

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549

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FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act Of 1934

October 13, 2008  
Date of Report (Date of earliest event reported)

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**ACURA PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Charter)

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**State of New York**  
(State of Other Jurisdiction  
of Incorporation)

**1-10113**  
(Commission File Number)

**11-0853640**  
(I.R.S. Employer  
Identification Number)

**616 N. North Court, Suite 120**  
**Palatine, Illinois 60067**  
(Address of principal executive offices) (Zip Code)

**(847) 705-7709**  
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e-4(c))

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**Item 8.01                      Other Events**

On October 13, 2008 we announced top-line results from Study AP-ADF-111 (Study 111) entitled "A Phase II, Single-Center, Randomized, Double-Blind, Assessment of the Abuse Liability of Acurox™ (oxycodone HCl and niacin) Tablets in Subjects with a History of Opioid Abuse." Study 111 results demonstrate that Acurox™ Tablets are disliked compared to oxycodone HCl tablets alone when excess doses are swallowed. These results are statistically significant based on the dislike/like scores ( $p = .033$ ), the primary measure of abuse deterrence potential for the study.

We are parties to a License, Development and Commercialization Agreement with King Pharmaceuticals Research and Development, Inc. ("King"), a wholly-owned subsidiary of King Pharmaceuticals, Inc. dated as of October 30, 2007, as amended, pursuant to which, among other things, we have licensed Acurox™ Tablets to King in the United States, Canada and Mexico.

A copy of the press release issued by us jointly with King Pharmaceuticals, Inc. with respect to the above is being furnished as Exhibit 99.1.

**Item 9.01                      Financial Statements and Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Joint Press Release of the Registrant and King Pharmaceuticals, Inc. dated October 13, 2008.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

### ACURA PHARMACEUTICALS, INC.

By: /s/ Peter Clemens

Peter A. Clemens

Senior Vice President & Chief Financial Officer

Date: October 13, 2008

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## EXHIBIT INDEX

Exhibit Number	Description
99.1	Joint Press Release of the Registrant and King Pharmaceuticals, Inc. dated October 13, 2008.

**King Pharmaceuticals Contacts:**

James E. Green, EVP, Corporate Affairs  
423-989-8125

David E. Robinson, Sr. Director, Corporate Affairs  
423-989-7045

**Acura Pharmaceuticals Contact:**

Peter A. Clemens, SVP Investor Relations & CFO  
847-705-7709

**ACURA PHARMACEUTICALS AND KING PHARMACEUTICALS  
ANNOUNCE POSITIVE TOP LINE RESULTS OF KEY CLINICAL STUDY  
ASSESSING ABUSE LIABILITY**

**Acurox™ Tablets Significantly Disliked  
When Excess Doses Are Swallowed**

**PALATINE, ILLINOIS and BRISTOL, TENNESSEE– October 13, 2008** – Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) and King Pharmaceuticals, Inc. (NYSE: KG) today announced top-line results from Study AP-ADF-111 (Study 111) entitled "A Phase II, Single-Center, Randomized, Double-Blind, Assessment of the Abuse Liability of Acurox™ (oxycodone HCl and niacin) Tablets in Subjects with a History of Opioid Abuse." Study 111 results demonstrate that Acurox™ Tablets are disliked compared to oxycodone HCl tablets alone when excess doses are swallowed. These results are statistically significant based on the dislike/like scores ( $p = .033$ ), the primary measure of abuse deterrence potential for the study.

Acurox™ Tablets contain a unique composition of oxycodone HCl, niacin, and essential functional inactive ingredients, and are intended to relieve moderate to severe pain while deterring common methods of prescription drug abuse. King and Acura entered into a License, Development and Commercialization Agreement in October 2007. Based on this Agreement, the companies are jointly developing three immediate-release opioid analgesics using Acura's patented Aversion® Technology and plan to submit an Acurox™ Tablet New Drug Application (NDA) to the FDA later this year.

