assets	$ 25,245	$ 29,054
Current liabilities	$ 2,175	$ 1,419
Other liabilities	5	5
Stockholders' equity	23,065	27,630
Total liabilities and stockholders' equity	$ 25,245	$ 29,054

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited, in thousands except per share amounts)

	Three Months Ended March 31,	
	2013	2012
Revenues:		
Royalty revenue	$ 4	$ -

Total revenues	4	-
Operating expenses:		
Research and development	2,206	903
Selling, general and administrative	2,222	1,441
Total operating expenses	4,248	2,344
Operating loss	(4,244)	(2,344)
Non-operating income:		
Investment income	10	11
Gain on sales of marketable securities	16	-
Total other income	26	11
Loss before income taxes	(4,218)	(2,333)
Provision for income taxes	-	-
Net loss	$ (4,218)	$ (2,333)
Other comprehensive income (loss):		
Unrealized gains on securities	52	-
Total other comprehensive income (loss)	52	-
Comprehensive income (loss)	$ (4,166)	$ (2,333)
Earnings (loss) per share:		
Basic	$ (0.09)	$ (0.05)
Diluted	$ (0.09)	$ (0.05)
Weighted average shares outstanding:		
Basic	46,685	47,517
Diluted	46,685	47,517

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Source: Acura Pharmaceuticals, Inc.