

# Acura Pharmaceuticals Announces Fourth Quarter and Full Year 2012 Financial Results

PALATINE, IL -- (Marketwire) -- 03/04/13 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, announced today financial results for the year and three months ended December 31, 2012.

The Company reported a net loss of \$3.0 million for the fourth quarter 2012 or \$0.06 per diluted share, compared to net loss of \$1.6 million or \$0.03 per diluted share for the same period in 2011. We recorded no revenue in either period.

Research and development expenses associated with product candidates utilizing the company's AVERSION® and IMPEDE<sup>™</sup> Technologies were \$1.2 million in the fourth quarter 2012, compared to \$0.8 million for the same period in 2011. Selling, general and administrative expenses were \$1.8 million in the fourth quarter 2012, versus \$1.1 million in the same period last year. Selling expenses for the three months ended December 31, 2012 primarily consisted of advertising and marketing activities for NEXAFED®.

As of December 31, 2012, the Company had cash, cash equivalents and marketable securities of \$27.4 million and no long term debt.

For the twelve months ended December 31, 2012, Acura recorded no revenue compared with revenue of \$20.5 million in the same period in 2011. Prior year results included \$20 million in milestone revenue from Pfizer Inc. following the U.S. Food and Drug Administration's ("FDA") approval of a New Drug Application for OXECTA® (oxycodone HCI, USP) Tablets CII. Research and development expenses were \$3.7 million in the twelve months ended December 31, 2012, compared to \$4.0 million in the same period in 2011. Selling, general and administrative expenses were \$6.0 million in the twelve months ended December 31, 2012, versus \$5.9 million in the same period last year. The Company reported a net loss of \$9.7 million or \$0.20 per diluted share, for the twelve months ending December 31, 2012, compared to a net income of \$10.4 million or \$0.22 per diluted share for the same period in 2011.

During the fourth quarter the Company submitted an Investigational New Drug application ("IND") with the FDA to allow clinical testing of Acura's hydrocodone bitartrate with acetaminophen formulated with AVERSION Technology. The IND was accepted in January, 2013 and the Company has initiated the intranasal abuse liability testing in recreational drug users of the crushed drug product.

In December, 2012 the Company launched NEXAFED [pseudoephedrine hydrochloride (HCI)], 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. As of February 28, 2013 the Company has entered into distribution agreements with most of the national and regional drug wholesalers and NEXAFED is available to pharmacies nationwide.

# 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<sup>™</sup> 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 forwardlooking 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)

	(audited) December 31,		(audited) December 31,	
	2	012	2011	
Current assets	\$	27,991	\$ 36	,129
Property, plant and equipment, net		1,052	1	,044
Other assets		11		-
Total assets	\$	29,054	\$ 37	,173
Current liabilities	\$	1,419	\$	530

Other liabilities	5		-
Stockholders' equity	27,630	:	36,643
Total liabilities and stockholders' equity	\$ 29,054	\$	37,173

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(in thousands, except per share data)

	(audited)		(unaudited)		
	Twelve Months Ended		Three Months Ended		
	December 31,		December 31,		
	2012	2011	2012	2011	
Revenues:					
Program fee revenue	\$ -	\$ 466	\$ - \$	-	
Milestone revenue	-	20,000	-	-	
Total revenues	-	20,466	-	-	
Operating expenses:					
Research and development	3,726	4,037	1,208	792	
Selling, general and					
administrative	6,013	5,895	1,849	1,055	
Total operating expenses	9,739	9,932	3,057	1,847	
Operating income (loss)	(9,739)	10,534	(3,057)	(1,847)	

Non-operating income (expense):				
Interest income	79	32	48	10
Other expense, net	(8)	(34)	(7)	(3)
Total other income				
(expense), net	71	(2)	41	7
Income (loss) before income				
taxes	(9,668)	10,532	(3,016)	(1,840)
Provision (benefit) for income				
taxes	-	147	-	(194)
Net income (loss)	\$ (9,668)	\$ 10,385	\$ (3,016)	\$ (1,646)
Other comprehensive income				
(loss), net of tax:				
Unrealized gains (losses) on				
securities	(40)	-	-	-
Total other comprehensive				
income (loss)	(40)	-	-	-
Comprehensive income (loss)	\$ (9,708)	\$ 10,385	\$ (3,016)	\$ (1,646)

Earnings (loss) per share: Basic \$ (0.20) \$ 0.22 \$ (0.06) \$ (0.03) Diluted \$ (0.20) \$ 0.22 \$ (0.06) \$ (0.03)

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## Weighted average shares

outstanding:

Diluted	47,521	48,007	47,523	47,806
Basic	47,521	47,496	47,523	47,806

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