November 6, 2012

Acura Pharmaceuticals Announces Third Quarter 2012 Financial Results

PALATINE, IL -- (Marketwire) -- 11/06/12 -- 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, 2012.

The Company reported a net loss of $2.2 million for the third quarter 2012 or $0.04 per diluted share, compared to net loss of $2.2 million or $0.05 per diluted share for the same period in 2011. We recorded no revenue in either period.

Research and development expenses associated with product candidates utilizing the company's AVERSION® and IMPEDE™ Technologies were $0.7 million in the third quarter 2012, compared to $1.0 million for the same period in 2011. Marketing, general and administrative expenses were $1.5 million in the third quarter 2012, versus $1.2 million in the same period last year. Marketing expenses during the three months ended September 30, 2012 primarily consisted of advertising and marketing activities we initiated on NEXAFED®. Marketing expenses during the three months ended September 30, 2011 primarily consisted of market research studies on our AVERSION® and IMPEDE™ Technologies. Our NEXAFED® advertising and marketing activities will continue in the fourth quarter of 2012 and we expect similar activities in 2013.

As of September 30, 2012, the Company had cash and cash equivalents of $29.3 million and no long term debt.

For the nine months ended September 30, 2012, Acura recorded no revenue compared with revenue of $20.5 million in 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® (oxycodone HCl, USP) Tablets CII. Research and development expenses were $2.5 million in the nine months ended September 30, 2012, compared to $3.2 million in the same period in 2011. Marketing, general and administrative expenses were $4.2 million in the nine months ended September 30, 2012, versus $4.8 million in the same period last year. The Company reported a net loss of $6.7 million or $0.14 per diluted share, for the nine months ending September 30, 2012, compared to a net income of $12.0 million or $0.25 per diluted share for the same period in 2011.

In the third quarter, the Company commenced its manufacturing process validation 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 make NEXAFED commercially available to pharmacies in December, 2012. We intend to market NEXAFED pursuant to the FDA's OTC Monograph regulations that do not require the submission of an ANDA or NDA with the FDA.

On September 26, 2012 the Company announced a letter agreement with Pfizer Inc. providing for the termination of Pfizer's license to Acura's AVERSION Technology used in three developmental opioid products as of that date and the earlier transfer of those products back to Acura. On July 26, 2012 Acura was notified by Pfizer of its intention to terminate the license to the three development products which carried a 12 month notice period under the terms of the companies' 2007 license agreement. The developmental products being returned to Acura are oxycodone hydrochloride with acetaminophen, hydrocodone bitartrate with acetaminophen and a third previously unnamed opioid, all of which utilize Acura's AVERSION technology.

Paragraph IV ANDA Filing
On September 20, 2012, we announced that we had received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from a generic sponsor of an ANDA for a generic drug listing OXECTA as the reference listed drug. Since such date, we have received similar Paragraph IV Notices from three other generic pharmaceutical companies that have filed ANDAs listing OXECTA as the reference drug. The Paragraph IV Notices refer to our U.S. Patent Numbers 7,201,920, 7,510,726 and 7,981,439, which cover our AVERSION Technology and OXECTA. The Paragraph IV Notices state that each generic sponsor believes that such patents are invalid, unenforceable or not infringed. We will take appropriate action to enforce our intellectual property rights and on October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. - Florida, Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement of our patent no. 7,510,726 listed in the FDA's Orange Book. The commencement of such litigation prohibits the FDA from granting approval of the filed ANDAs until the earliest of 30 months from the date the FDA accepted the application for filing, or the conclusion of litigation.

Citizen's Petition filing with FDA

On September 21, 2012, Pfizer, as licensee of our AVERSION Technology used in OXECTA under the Pfizer Agreement, filed a Citizen's Petition with the FDA requesting that the FDA: (i) refrain from permitting an ANDA applicant to rely on OXECTA as a reference listed drug unless the ANDA applicant demonstrates that its product uses the same inactive ingredients as those in OXECTA; (ii) require an ANDA applicant seeking approval of a product that relies on OXECTA as the reference listed drug and uses inactive ingredients different from those in OXECTA to submit an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetics Act; and (iii) refrain from rating a product as therapeutically equivalent to OXECTA unless it has the same inactive ingredients as OXECTA. The FDA has not yet responded to this Citizen's Petition and there can be no assurance that the FDA will take some or all of the actions requested.

Conference Call Information
Acura Pharmaceuticals, Inc. will host a conference call on Wednesday, November 7, 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 888-359-3624 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 4454583.

A replay of the call will be available beginning November 8, 2012 at 11:30 a.m. ET and ending on November 20, 2012 on the company's website, and by dialing 888-203-1112 (U.S. and Canada). The replay participant code is 4454583.

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. In June 2011, the U.S. Food and Drug Administration approved OXECTA® 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® is owned by Pfizer Inc.

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 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.

ACURA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	(unaudited) September 30, 2012	(audited) December 31, 2011
Current assets	$ 29,838	$ 36,129
Property, plant and equipment, net	1,076	1,044
Total assets	30,914	$ 37,173
Current liabilities	$ 687	$ 530
Stockholders' equity	30,227	36,643
Total liabilities and stockholders' equity	$ 30,914	$ 37,173

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	(unaudited) Nine Months Ended September 30,		(unaudited) Three Months Ended September 30,	
	2012	2011	2012	2011
Revenues				
Program fee revenue	-	$ 466	-	-

Milestone revenue	-	20,000	-	-
Total revenues	-	20,466	-	-
Operating expenses				
Research and development	2,518	3,245	696	962
Marketing, general and administrative	4,164	4,840	1,453	1,185
Total operating expenses	6,682	8,085	2,149	2,147
Income (loss) from operations	(6,682)	12,381	(2,149)	(2,147)
Other income (expense), net	30	(9)	9	6
Income (loss) before income tax	(6,652)	12,372	(2,140)	(2,141)
Income tax expense	-	341	-	-
Net income (loss)	$ (6,652)	$ 12,031	$ (2,140)	$ (2,141)
Income (loss) per share				
Basic	$ (0.14)	$ 0.25	$ (0.04)	$ (0.05)
Diluted	$ (0.14)	$ 0.25	$ (0.04)	$ (0.05)
Weighted average shares				
Basic	47,520	47,392	47,522	47,802
Diluted	47,520	47,627	47,522	47,802

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