**About Study 111**

Study 111 was a phase II, single-center, randomized, double-blind, assessment of the abuse liability potential of Acurox™ (oxycodone HCl/niacin) Tablets in 30 subjects with a history of opioid abuse. Fasted subjects received a single dose of study drugs every 48 hours for 9 days and were enrolled in two dosing sequences. The first dosing sequence (Sequence 1) included randomized doses of (i) niacin 240mg alone; (ii) a combination of oxycodone HCl 40mg with niacin 240mg (4 times the expected recommended dose of Acurox™ Tablets 5/30mg); and (iii) placebo tablets. The objective of Sequence 1 was to assess the effects of oxycodone HCl on the effects of niacin. The second dosing sequence (Sequence 2) included randomized doses of (i) a combination of oxycodone HCl 40mg with niacin 240mg (4 times the expected recommended dose of Acurox™ Tablets 5/30mg) and (ii) oxycodone HCl 40mg alone. Sequence 2 was designed to assess the abuse liability and abuse deterrence potential of Acurox™ Tablets versus oxycodone HCl alone. On each dosing day, vital sign measures and subjective and behavioral effects were assessed before dosing (baseline) and at 0.5, 1, 1.5, 2, 3, 4, 5, 6, and 12 hours after dosing. Vital signs included measurement of pupil size, blood pressure, heart rate, oral temperature and respiratory rate. For both Sequence 1 and Sequence 2, subjective changes were measured with a two item Drug Rating Questionnaire-Subject (DRQS) and a 40 item short form of the Addiction Research Center Inventory (ARCI). The ARCI was comprised of three scale scores including the Morphine Benzodrine Group scale (MBG) measuring euphoria, the LSD/dysphoria scale measuring somatic/bodily discomfort and dysphoria and the Pentobarbital Chlorpromazine Alcohol Group scale (PCAG) measuring apathetic sedation. For Sequence 2 only, in addition to the DRQS and ARCI, subjects also completed a Street Value Assessment Questionnaire and a Treatment Enjoyment Assessment Questionnaire.

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Sequence 1 results demonstrated that response to niacin 240 mg alone compared to placebo causes significant dislike scores ( $p = .03$ ), and significant LSD/dysphoria scores ( $p < .001$ ) with these negative niacin induced effects manifesting rapidly, reaching peak at 0.5-1.5 hours and thereafter diminishing. At 0.5 hours after drug administration, oxycodone HCl 40 mg has limited effect on niacin-induced disliking and dysphoric effects. At the one hour observation and afterward, oxycodone may attenuate niacin-induced disliking and dysphoric effects.

Sequence 2 demonstrated that the combination of oxycodone HCl 40mg and niacin 240mg (4 times the expected recommended dose of Acurox™ Tablets 5/30mg) had the potential to be aversive when compared to oxycodone HCl 40mg alone as shown by statistically significant and clinically meaningful results in the dislike/like scores ( $p = .033$ ), the Treatment Enjoyment Assessment scores ( $p = .005$ ) and the LSD/dysphoria scores ( $p < .001$ ). The dislike/like score at 0.5 hours was designated the primary measure of abuse liability and abuse deterrence potential for Acurox™ Tablets 5/30mg and the Treatment Enjoyment Assessment scores and LSD/dysphoria scores at 0.5 hours were additional measures of the abuse deterrence potential of Acurox™ Tablets. Subjective measures not achieving statistical significance included the MBG scores measuring euphoria, the PCAG score measuring apathetic sedation and the Street Value Assessment Questionnaire score, in which subjects indicated they would pay more for oxycodone HCl alone compared to Acurox™ Tablets ( $p = .097$ ).

In this study of 30 subjects with a history of opioid abuse there were no serious adverse events reported. Alterations by niacin compared to placebo on vital signs were minimal and not clinically meaningful. The differences in vital signs between oxycodone HCl/niacin and niacin alone at 4 times the expected recommended dose of Acurox™ Tablets were minimal and not clinically meaningful.

## About Prescription Drug Abuse

The under-treatment of pain is a major public health issue complicated by abuse of prescription opioids. More than 75 million Americans suffer from pain, which is more than the number of people with diabetes, heart disease and cancer combined. While there are a number of prescription pain medications available, the increasing misuse, abuse and diversion of prescription pain medications, especially among young people, is having an impact on physicians' ability and/or willingness to treat pain using opioid analgesics and is impeding patient access to these medicines and appropriate care. According to the National Institute on Drug Abuse, nearly 10 percent of high school seniors have abused Vicodin®<sup>1</sup>, a commonly used short acting opioid pain medicine. The increasing misuse, abuse and diversion of opioid pain medications have become widespread and pose a costly and significant public health issue in and of itself. In 2005, the estimated total cost associated with opioid abuse, including health care, justice, and work-related costs, totaled \$9.5 billion<sup>2</sup>. The pain relief medicines that Acura is developing with King are designed to address this problem.

