

## Acura Pharmaceuticals Announces Second Quarter 2012 Financial Results

Palatine, IL - (July 30, 2012) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address <u>medication abuse and</u> <u>misuse</u>, announced today financial results for the three and six months ended June 30, 2012.

The Company reported a net loss of \$2.2 million for the second quarter 2012 or \$0.05 per diluted share, compared to net income of \$17.0 million or \$0.35 per diluted share for 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 approval of a New Drug Application for OXECTA<sup>®</sup> (oxycodone HCI, USP) Tablets CII.

Research and development expenses associated with product candidates utilizing the company's AVERSION® and IMPEDE<sup>™</sup> Technologies were \$0.9 million in the second quarter 2012, compared to \$1.1 million for the same period in 2011. Marketing, general and administrative expenses were \$1.3 million in the first quarter 2012, versus \$1.7 million in the same period last year.

As of June 30, 2012, the Company had cash and cash equivalents of \$31.2 million and no long term debt.

For the six months ended June 30, 2012, Acura recorded no revenue compared with revenue of \$20.5 million in the same period in 2011. Research and development expenses were \$1.8 million in the six months ended June 30, 2012, compared to \$2.3 million in the same period in 2011. General and administrative expenses were \$2.7 million in the six months ended June 30, 2012, versus \$3.7 million in the same period last year. The Company reported a net loss of \$4.5 million or \$0.10 per diluted share, for the six months ending June 30, 2012, compared to a net income of \$14.2 million or \$0.30 per diluted share for the same period in 2011.

In the second quarter, the Company completed the commercial scale-up of our manufacturing process for NEXAFED®, an over-the-counter immediate-release pseudoephedrine (PSE) tablet that is intended to impede the illicit manufacture of methamphetamine from PSE. NEXAFED will be the first marketed product utilizing Acura's proprietary IMPEDE technology. The Company expects to commence manufacturing process validation in the near future and make NEXAFED commercially available to pharmacies later this year.

On July 26, 2012 Pfizer, Inc. provided notice that it is exercising its right to terminate the license to three development stage products using Acura's AVERSION® Technology and return such products to Acura. The termination will become effective in 12-months under the terms of our License Agreement with a subsidiary of Pfizer. A fourth product utilizing Acura's AVERSION Technology, OXECTA® (oxycodone hydrochloride) Tablets CII, is being commercialized by Pfizer and Pfizer will retain all rights and obligations to OXECTA under the License Agreement.

### **Conference Call Information**

Acura Pharmaceuticals, Inc. will host a conference call on Tuesday, July 31, 2012 at 8:30 a.m. ET to discuss the quarterly results and Pfizer's return of the development products.

To participate in the live conference call, please dial 800-967-0627 (U.S. and Canada) or 913-981-5535 (international) five to ten minutes prior to the start of the call. The participant passcode is 8419237. A live audio webcast will also be available through the "<u>Investors</u>" section of the company's website, <u>http://www.acurapharm.com.</u>

The conference call and the webcast will be archived for two weeks. The telephone replay of the call will be available approximately two hours after completion of the call by dialing 888-203-1112 (U.S. and Canada) or 719-457-0820 (international), and providing passcode 8419237.

#### **About Acura Pharmaceuticals**

Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of product candidates intended to address <u>medication</u> <u>abuse and misuse</u>, utilizing its proprietary AVERSION<sup>®</sup> and IMPEDE<sup>™</sup> technologies. In June 2011, the U.S. Food and Drug Administration approved OXECTA<sup>®</sup> which incorporates the AVERSION technology. The Company has a development pipeline of additional AVERSION technology products including other opioids and its IMPEDE technology for pseudoephedrine hydrochloride products.

The trademark OXECTA<sup>®</sup> is owned by Pfizer Inc.

#### **OXECTA Important Safety Information**

OXECTA is contraindicated in patients with respiratory depression in unmonitored settings and in the absence of resuscitative equipment, in any patient who has or is suspected of having paralytic ileus, in patients with acute or severe bronchial asthma or hypercarbia, and in patients with known hypersensitivity to oxycodone, oxycodone salts, or any components of the product.

Respiratory depression is the primary risk of OXECTA. This is more common in elderly or debilitated patients, in those suffering from conditions such as COPD, severe asthma, or upper airway obstruction, or following large initial doses of opioids given to non-tolerant patients.

