



November 4, 2013

## **Acura Pharmaceuticals Announces Third Quarter 2013 Financial Results**

PALATINE, IL -- (Marketwired) -- 11/04/13 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, announced today financial results for the three and nine months ended September 30, 2013.

The Company reported a net loss of \$3.2 million for the third quarter 2013 or \$0.07 per diluted share, compared to net loss of \$2.1 million or \$0.04 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 \$1.3 million in the third quarter 2013, versus \$0.7 million for the same period in 2012. Selling, marketing, general and administrative expenses were \$1.9 million in the third quarter 2013, versus \$1.5 million in the same period last year, the increase primarily consisting of advertising and marketing activities for NEXAFED and litigation costs associated with OXECTA.

The Company reported a net loss of \$10.5 million or \$0.22 per diluted share, for the nine months ended September 30, 2013, compared to a net loss of \$6.7 million or \$0.14 per diluted share for the same period in 2012. Research and development expenses were \$4.1 million in the nine months ended September 30, 2013, compared to \$2.5 million in the same period in 2012. Selling, marketing, general and administrative expenses were \$6.1 million in the nine months ended September 30, 2013, versus \$4.2 million in the same period last year, the increase primarily consisting of advertising and marketing activities for NEXAFED and litigation costs associated with OXECTA.

For the third quarter and nine months we recorded royalties of approximately \$3 thousand and \$8 thousand, respectively, earned from Pfizer Inc. for their sales of OXECTA which is sold pursuant to a license from us for our AVERSION technology. 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 October 30, 2013, the Company had cash, cash equivalents and marketable securities of \$18.7 million and no long term debt.

### ***AVERSION Product Development***

We have 7 opioid products utilizing AVERSION in various stages of development. Our product containing hydrocodone bitartrate and acetaminophen utilizing the AVERSION technology, or AVERSION hydrocodone/acetaminophen, is the most advanced opioid product in development and the primary focus of our opioid development efforts.

Hydrocodone/acetaminophen is the most widely prescribed and often abused opioid product in the United States. On August 26, 2013, we announced the top-line results from Study AP-ADF-301 ("Study 301"), a phase II clinical study in 40 recreational drug abusers assessing the liability of snorting AVERSION hydrocodone/acetaminophen product. Study 301's primary endpoint indicated that AVERSION hydrocodone/acetaminophen had slightly lower numeric mean maximum drug liking compared to an equivalent dose of a generic hydrocodone/acetaminophen tablet, however these results were not statistically significant. The Study 301 secondary endpoints demonstrated statistical significance in mean minimum drug liking, the Overall Drug Liking score and the Take Drug Again assessment. We intend to further evaluate the data from Study 301 and will meet with the FDA on December 5, 2013, to discuss the Study 301 results. The projected timeline for submission of the NDA for AVERSION hydrocodone/acetaminophen is expected to be delayed. The revised timeline for submission of the NDA for AVERSION hydrocodone/acetaminophen will be determined following our meeting with the FDA.

### ***Nexafed and Impede Technology***

Distribution of our meth-resistant NEXAFED (pseudoephedrine HCl) has expanded and we estimate that it is currently stocked in approximately 2,900 US pharmacies or about 4.5% of the 65,000 pharmacy outlets. We have shipped approximately \$92 thousand and \$150 thousand in NEXAFED product during the quarter and nine months ended September 30, 2013, respectively and have recognized revenue of \$80 thousand for each of these reporting periods. On November 1, 2013, we received a purchase order for NEXAFED from Rite Aid Corporation.

We are conducting research on IMPEDE 2.0, our next generation IMPEDE Technology, to further improve our NEXAFED franchise. We have further tested a prototype formulation of IMPEDE 2.0, which initially showed a substantial reduction in the yield of methamphetamine in the one-pot method, but found this formulation demonstrated variability in the one-pot conversion

method making it unsuitable for market introduction. We continue to perform research into improvements for our IMPEDE technology.

### **Conference Call Information**

Acura Pharmaceuticals, Inc. will host a conference call on Tuesday, November 5, 2013 at 8:30 a.m. ET to discuss the quarterly results.

To participate in the live conference call, please dial 877-879-6207 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 2215110.

A replay of the call will be available beginning November 6, 2013 and ending on November 27, 2013 on the company's website, and by dialing 888-203-1112 (U.S. and Canada). The replay participant code is 2215110.

### **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 September 2011, the U.S. Food and Drug Administration approved OXECTA® (oxycodone HCl 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 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)

	September 30, 2013	December 31, 2012
Current assets	20,766	27,991
Property, plant and equipment, net	972	1,052
Other assets	24	11
Total assets	<u>\$ 21,762</u>	<u>\$ 29,054</u>
Current liabilities	1,111	1,419
Other liabilities	5	5
Stockholders' equity	20,646	27,630
Total liabilities and stockholders' equity	<u>\$ 21,762</u>	<u>\$ 29,054</u>

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

	Unaudited Three Months Ended September 30,		Unaudited Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
Royalty revenue	\$ 3	\$ -	\$ 8	\$ -
Product sales, net	80	-	80	-
Total revenues, net	<u>83</u>	<u>-</u>	<u>88</u>	<u>-</u>
Operating expenses:				
Cost of sales (excluding inventory write-down)	78	-	78	-
Inventory write-down	-	-	361	-
Research and development	1,289	696	4,120	2,518
Selling, general and administrative	1,941	1,453	6,138	4,164
Total operating expenses	<u>3,308</u>	<u>2,149</u>	<u>10,697</u>	<u>6,682</u>
Operating loss	<u>(3,225)</u>	<u>(2,149)</u>	<u>(10,609)</u>	<u>(6,682)</u>
Non-operating income:				
Investment income	55	9	136	30
Loss on sales of marketable securities	(20)	-	(11)	-
Total other income	<u>35</u>	<u>9</u>	<u>125</u>	<u>30</u>
Loss before income taxes	(3,190)	(2,140)	(10,484)	(6,652)
Provision for income taxes	-	-	-	-
Net loss	<u>\$ (3,190)</u>	<u>\$ (2,140)</u>	<u>\$ (10,484)</u>	<u>\$ (6,652)</u>
Other comprehensive income:				
Unrealized gains on securities	114	-	35	-
Total other comprehensive income	<u>114</u>	<u>-</u>	<u>35</u>	<u>-</u>
Comprehensive loss	<u>\$ (3,076)</u>	<u>\$ (2,140)</u>	<u>\$ (10,449)</u>	<u>\$ (6,652)</u>
Loss per share:				
Basic	\$ (0.07)	\$ (0.04)	\$ (0.22)	\$ (0.14)
Diluted	<u>\$ (0.07)</u>	<u>\$ (0.04)</u>	<u>\$ (0.22)</u>	<u>\$ (0.14)</u>
Weighted average shares outstanding:				
Basic	47,458	47,522	47,297	47,520
Diluted	<u>47,458</u>	<u>47,522</u>	<u>47,297</u>	<u>47,520</u>

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