

Acura Pharmaceuticals Announces Fourth Quarter and Full Year 2011 Financial Results

Palatine, IL - (March 5, 2012) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address <u>medication abuse and misuse</u>, announced today financial results for the three months and fiscal year ended December 31, 2011.

The Company reported a net loss of \$1.6 million for the fourth quarter 2011 or \$0.03 per diluted share, compared to a net loss of \$2.9 million or \$0.06 per diluted share for the same period in 2010. Research and development expenses were \$0.8 million in the fourth quarter 2011, compared to \$1.5 million for the same period in 2010. General and administrative expenses were \$1.1 million in the fourth quarter 2011, versus \$1.8 million in the same period last year. As of December 31, 2011, the Company had cash and cash equivalents of \$35.7 million.

For the twelve months ended December 31, 2011, Acura generated \$20.5 million in revenue, compared to \$3.3 million in the same period in 2010. The increase was due to a \$20 million milestone payment the Company received from Pfizer as a result of the U.S. Food and Drug Administration's approval of a New Drug Application for OXECTA® (oxycodone HCI, USP) Tablets CII. Research and development expenses were \$4.0 million in the twelve months ended December 31, 2011, compared to \$7.2 million for the same period in 2010. Included in the 2011 and 2010 research and development expenses are non-cash share-based compensation expenses of \$0.5 million and \$1.7 million, respectively. Excluding the sharebased compensation expense, there is a \$2.0 million decrease in research and development expenses primarily attributable to a reduction in clinical study costs. General and administrative expenses were \$5.9 million in the twelve months ended December 31, 2011, versus \$8.9 million in the same period last year. Included in the 2011 and 2010 general and administrative expenses are non-cash share-based compensation expenses of \$1.9 million and \$5.1 million, respectively. The Company reported net income of \$10.4 million or \$0.22 per diluted share, for the twelve months ending December 31, 2011, compared to a loss of \$12.7 million or \$0.27 per diluted share for the twelve months of 2010.

"2011 was a landmark year for Acura as the first product using our AVERSION® technology platform was approved by the FDA and we made solid progress advancing our portfolio of products addressing medication abuse and misuse," commented Bob Jones, President and Chief Executive Officer of Acura Pharmaceuticals. "OXECTA is now commercially available and Pfizer continues to develop two additional products utilizing our AVERSION technology. We look forward to advancing the commercial potential of NEXAFED™ and evaluating opportunities to acquire complimentary products or technologies."

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.

• The Company announced that it expects to make NEXAFED, a 30 mg pseudoephedrine hydrochloride tablet formulation utilizing Acura's IMPEDE Technology, available to pharmacies later this year. Independent laboratory tests demonstrated that NEXAFED disrupted the conversion of the pseudoephedrine in the product into methamphetamine. These most recent laboratory tests used the direct conversion or "one-pot" method. In previous testing, NEXAFED has also demonstrated the ability to block the extraction of the pseudoephedrine from the tablets, which is the first step in the two other common methods of producing the illicit drug methamphetamine.

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 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 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, the ability of Pfizer (to whom we have licensed our AVERSION Technology for certain opioid analgesic products in the United States, Canada and Mexico) to successfully launch and commercialize such products, the ability of Pfizer and the ability of other pharmaceutical companies, if any, to whom we may license our AVERSION Technology or IMPEDE Technology, to obtain necessary regulatory approvals and commercialize products utilizing such technologies and the market acceptance of such products, expectations regarding potential market share for our products, 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 FDA's 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 and the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates, 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 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 or for abuse deterrent features, whether our product candidates will ultimately deter abuse in commercial settings, whether chain or independent pharmacies will stock NEXAFED for sale, whether pharmacists at chain or independent pharmacies will be able to influence such pharmacies to stock NEXAFED for sale, whether pharmacists will recommend NEXAFED to customers seeking their advise for the selection of a nasal decongestant, whether our IMPEDE Technology will disrupt the processing of pseudoephedrine into methamphetamine, whether other methods to convert or extract pseudoephedrine for methamphetamine production will be developed and which are not disrupted by our IMPEDE Technology, and the market acceptance of NEXAFED or any product utilizing our IMPEDE Technology. 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)

	(audited) at December 31,					
		2011		2010		
Current Assets	\$	36,129	\$	24,441		
Property, Plant and Equipment, net		1,044		1,052		
Total Assets	\$	37,173	\$	25,493		
Accounts Payable	\$	53	\$	-		
Accrued Expenses		477		686		
Deferred Program Fee Revenue		-		466		
Stockholders' Equity		36,643		24,341		
Total Liabilities and Stockholders' Equity	\$	37,173	\$	25,493		

ACURA PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	(unaudited)			(audited)				
	Three Mths Ended Dec 31,		Twelve Mths End			· ·		
		2011		2010		2011		2010
Revenues								
Program Fee Revenue	\$	-	\$	233	\$	466	\$	1,088
Collaboration Revenue		-		126		-		2,223
Milestone Revenue		=		=		20,000		
Total Revenues		-		359		20,466		3,311
Operating Expenses								
Research and Development		792		1,463		4,037		7,177
Marketing, General and Administrative		1,055		1,833		5,895		8,858
Total Operating Expenses		1,847		3,296		9,932		16,035
Income (Loss) from Operations		(1,847)		(2,937)		10,534		(12,724)
Other Income (Expense)								
Interest Income		10		11		32		42
Other Expense		(3)		-		(34)		(14)
Total Other Income (Expense)		7		11		(2)		28
Income (Loss) Before Income Tax		(1,840)		(2,926)		10,532		(12,696)
Income Tax Expense (Benefit)		(194)		1		147		11
Net Income (Loss) Applicable to Common Stockholders	\$	(1,646)	\$	(2,927)	\$	10,385	\$	(12,707)
Income (Loss) Per Common Share Applicable to Common Stockholders								
Basic	\$	(0.03)	\$	(0.06)	\$	0.22	\$	(0.27)
Diluted	\$	(0.03)	\$	(0.06)	\$	0.22	\$	(0.27)
Weighted Average Number of								
Outstanding Common Shares								
Basic		47,806		47,139		47,496		47,029
Diluted		47,806		47,139		48,007		47,029