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

#### FORM 8-K

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

June 17, 2008

Date of Report (Date of earliest event reported)

# ACURA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

**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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e-4(c))

#### Item 8.01 Other Events

On June 17, 2008 we announced positive top-line results from a pivotal Phase III study, AP-ADF-105 ("Study 105"). Both strengths of Acurox<sup>TM</sup> Tablets met the primary pain relief endpoint compared to placebo (p=.0001, and p<.0001). The most prevalent reported adverse events in patients receiving Acurox<sup>TM</sup> Tablets were nausea, vomiting, dizziness, pruritis and flushing. Study 105 was conducted under the U.S. Food and Drug Administration ("FDA") Special Protocol Assessment ("SPA") provision. We have licensed the rights to Acurox<sup>TM</sup> Tablets to King Pharmaceuticals Research and Development, Inc. ("King"), a wholly-owned subsidiary of King Pharmaceuticals, Inc., pursuant to a License, Development and Commercialization Agreement between King and us, dated as of October 30, 2007. We expect to submit a New Drug Application ("NDA") for Acurox<sup>TM</sup> Tablets to the FDA by the end of this year with a targeted indication for the relief of moderate to severe pain where the use of an immediate release, orally administered, opioid analgesic tablet is appropriate.

Study 105 was a pivotal Phase III, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of Acurox<sup>TM</sup> Tablets for relief of moderate to severe pain following bunionectomy surgery. A total of 405 patients were randomized to one of three treatment arms of approximately 135 patients per arm. One treatment arm received a dose of two Acurox<sup>TM</sup> (oxycodone HCl/niacin) Tablets 5/30mg, a second treatment arm received a dose of two placebo tablets. Study drugs were administered every 6 hours. The primary endpoint was the sum of the difference in pain intensity, measured on a 100mm visual analog scale (VAS), compared to baseline over a 48 hour period ("SPID<sub>48</sub>"). Prior to initiating Study 105, the study design, endpoints and statistical analysis plan were submitted to and agreed by the FDA under a Special Protocol Assessment and the study was conducted accordingly. Both Acurox<sup>TM</sup> Tablet strengths met the primary endpoint: p=.0001 for Acurox<sup>TM</sup> Tablets 5mg/30mg and p<.0001 for Acurox<sup>TM</sup> Tablets 7.5mg/30mg. The most prevalent reported adverse events in patients receiving Acurox<sup>TM</sup> Tablets were nausea, vomiting, dizziness, pruritis and flushing. Most adverse events were reported as mild or moderate and there were no serious adverse events. Six patients (2.2%) receiving Acurox<sup>TM</sup> Tablets withdrew from the study due to treatment-emergent adverse events compared with no withdrawals for the placebo group.

A copy of the press release issued by us is being furnished as Exhibit 99.1.

# **Exhibit Number** Description

99.1 Joint Press Release of the Registrant and King Pharmaceuticals, Inc. dated June 17, 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: June 17, 2008

### EXHIBIT INDEX

Exhibit Number	Description
99.1	Joint Press Release of the Registrant and King Pharmaceuticals, Inc. dated June 17, 2008.

# PRESS RELEASE



**King Pharmaceuticals Contacts:** 

James E. Green, Executive Vice President, Corporate Affairs 423-989-8125 David E. Robinson, Senior Director, Corporate Affairs 423-989-7045

### **Acura Pharmaceuticals Contact:**

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



### ACUROX<sup>TM</sup> TABLETS MEET PRIMARY ENDPOINT IN PIVOTAL PHASE III STUDY

Opioid With a Unique Composition of Ingredients Intended to Deter Common Methods of Prescription Drug Abuse

PALATINE, ILLINOIS and BRISTOL, TENNESEE- June 17, 2008 - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) and King Pharmaceuticals, Inc. (NYSE: KG) today announced positive top-line results from Acura's pivotal Phase III study, AP-ADF-105 ("Study 105"). Both strengths of Acurox™ Tablets met the primary pain relief endpoint compared to placebo (p=.0001, and p<.0001). The most prevalent reported adverse events in patients receiving Acurox<sup>TM</sup> Tablets were nausea, vomiting, dizziness, pruritis and flushing. Study 105 was conducted under the U.S. Food and Drug Administration ("FDA") Special Protocol Assessment ("SPA") provision. Acura and King expect to submit a New Drug Application ("NDA") for Acurox™ Tablets to the FDA by the end of this year with a targeted indication for the relief of moderate to severe pain where the use of an immediate release, orally administered, opioid analgesic tablet is appropriate.

