

Acura Pharmaceuticals Announces First Quarter 2012 Financial Results

Palatine, IL - (May 1, 2012) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address <u>medication</u> <u>abuse and misuse</u>, announced today financial results for the three months ended March 31, 2012.

The Company reported a net loss of \$2.3 million for the first quarter 2012 or \$0.05 per diluted share, compared to a net loss of \$2.9 million or \$0.06 per diluted share for the same period in 2011.

Acura Pharmaceuticals recorded no revenue in the three months ended March 31, 2012 compared to revenue of \$233,000 in the same period last year. The company will begin earning royalties on sales of OXECTA® in the first quarter of 2013.

Research and development expenses associated with product candidates utilizing the company's AVERSION® and IMPEDE[™] Technologies were \$0.9 million in the first quarter 2012, compared to \$1.1 million for the same period in 2011.

Marketing, general and administrative expenses were \$1.4 million in the first quarter 2012, versus \$1.9 million in the same period last year.

As of March 31, 2012, the Company had cash and cash equivalents of \$33.2 million and no long term debt.

"In the first quarter we were pleased that OXECTA, the first product utilizing our AVERSION technology, became commercially available from Pfizer," said Bob Jones, President and Chief Executive Officer of Acura Pharmaceuticals. "We are making progress in our strategy to leverage Acura's proprietary technology platforms to develop products intended to address <u>medication abuse and misuse</u>. The abuse and misuse of opioids and other medications is a serious public health and safety issue and we believe that the products we've developed through our AVERSION and IMPEDE technology platforms can be part of the solution. Looking ahead, we remain on track to make NEXAFED available to pharmacies later this year."

Recent Highlights and Developments

• The Company announced that Pfizer made OXECTA (oxycodone HCI, USP) Tablets CII commercially available on January 23, 2012. Acura is eligible to receive tiered royalties from Pfizer ranging from 5% to 25% on net sales of OXECTA commencing in February 2013. • In the first quarter, Pfizer completed enrollment in a pharmacokinetic and bioequivalence study of hydrocodone bitartrate / acetaminophen tablets utilizing Acura's AVERSION Technology.

Conference Call Information

Acura Pharmaceuticals will host a conference call tomorrow, May 2, 2012 at 8:30 AM ET to discuss its first quarter 2012 financial results. To participate in the live conference call, please dial 888-857-6929 (U.S. and Canada) or 719-457-2658 (international), and provide passcode 5534513. A live webcast of the call will also be available through the "Investors" section of the Company's website at www.acurapharm.com.

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 5534513.

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 abuse and misuse</u>, utilizing its proprietary AVERSION and IMPEDE technologies. In June 2011, the U.S. Food and Drug Administration approved the first product incorporating the AVERSION technology. The Company has a development pipeline of additional AVERSION technology products and its IMPEDE technology for pseudoephedrine hydrochloride products.

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 immediate-release 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 http://www.pfizer.com/products/rx/prescription.jsp

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 forwardlooking 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 forwardlooking 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) March 31, 2012		(audited) Dec 31, 2011	
Current Assets	33,556		36,129	
Property, Plant and Equipment, net	1,083		1,044	
Total Assets	\$ 34,639	\$	37,173	
Accrued Payable	\$ 179	\$	53	
Accrued Expenses	758		477	
Stockholders' Equity	33,702		36,643	
Total Liabilities and Stockholders' Equity	\$ 34,639	\$	37,173	

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

		(unaudited) Three Months Ended March 31,			
	^	2012	•	2011	
Program Fee Revenue	\$	0	\$	233	
Operating Expenses					
Research And Development		903		1,141	
Marketing, General And Administrative		1,441		1,926	
Total Operating Expenses		2,344		3,067	
Loss From Operations		(2,344)		(2,834)	
Other Income (Expense), Net		11		(20)	
Loss Before Income Tax		(2,333)		(2,854)	
Income Tax Expense		Ó		Śź	
Net Loss	\$	(2,333)	\$	(2,857)	
Loss Per Share - Basic And Diluted	\$	(0.05)	\$	(0.06)	
Weighted Average Shares – Basic And Diluted	-	47,517	-	46,987	
Research And Development Marketing, General And Administrative Total Operating Expenses Loss From Operations Other Income (Expense), Net Loss Before Income Tax Income Tax Expense Net Loss Loss Per Share - Basic And Diluted	•	1,441 2,344 (2,344) 11 (2,333) 0 (2,333) (0.05)		1,926 3,067 (2,834) (20) (2,854) 3 (2,857) (0.06)	