OXECTA contains oxycodone HCI, an opioid agonist and a Schedule II controlled substance. Such drugs are sought by drug abusers and people with addictions. OXECTA can be abused in a manner similar to other opioids and narcotics. This should be considered when prescribing or dispensing oxycodone HCI in situations where the physician or pharmacist is concerned about an increased risk of misuse or abuse. OXECTA may be abused by crushing, chewing, snorting or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death. OXECTA should not be given to anyone other than the individual for whom it was prescribed. Keep OXECTA in a locked cabinet, drawer or medicine safe so that it will not be stolen.

There is no evidence that OXECTA has a reduced abuse liability compared to immediaterelease oxycodone.

Take each OXECTA tablet with enough water to ensure complete swallowing immediately after placing in the mouth, and OXECTA must be swallowed whole. As OXECTA is not amenable to crushing and dissolution, do not use OXECTA in nasogastric, gastric or other feeding tubes as it may cause obstruction of feeding tubes.

Patients who have not been receiving opioid analgesics should start on OXECTA in a dosing range of 5 to 15 mg every 4 to 6 hours as needed for pain. The dose should be titrated based upon the individual patient's response to their first dose of OXECTA. Patients with chronic pain may need to be dosed at the lowest dosage level that will achieve acceptable pain relief and tolerable adverse reactions, on an around-the-clock basis rather than on an as needed basis. When a patient no longer needs treatment with OXECTA after long-term use, it is important to gradually taper OXECTA over time to prevent withdrawal symptoms.

Patients taking OXECTA in combination with other medicines like sedatives, anesthetics or narcotics may have serious problems such as respiratory depression, low blood pressure, profound sedation, or coma. Do not drink alcoholic beverages or take any medicines containing alcohol while taking OXECTA.

Use OXECTA with caution in patients with head injuries or other conditions that increase pressure in the brain, shock with low blood volume, severe undiagnosed abdominal conditions, history of seizures, severe kidney or liver disease, gall bladder disease, Addison's disease, hypothyroidism, enlarged prostate or other illnesses that make urination difficult and elderly or debilitated patients. Do not use OXECTA in patients with intestinal obstruction especially paralytic ileus.

Patients taking OXECTA should use caution when driving a car, operating heavy machinery or doing similar, potentially dangerous tasks as OXECTA may impair abilities needed to drive or perform potentially dangerous activities.

The most common adverse reactions are nausea, constipation, vomiting, headache, itchiness, trouble sleeping, dizziness, loss of strength/energy, and sleepiness.

Keep OXECTA out of the reach of children. If a child accidently takes OXECTA, seek emergency medical help immediately.

Additional information on the prescribing information for OXECTA can be found here <u>http://www.pfizer.com/products</u>

### 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®, the ability of us or our licensee's to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, 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, 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, and the ability to fulfill the U.S. Food and Drug Administration's, or 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 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.

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

	(unaudited) June 30, 2012	(audited) Dec 31, 2011
Current assets	\$31,746	\$36,129
Property, plant and equipment, net	1,090	1,044
Total assets	32,836	\$37,173
Current liabilities	\$894	\$530
Stockholders' equity	31,942	36,643
Total liabilities and stockholders' equity	\$32,836	\$37,173

# ACURA PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share data)

	(unaudited) Six Months Ended June 30,		(unaudited) Three Months Ended June 30,	
	2012	2011	2012	2011
Revenues				
Program fee revenue	-	\$466	-	\$233
Milestone revenue	-	20,000	-	20,000
Total revenues	-	20,466	-	20,233
Operating expenses				
Research and development	1,822	2,283	919	1,142
Marketing, general and				
administrative	2,711	3,655	1,270	1,729
Total operating expenses	4,533	5,938	2,189	2,871
Income (loss) from operations	(4,533)	14,528	(2,189)	17,362
Other income (expense), net	21	(15)	10	5
Income (loss) before income tax	(4,512)	14,513	(2,179)	17,367
Income tax expense	-	341	-	338
Net income (loss)	\$(4,512)	\$14,172	\$(2,179)	\$17,029
Income (loss) per share				
Basic	\$(0.10)	\$0.30	\$(0.05)	\$0.36
Diluted	\$(0.10)	\$0.30	\$(0.05)	\$0.35
Weighted average shares				
Basic	47,519	47,183	47,521	47,364
Diluted	47,519	47,547	47,521	48,009