# 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

**April 24, 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 (17CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17CFR240.14d-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 April 24, 2008, the Registrant issued a press release announcing the completion of patient enrollment for a Phase III clinical trial evaluating Acurox.

#### Item 9.01 Financial Statements and Exhibits.

Exhibit <u>Number</u>

#### **Description**

99.1 Press Release dated April 24, 2008 announcing the completion of patient enrollment for a Phase III clinical trial evaluating Acurox.

#### **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 A. Clemens

Peter A. Clemens Senior Vice President & Chief Financial Officer

Date: April 24, 2008

#### EXHIBIT INDEX

Exhibit <u>Number</u>	<u>Description</u>
99.1	Press Release dated April 24, 2008 announcing the completion of patient enrollment for a Phase III clinical trial evaluating Acurox.



#### PRESS RELEASE

**King Pharmaceuticals Contacts:** 

423-989-7045

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



Acura Pharmaceuticals Contact:
Peter A. Clemens, SVP Investor Relations & CFO
847-705-7709

FOR IMMEDIATE RELEASE

## KING PHARMACEUTICALS AND ACURA PHARMACEUTICALS ANNOUNCE COMPLETION OF PATIENT ENROLLMENT FOR PIVOTAL PHASE III CLINICAL TRIAL EVALUATING ACUROX $^{TM}$

#### Top-line Clinical Trial Results Expected by July 2008 NDA Submission Expected before end of 2008

BRISTOL, TENNESSEE and PALATINE, ILLINOIS, April 24, 2008 - King Pharmaceuticals, Inc. (NYSE: KG) and Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) announced today the completion of patient enrollment for the pivotal Phase III clinical trial evaluating ACUROX<sup>TM</sup> Tablets for relief of moderate to severe pain. The companies expect to report top-line results from this pivotal trial by July 2008 and submit a New Drug Application (NDA) for ACUROX<sup>TM</sup> Tablets to the U.S. Food and Drug Administration (FDA) before the end of 2008.

ACUROX<sup>TM</sup>, an immediate-release tablet, is a proprietary composition of oxycodone HCl, niacin, and functional inactive ingredients intended to relieve moderate to severe pain and resist or deter 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.

Dr. Eric Carter, Chief Science Officer of King, commented, "This development milestone is an important measure of our continued success in advancing exciting projects to further expand our pain management franchise. We expect that ACUROX<sup>TM</sup> Tablets will be the first approved immediate-release opioid analgesic designed to resist or deter common methods of prescription drug abuse."

Dr. Carter emphasized, "We are committed to developing immediate-release and extended-release opioid analgesics that are proven safe and effective and incorporate appropriate means to resist or deter abuse and misuse."

King and Acura are working together to develop a wide range of immediate-release opioid analgesics, including ACUROX<sup>TM</sup> Tablets, designed to resist or deter common methods of prescription drug abuse. This will complement King's ongoing development of extended-release opioid analgesics designed to resist or deter common methods of 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 and is impeding patient access to these medicines and appropriate care. 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. The medicines King is developing with Acura and other partners to treat pain are designed to address this problem.

#### About Immediate-Release and Extended-Release Opioid Analgesics

Immediate-release opioid analgesics are typically administered every 6 hours for up to 30 days for relief of moderate to severe pain whereas extended-release opioid analgesics are usually administered every 12 to 24 hours for durations ranging from a few weeks to several months or longer for relief of chronic moderate to severe pain. According to IMS Health, in 2007 there were approximately 221 million dispensed prescriptions for immediate-release opioid analgesics and approximately 14 million dispensed prescriptions for extended-release opioid analgesics in the United States.

#### About ACUROX<sup>TM</sup> Tablets

ACUROX™ Tablets, an investigational drug, is an orally administered immediate-release tablet containing oxycodone HCl as an active analgesic ingredient, niacin as an active ingredient in subtherapeutic amounts, and a proprietary composition of functional inactive ingredients. ACUROX™ Tablets are intended to relieve moderate to severe pain while resisting or 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. ACUROX™ is a proposed brand name subject to FDA approval.

In 2007, Acura reached agreement with the FDA on a Special Protocol Assessment for the pivotal Phase III clinical trial evaluating ACUROX™ Tablets. This clinical trial is a randomized, double-blind, placebo-controlled, multi-center, repeat-dose study evaluating the safety and efficacy of ACUROX™ Tablets for the relief of moderate to severe postoperative pain. The 3-arm clinical trial compares two dose levels of ACUROX™ Tablets to placebo, enrolling approximately 135 patients per arm (405 patients in total). Study medication is administered to patients every 6 hours for 48 hours following the onset of moderate to severe pain following bunionectomy surgery. Patient enrollment in this Phase III clinical trial is now complete.

#### **About King Pharmaceuticals**

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.

#### **About Acura Pharmaceuticals**

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion® (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 the release of top-line data from the pivotal Phase III clinical trial evaluating ACUROX™ Tablets and submission of the NDA for ACUROX™ Tablets with the FDA; the expectation that ACUROX™ Tablets will be the first approved immediate-release opioid treatment for relief of moderate to severe pain that is uniquely designed to deter common methods of abuse; and plans to develop other immediate-release and extended-release opioid pain medicines. 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™ and other immediate-release and extended-release opioid pain medicines; dependence on King's and Acura's ability to release clinical data as planned; dependence on the timely submission of an NDA for ACUROX<sup>TM</sup> 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, 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**

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