

**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**

March 3, 2009
Date of Report (Date of earliest event reported)

Acura Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

State of New York
(State or other jurisdiction
of incorporation)

1-10113
(Commission File Number)

11-0853640
(IRS Employer
Identification No.)

**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 (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On March 3, 2009, we issued a press release, attached hereto as Exhibit 99.1, announcing that the U.S. Food and Drug Administration (FDA) had accepted for filing our New Drug Application (NDA) for Acurox® (oxycodone HCl/niacin) Tablets with a priority review classification. We also announced that the user fee goal date under the Prescription Drug User Fee Act (PDUFA) is June 30, 2009, but that the FDA's timelines described in the PDUFA guidance are flexible and subject to change based on workload and other potential review issues.

Acurox®, 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® utilizes Acura's patented Aversion® Technology, which is designed to deter misuse and abuse by intravenous injection of dissolved tablets, nasal snorting of crushed tablets, and intentional swallowing of excess quantities of tablets.

We have licensed the rights to the Acurox® 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.

Item 9.01. Financial Statements and Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
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99.1	Press Release dated March 3, 2009.
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SIGNATURES

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

Acura Pharmaceuticals, Inc.

Date: March 3, 2009

By: /s/ PETER A. CLEMENS
Peter A. Clemens

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated March 3, 2009.

Acurox(r) Tablets New Drug Application Accepted for Filing With a Priority Review Classification

PALATINE, Ill., and BRISTOL, Tenn., March 3, 2009 (GLOBE NEWSWIRE) -- Acura Pharmaceuticals, Inc. (Nasdaq:ACUR) and King Pharmaceuticals, Inc. (NYSE:KG) (the Companies) today announced that Acura's New Drug Application (NDA) for Acurox(r) (oxycodone HCl/niacin) Tablets was accepted for filing by the U.S. Food and Drug Administration (FDA) with a Priority review classification. Acurox(r) is an immediate release opioid analgesic, has a proposed indication for relief of moderate-to-severe pain and is designed to deter common methods of misuse and abuse.

The user fee goal date under the Prescription Drug User Fee Act (PDUFA) is June 30, 2009. The FDA's timelines described in the PDUFA guidance are flexible and subject to change based on workload and other potential review issues.

About Priority Review Classifications

The FDA may grant an NDA a Priority review classification if its assessment of conditions and information available at the time the application is filed indicates the drug product has the potential to provide, among other things, significant improvements compared to marketed products. A Priority review classification by the FDA determines an NDA's review timeline under PDUFA and is not intended to predict a drug's market acceptance or sales potential. If the Acurox(r) Tablets NDA is ultimately approved by FDA, for which no assurances can be provided, the Companies believe Acurox(r) Tablets will be the first approved immediate release opioid analgesic designed to deter the most common methods of opioid 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 were abused approximately 10 times more frequently than extended-release opioids.¹

Expectations for Acurox(r) Tablets Product Labeling

The FDA has indicated that an explicit claim of abuse deterrence requires the demonstration of an actual reduction in product abuse by patients or drug abusers in routine clinical practice, after approval. The FDA has stated that information describing the physical characteristics of a product candidate and/or the scientifically derived results of laboratory and clinical studies simulating product abuse may be acceptable to include in the product label. The Companies have included in the proposed label in the Acurox(r) Tablets NDA both a physical description of the abuse deterrent characteristics of Acurox(r) Tablets and information from a number of laboratory and clinical studies designed to simulate the relative difficulty of abusing product candidates utilizing Acura's Aversion(r) Technology. The extent to which such information will be included in the FDA approved product label will be the subject of discussions with and agreement by the FDA as part of the Acurox(r) Tablets NDA review process. There can be no assurance that the proposed label for Acurox Tablets will be approved by the FDA.

About Acurox(r) Tablets

Acurox(r) is a patented, orally administered, immediate release tablet containing oxycodone HCl as its sole active analgesic ingredient with a proposed indication for the relief of moderate to severe pain. Acurox(r) utilizes Acura's proprietary Aversion(r) 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.

About Acura Pharmaceuticals, Inc.

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion(r) (abuse deterrent) Technology and related product candidates. Acura entered into a License, Development and Commercialization Agreement with King Pharmaceuticals Research and Development, Inc. ("King"), a wholly-owned subsidiary of King Pharmaceuticals, Inc., in October 2007 pursuant to which Acura and King are now jointly developing Acurox(r) Tablets and three additional opioid analgesic product candidates utilizing Aversion(r) Technology.

The Acura Pharmaceuticals, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=4847>

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 and hospital. King is also a leader in the development, registration, manufacturing and marketing of pharmaceutical products for food producing animals.

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, our ability to gain FDA approval of the Acurox(r) Tablets NDA, the expectation that Acurox(r) Tablets will be the first approved immediate release opioid analgesic indicated for relief of moderate to severe pain designed to deter the most common methods of opioid abuse, the Companies' ability to gain FDA approval of product labeling for the proposed indication or the abuse deterrent features and benefits of Acurox(r), and the market acceptance and sales potential for Acurox(r) Tablets. You are encouraged to review these and other risks and uncertainties detailed in each company's respective 2008 Form 10-K filed with the Securities and Exchange Commission.

1 National Survey on Drug Use and Health Report, Issue 22, 2006

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