## About Aversion® Technology

Opioid pain medicines developed with Aversion® Technology are intended to relieve moderate to severe pain while deterring common methods of prescription drug abuse including, intravenous injection of dissolved tablets, nasal snorting of crushed tablets and intentional swallowing of excess numbers of tablets. Tablets or capsules incorporating Aversion® Technology, when dissolved in water or other common solvents in a volume suitable for intravenous injection, form a gelatinous mass that increases the difficulty of chemically extracting oxycodone HCl and creates a physical impediment to drawing the dissolved drug into a syringe. Products developed using Aversion® Technology are expected to cause irritation to the nasal passages when attempts are made to snort crushed tablets. In addition, products utilizing Aversion® Technology are designed to cause disliking, bodily discomfort and dysphoric or unpleasant effects when excess quantities of tablets are swallowed.

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<sup>1</sup> Johnston, LD, O'Malley, PM, Bachman, JG, Schulenberg, JE. Secondary School Students. Monitoring the Future: National Survey Results on Drug Use, 1975-2006. Bethesda, MD: National Institute on Drug Abuse; 2007. NIH Publication 07-6205.

<sup>2</sup> Birnbaum HG, White AG, Reynolds JL, et al. Estimated Costs of Prescription Opioid Analgesic Abuse in the United States in 2001. Clin J Pain 2006; 22(8).

## **About King Pharmaceuticals, Inc.**

King, headquartered in Bristol, Tennessee, is a vertically integrated branded pharmaceutical company. King, an S&P 500 Index company, seeks to capitalize on opportunities in the pharmaceutical industry through the development, including in-licensing arrangements and acquisitions, of novel branded prescription pharmaceutical products in attractive markets and the strategic acquisition of branded products that can benefit from focused promotion and marketing and life-cycle management.

## **About Acura Pharmaceuticals, Inc.**

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion<sup>®</sup> (abuse deterrent) Technology and related product candidates.

## **About Forward-looking Statements**

This release contains forward-looking statements reflecting current views of future events including, but not limited to, statements pertaining to the expected timing for submission of the NDA for Acurox<sup>™</sup> Tablets with the FDA; and statements and expectations relating to the potential of Acurox<sup>™</sup> Tablets and other Aversion<sup>®</sup> Technology product candidates. These forward-looking statements involve certain significant risks and uncertainties, and actual results may differ materially from the forward-looking statements. Some important factors which may cause actual results to differ materially from the forward-looking statements include dependence on the successful development of Acurox<sup>™</sup> and other opioid pain medicines; dependence on King's and Acura's ability to complete clinical and laboratory studies as planned; dependence on the timely submission of an NDA for Acurox<sup>™</sup> with the FDA; dependence on whether information about the abuse deterrent characteristics of Aversion<sup>®</sup> Technology product candidates are included in the FDA approved label for such products; dependence on Acura's and King's ability to differentiate Aversion<sup>®</sup> Technology product candidates from other opioid products based on information included in the FDA approved label for such products ; dependence on the companies' ability to continue to advance the development of its pipeline products as planned; dependence on the uncertainty of research, clinical trials, and other development activities involving pharmaceutical products in which the companies have an interest; dependence on the unpredictability of the duration and results of FDA review of Investigational New Drug applications (IND), NDAs and/or the review of other regulatory agencies worldwide that relate to products in development; dependence on the availability and cost of raw materials; dependence on no material interruptions in supply by contract manufacturers of products in development; dependence on the affect of the potential development and approval of other new competitive products; dependence on unexpected adverse side-effects or inadequate therapeutic efficacy of the companies' drug candidates that could slow or prevent product approval or market acceptance (including the risk that current and past results of clinical trials are not necessarily indicative of future results of clinical trials). Other important factors that may cause actual results to differ materially from the forward-looking statements are discussed in the "Risk Factors" section and other sections of each of King's and Acura's respective Form 10-K for the year ended December 31, 2007 and Form 10-Q for the quarter ended June 30, 2008, which are on file with the U.S. Securities and Exchange Commission. The companies do not undertake to publicly update or revise any of their forward-looking statements even if experience or future changes show that the indicated results or events will not be realized.

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**EXECUTIVE OFFICES**

**KING PHARMACEUTICALS, INC.  
501 FIFTH STREET, BRISTOL, TENNESSEE 37620**

**ACURA PHARMACEUTICALS, INC.  
616 N. NORTH COURT, PALATINE, ILLINOIS 60067**