



Acura Pharmaceuticals Announces Third Quarter 2011 Financial Results

Palatine, IL - (October 31, 2011) - 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, 2011.

The Company reported a net loss of \$2.1 million for the third quarter 2011 or \$0.05 per diluted share, compared to a net loss of \$2.6 million or \$0.05 per diluted share for the same period in 2010. Research and development expenses were \$0.96 million in the third quarter 2011, compared to \$1.1 million for the same period in 2010. General and administrative expenses were \$1.2 million in the third quarter 2011, versus \$1.7 million in the same period last year. As of September 30, 2011, the Company had cash and cash equivalents of \$37.7 million.

For the nine months ended September 30, 2011, Acura generated \$20.5 million in revenue, compared to \$3.0 million in the first nine months of 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 HCl, USP) Tablets CII. Research and development expenses were \$3.2 million in the nine months ended September 30, 2011, compared to \$5.7 million for the same period in 2010. Included in the 2011 and 2010 results are non-cash share-based compensation expenses of \$0.5 million and \$1.4 million, respectively. Excluding the share-based compensation expense, there is a \$1.6 million decrease in development expenses primarily attributable to a reduction of our clinical study costs. General and administrative expenses were \$4.8 million in the nine months ended September 30, 2011, versus \$7.0 million in the same period last year. Included in the 2011 and 2010 results are non-cash share-based compensation expenses of \$1.7 million and \$4.2 million, respectively. The Company reported net income of \$12.0 million or \$0.25 per diluted share for the nine months ending September 30, 2011, compared to a loss of \$9.8 million or \$0.21 per diluted share for the first nine months of 2010.

"We are making progress in our strategy to leverage Acura's proprietary technology platforms to develop products intended to address [medication abuse and misuse](#)," commented Bob Jones, President and Chief Executive Officer of Acura Pharmaceuticals. "The abuse and misuse of opioids and other medications is a serious public health and safety issue and we believe that the products developed through our AVERSION[®] and IMPEDE[™] technology platforms can be part of the solution."

AVERSION contains polymers and other ingredients intended to discourage improper administration of the drugs often associated with abuse. IMPEDE is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

Recent Highlights and Developments

- Acura announced plans to conduct testing to further evaluate NEXAFED[™], a pseudoephedrine tablet formulation utilizing Acura's IMPEDE Technology. As a result, the company will delay NEXAFED commercialization activities.

- The Company announced that Pfizer has begun executing its commercialization plan for OXECTA (oxycodone HCl, USP) Tablets CII in the United States. Acura is eligible to receive tiered royalties ranging from 5% to 25% on net sales of OXECTA. The royalties commence on the first anniversary of the first commercial sale of OXECTA which Acura does not expect to occur during 2011.
- Brad Rivet was appointed the Company's Vice President of Marketing. Mr. Rivet was formerly Vice President at Effcon Laboratories, Inc. where he was responsible for OTC product marketing and new product initiatives.
- The United States Patent and Trademark Office issued Acura U.S. Patent No. 7,981,439 titled "Methods and compositions for deterring abuse of drugs susceptible to abuse and dosage forms thereof." This patent covers Acura's AVERSION polymer matrix technology when utilized with any water soluble drug of abuse. The opioid, stimulant and benzodiazepine products being developed by Acura are covered by this newly issued patent.

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 the first product incorporating the AVERSION technology. The Company has a development pipeline of additional AVERSION technology products including other opioids, stimulants and benzodiazepines 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 HCl, 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 HCl 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 accidentally 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 and whether our Impede technology will disrupt the processing of pseudoephedrine tablets 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) September 30, 2011	(Audited) December 31, 2010
Current assets	\$ 38,086	\$ 24,441
Property, plant and equipment, net	1,002	1,052
Total assets	<u>\$ 39,088</u>	<u>\$ 25,493</u>
Other current liabilities	\$ 1,116	\$ 686
Deferred program fee revenue - current	-	466
Stockholders' equity	37,972	24,341
Total liabilities and stockholders' equity	<u>\$ 39,088</u>	<u>\$ 25,493</u>

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,	
	2011	2010	2011	2010
Revenues				
Program fee revenue	\$ 466	\$ 855	\$ -	\$ 233
Milestone revenue	20,000	-	-	-
Collaboration revenue	-	2,097	-	59
Total revenues	<u>20,466</u>	<u>2,952</u>	<u>-</u>	<u>292</u>
Operating expenses				
Research and development	3,245	5,714	962	1,142
Marketing, general and administrative	4,840	7,024	1,185	1,716
Total operating expenses	<u>8,085</u>	<u>12,739</u>	<u>2,147</u>	<u>3,806</u>
Income (loss) from operations	<u>12,381</u>	<u>(9,787)</u>	<u>(2,147)</u>	<u>(2,566)</u>
Other (expense) income, net	(9)	17	6	15
Income (loss) before income tax	<u>12,372</u>	<u>(9,770)</u>	<u>(2,141)</u>	<u>(2,551)</u>
Income tax expense	341	10	-	2
Net income (loss)	<u>\$ 12,031</u>	<u>\$ (9,780)</u>	<u>\$ (2,141)</u>	<u>\$ (2,553)</u>
Income (loss) per share				
Basic	<u>\$ 0.25</u>	<u>\$ (0.21)</u>	<u>\$ (0.05)</u>	<u>\$ (0.05)</u>
Diluted	<u>\$ 0.25</u>	<u>\$ (0.21)</u>	<u>\$ (0.05)</u>	<u>\$ (0.05)</u>
Weighted average shares				
Basic	<u>47,392</u>	<u>46,992</u>	<u>47,802</u>	<u>47,100</u>
Diluted	<u>47,627</u>	<u>46,992</u>	<u>47,802</u>	<u>47,100</u>