

ACURA PHARMACEUTICALS, INC
Form 8-K
March 03, 2009

**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 PUDFA 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

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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>
99.1	Press Release dated March 3, 2009.

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.

By: /s/ PETER A. CLEMENS

Peter A. Clemens

Senior Vice President & Chief Financial Officer

Date: March 3, 2009

EXHIBIT INDEX

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