

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**

January 2, 2009  
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 January 2, 2009, we announced that we submitted a New Drug Application (NDA) for Acurox<sup>®</sup> (oxycodone HCl/niacin) Tablets to the U.S. Food and Drug Administration (FDA) including a request for priority review. The FDA is expected to determine whether to accept the NDA for filing and consider the priority review request within 60 days. Acurox<sup>®</sup>, a patented, orally administered, immediate release tablet containing oxycodone HCl as its sole active analgesic ingredient, has a proposed indication for the relief of moderate to severe pain. Acurox<sup>®</sup> utilizes Acura’s patented Aversion<sup>®</sup> Technology, which is designed to deter misuse and abuse by intentional swallowing of excess quantities of tablets, intravenous injection of dissolved tablets and nasal snorting of crushed tablets.

We have licensed the rights to the Acurox<sup>®</sup> tablets in the United States, Canada and Mexico to King Pharmaceuticals Research and Development, Inc. (“King”), a wholly-owned subsidiary of King Pharmaceuticals, Inc., pursuant to a License, Development and Commercialization Agreement dated as of October 30, 2007 between King and us, as amended. A press release issued by us in connection with the NDA filing is furnished as Exhibit 99.1.

Item 9.01

Financial Statements and Exhibits

Exhibit Number	Description
99.1	Joint Press Release of the Registrant and King Pharmaceuticals, Inc. dated January 2, 2009.

## 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: January 2, 2009

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## EXHIBIT INDEX

Exhibit Number	Description
99.1	Joint Press Release of the Registrant and King Pharmaceuticals, Inc. dated January 2, 2009.

**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

**NEW DRUG APPLICATION SUBMITTED FOR ACUROX<sup>®</sup> TABLETS****— Opioid Analgesic Product Designed to Deter Prescription Drug Abuse —**

PALATINE, ILLINOIS and BRISTOL, TENNESSEE, January 2, 2009 – Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) and King Pharmaceuticals, Inc. (NYSE: KG) today announced that Acura has submitted a New Drug Application (NDA) for Acurox<sup>®</sup> (oxycodone HCl/niacin) Tablets to the U.S. Food and Drug Administration (FDA) including a request for priority review. The FDA is expected to determine whether to accept the NDA for filing and consider the priority review request within 60 days. If approved, Acura and King believe Acurox<sup>®</sup> will be the first FDA approved immediate release opioid analgesic designed to deter swallowing excess quantities of tablets and other common methods of misuse and abuse. According to the National Survey on Drug Use and Health published by the Substance Abuse and Mental Health Services Administration in 2006, immediate-release opioids are abused 10 times more frequently than extended-release opioids.<sup>1</sup>

**About Acurox<sup>®</sup> Tablets and the NDA Submission**

Acurox<sup>®</sup>, a patented, orally administered, immediate release tablet containing oxycodone HCl as its sole active analgesic ingredient, has a proposed indication for the relief of moderate to severe pain. Acurox<sup>®</sup> utilizes Acura's patented Aversion<sup>®</sup> Technology, which is designed to deter misuse and abuse by intentional swallowing of excess quantities of tablets, intravenous injection of dissolved tablets and nasal snorting of crushed tablets. The NDA submission for Acurox<sup>®</sup> Tablets includes positive results from the following studies and a proposed product label describing these studies:

- a pivotal Phase III clinical efficacy and safety study conducted pursuant to an FDA agreed Special Protocol Assessment with statistically significant ( $p \leq 0.0001$ ) primary efficacy endpoints;
- three clinical studies assessing the abuse-liability potential of Acurox<sup>®</sup>, demonstrating with statistical significance that subjects with a history of opioid abuse disliked Acurox<sup>®</sup> compared to immediate release oxycodone HCl alone when snorting crushed tablets or swallowing excess numbers of tablets; and
- two laboratory studies assessing the difficulty of intravenously injecting the oxycodone active opioid ingredient contained in Acurox<sup>®</sup> Tablets.

**About Aversion<sup>®</sup> Technology**

Aversion<sup>®</sup> Technology is a patented composition of active and inactive ingredients intended to relieve moderate to severe pain and deter 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.

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## About Prescription Drug Abuse

The misuse, abuse and diversion of opioid containing pain medications has become widespread in the U.S. and poses a costly and significant public health issue. In addition to the often harmful impact on abusers and their families the estimated cost associated with prescription opioid abuse, including health care, justice, and work-related costs, totaled \$9.5 billion in 2005.<sup>2</sup> The pain relief medicines that Acura is developing with King are designed to address this rapidly growing problem.

## 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 and technologies that complement the Company's focus in specialty-driven markets, particularly neuroscience, hospital and acute care. King is also a leader in the development, registration, manufacturing and marketing of pharmaceutical products for food producing animals.

## About Acura Pharmaceuticals, Inc.

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion® (abuse deterrent) Technology and related product candidates. Acura entered into a License, Development and Commercialization Agreement (the "Agreement") with King Pharmaceuticals, Inc. in October 2007 pursuant to which the Companies are now jointly developing Acurox® and three additional Aversion® Technology immediate release opioid product candidates. The Agreement provides King with an option to license all opioid analgesic products utilizing Aversion® Technology for development and commercialization in the United States, Canada and Mexico.

## Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Act"). When used in this press release, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions are intended to identify forward-looking statements. Acura Pharmaceuticals, Inc. and King Pharmaceuticals, Inc. disclaim any intent or obligation to update these forward-looking statements, and claim the protection of the Safe Harbor for forward-looking statements contained in the Act. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. These risk factors include, but are not limited to, the timing and ability to gain FDA filing acceptance for the Acurox® Tablets NDA, the timing and results of FDA's review for the request for priority review of the Acurox® Tablets NDA, the expectation that Acurox® Tablets will be the first FDA approved immediate release opioid analgesic indicated for relief of moderate to severe pain designed to deter common methods of abuse, the plans and ability to develop, obtain regulatory approvals, manufacture and commercialize Acurox® Tablets and the other Aversion® Technology opioid product candidates, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, the market size, market potential, and competition for Acurox® and the other Aversion® Technology opioid product candidates, and the ability to gain FDA approval of product labeling for the proposed indication or the abuse deterrent features and benefits of Acurox®. You are encouraged to review these and other risks and uncertainties detailed in each company's respective 2007 SEC Form 10-K and September 30, 2008 SEC Form 10-Q.

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<sup>1</sup>National Survey on Drug Use and Health Report, Issue 22, 2006

<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).

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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**

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