Acurox<sup>TM</sup> Tablets contain a unique composition of the opioid oxycodone HCl, niacin, and several functional inactive ingredients and are intended to relieve 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 now jointly developing three immediate-release opioid analgesics, including Acurox<sup>TM</sup> Tablets, using Acura's patented Aversion® Technology.

Dr. Ron Spivey, Acura's Chief Scientific Officer, stated, "The successful achievement of the primary end point in Study 105 adds another important milestone to a growing array of laboratory and clinical studies designed and conducted by Acura in the development of products using our Aversion® Technology. After nearly five years of work, we look forward to submitting an Acurox<sup>TM</sup> NDA to the FDA by the end of this year and have several additional NDA submissions planned over the next few years."

"These solid Phase III results for Acurox<sup>TM</sup> represent continued progress toward our goal to deliver medicines to physicians and patients that effectively manage pain, while addressing the rise in prescription drug abuse," stated Dr. Eric Carter, Chief Science Officer of King. "At King Pharmaceuticals, we are dedicated to developing innovative, clinically-differentiated pain medicines and Acurox<sup>TM</sup> has the potential to be the first immediate release opioid on the U.S. market that is designed to reduce the risk of misuse and abuse."

#### **About Study 105**

Study 105 was a pivotal Phase III, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of Acurox<sup>TM</sup> Tablets for relief of moderate to severe pain following bunionectomy surgery. A total of 405 patients were randomized to one of three treatment arms of approximately 135 patients per arm. One treatment arm received a dose of two Acurox<sup>TM</sup> (oxycodone HCl/niacin) Tablets 5/30mg, a second treatment arm received a dose of two Acurox<sup>TM</sup> Tablets 7.5/30mg, and the third treatment arm received a dose of two placebo tablets. Study drugs were administered every 6 hours. The primary endpoint was the sum of the difference in pain intensity, measured on a 100mm visual analog scale (VAS), compared to baseline over a 48 hour period ("SPID<sub>48</sub>"). Prior to initiating Study 105, the study design, endpoints and statistical analysis plan were submitted to and agreed by the FDA under a Special Protocol Assessment and the study was conducted accordingly. Both Acurox<sup>TM</sup> Tablet strengths met the primary endpoint: p=.0001 for Acurox<sup>TM</sup> Tablets 5mg/30mg and p<.0001 for Acurox<sup>TM</sup> Tablets 7.5mg/30mg. The most prevalent reported adverse events in patients receiving Acurox<sup>TM</sup> Tablets were nausea, vomiting, dizziness, pruritis and flushing. Most adverse events were reported as mild or moderate and there were no serious adverse events. Six patients (2.2%) receiving Acurox<sup>TM</sup> Tablets withdrew from the study due to treatment-emergent adverse events compared with no withdrawals for the placebo group.

### **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.

Additionally, the increasing misuse, abuse and diversion of opioid pain medications has become wide spread and poses a costly and significant public health issue in and of itself. In 2005, the total cost associated with opioid abuse, including health care, justice, and work-related costs, totaled \$9.5 billion<sup>2</sup>. The medicines that King is developing with Acura and other partners to treat pain are designed to address this problem.

### About Aversion® Technology

Opioid pain medicines developed with the Aversion<sup>®</sup> 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 excessive numbers of tablets. Tablets or capsules incorporating the Aversion® Technology, when dissolved in water or other common solvents in a volume suitable for injection, form a gelatinous mass that increases the difficulty of chemically extracting oxycodone HCl and creates a physical impediment to draw the dissolved drug into a syringe. Pulverized and snorted tablets and capsules use the same technology to limit the availability of drug through the nasal mucosa and cause minor but unpleasant irritation to the nasal tissue. In addition, consumption of quantities of drug in excess of the intended amount generates undesirable, yet reversible, effects causing general feelings of discomfort.

### 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 through 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.

<sup>&</sup>lt;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>&</sup>lt;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 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.

### **Forward-looking Statements**

This release contains forward-looking statements which reflect managements' current views of future events and operations, including, but not limited to, statements pertaining to the expected timetable for submission of the NDA for Acurox<sup>TM</sup> Tablets with the FDA; the expectation that Acurox<sup>TM</sup> Tablets will be the first approved immediate-release opioid treatment for relief of moderate to severe pain designed to deter common methods of abuse; and plans to develop other opioid pain medicines intended to deter abuse. 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 forwardlooking statements include dependence on the successful development of Acurox and other immediate-release and extended-release opioid pain medicines; dependence on King's and Acura's ability to release clinical and laboratory data as planned; dependence on the timely submission of an NDA for Acurox™ with the FDA; dependence on the companies' ability to continue to advance the development of its pipeline products as planned; dependence on the high cost and 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 March 31, 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.

###

#### **EXECUTIVE OFFICES**

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

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