August 1, 2013

Acura Pharmaceuticals Announces Second Quarter 2013 Financial Results

PALATINE, IL -- (Marketwired) -- 08/01/13 -- 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 and six months ended June 30, 2013.

The Company reported a net loss of $3.1 million for the second quarter 2013 or $0.07 per diluted share, compared to net loss of $2.2 million or $0.05 per diluted share for the same period in 2012. Research and development expenses associated with product candidates utilizing the company's AVERSION and IMPEDE Technologies were $0.8 million in the second quarter 2013, versus $0.9 million for the same period in 2012. Selling, general and administrative expenses were $2.3 million in the second quarter 2013, versus $1.3 million in the same period last year. Selling expenses for the second quarter 2013 primarily consisted of advertising and marketing activities for NEXAFED.

The Company reported a net loss of $7.3 million or $0.16 per diluted share, for the six months ended June 30, 2013, compared to a net loss of $4.5 million or $0.10 per diluted share for the same period in 2012. Research and development expenses were $2.8 million in the six months ended June 30, 2013, compared to $1.8 million in the same period in 2012. Selling, general and administrative expenses were $4.6 million in the six months ended June 30, 2013, versus $2.7 million in the same period last year.

In connection with our Pfizer Agreement, we began to earn royalties on net sales of OXECTA by Pfizer starting in February 2013. These royalties are paid to Acura within 45 days after the end of each calendar quarter. We previously indicated that OXECTA sales were expected to be nominal until Pfizer commences promotional efforts to health care providers and for the second quarter and six months we recorded royalties of approximately $1 thousand and $5 thousand, respectively. Following Pfizer's April 2013 receipt of the US Food and Drug Administration's (FDA) advice on its OXECTA promotional materials, we have been informed by Pfizer that it will expand commercialization of OXECTA to health care providers in the fourth quarter of 2013. These activities will be directed to a national cross section of healthcare professionals who treat pain, but will not include the use of field representatives.

As of July 30, 2013, the Company had cash, cash equivalents and marketable securities of $18.4 million and no long term debt.

The Company completed enrollment in an intranasal abuse liability study in recreational drug users of our AVERSION® hydrocodone/acetaminophen product and is conducting the statistical analysis for this study with results expected in the 3rd quarter of this year. At the same time, we have commenced scale-up activities for this product to the proposed commercial manufacturer with the expected completion of our registration batches by 3rd quarter of this year. 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.

We continue to evaluate possible partnering of our Aversion development products with alternative strategic partners.

Distribution of our meth-resistant NEXAFED (pseudoephedrine HCl) expanded to approximately 1,400 US pharmacies or about 2% of the 65,000 pharmacy outlets. About 2/3 of these pharmacies are consistent repeat customers with the top pharmacy averaging approximately 5 boxes per week. We continue to work to expand the wholesale and retail distribution network for NEXAFED and intend to re-approach some chain customers already stocking NEXAFED with programs designed to improve penetration in those chains. We have shipped approximately $25 thousand and $58 thousand in NEXAFED product during the quarter and six months ended June 30, 2013, respectively.

We are conducting research on Impede 2.0, our next generation IMPEDE Technology, to further improve our NEXAFED franchise. Studies sponsored by us at an independent laboratory using an optimized, high yield direct conversion test method that is designed to replicate the direct conversion, or one-pot, process commonly used by clandestine methamphetamine laboratories yielded no measurable amount of methamphetamine compared to an approximate 38% yield with our older IMPEDE Technology. We have manufactured pilot scale quantities of NEXAFED with IMPEDE 2.0 for further meth-resistance testing and pharmacokinetic testing and, if successful, intend to incorporate IMPEDE 2.0 into NEXAFED for commercial introduction.

Conference Call Information

Acura Pharmaceuticals, Inc. will host a conference call on Friday, August 2, 2013 at 8:30 a.m. ET to discuss the quarterly results.

To participate in the live conference call, please dial *888-576-4387* (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 5000537.

A replay of the call will be available beginning August 5, 2013 and ending on August 26, 2013 on the company's website, and by dialing *888-203-1112* (U.S. and Canada). The replay participant code is 5000537.

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.

In December, 2012 the Company launched in the United States NEXAFED (pseudoephedrine (HCl), a 30 mg immediate-release abuse-deterrent. The next generation pseudoephedrine tablet combines 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.

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 other product candidates, our exposure to product liability and other lawsuits in connection with the commercialization of our products, the increased 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 over-the-counter, or 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," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views and beliefs with respect to future events and are based on assumptions and subject to significant 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
(Unaudited, in thousands)

	June 30, 2013	December 31, 2012
Current assets	20,491	27,991
Property, plant and equipment, net	1,006	1,052
Other assets	8	11
Total assets	$ 21,505	$ 29,054
Current liabilities	1,076	1,419
Other liabilities	5	5
Stockholders' equity	20,424	27,630
Total liabilities and stockholders' equity	$ 21,505	$ 29,054

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited, in thousands except per share amounts)

	Unaudited Three Months Ended June 30,		Unaudited Six Months Ended June 30,	
	2013	2012	2013	2012
Revenues:				
Royalty revenue	$ 1	$ -	$ 5	$ -
Total revenues	1	-	5	-
Operating expenses:				
Research and development	805	919	2,831	1,822
Selling, general and administrative	2,336	1,270	4,558	2,711
Total operating expenses	3,141	2,189	7,389	4,533
Operating loss	(3,140)	(2,189)	(7,384)	(4,533)
Non-operating income:				
Investment income	71	11	81	22
Gain (loss) on sales of marketable securities	(7)	-	9	-
Other income (expense)	-	(1)	-	(1)
Total other income	64	10	90	21
Loss before income taxes	(3,076)	(2,179)	(7294)	(4,512)
Provision for income taxes	-	-	-	-
Net loss	$ (3,076)	$ (2,179)	$ (7,294)	$ (4,512)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities	(131)	-	(79)	-
Total other comprehensive income (loss)	(131)	-	(79)	-
Comprehensive income (loss)	$ (3,207)	$ (2,179)	$ (7,373)	$ (4,512)
Income (loss) per share:				
Basic	$ (0.07)	$ (0.05)	$ (0.16)	$ (0.10)
Diluted	$ (0.07)	$ (0.05)	$ (0.16)	$ (0.10)
Weighted average shares outstanding:				
Basic	47,228	47,521	47,215	47,519
Diluted	47,228	47,521	47,215	47,519

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Source: Acura Pharmaceuticals, Inc.