ACURA PHARMACEUTICALS, INC
Form 8-K
June 23, 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

June 23, 2009
Date of Report (Date of earliest event reported)

ACURA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

State of New York	1-10113	11-0853640
(State of Other Jurisdiction of Incorporation)	(Commission File Number)	(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 June 18, 2009 we (the "Company") received from the U.S. Food and Drug Administration ("FDA") a review letter related to our New Drug Application ("NDA") for Acurox® (oxycodone hydrochloride/niacin) Tablets. On February 22, 2009, Acurox® was granted a priority review classification by the FDA with a Prescription Drug User Fee Act ("PDUFA") date of June 30, 2009. FDA stated in the review letter that their comments are preliminary, subject to change, and do not reflect a final decision on the information reviewed or a review of the entire NDA.

Based on this review letter, we do not believe Acurox® Tablets will receive NDA approval on the PDUFA date. As previously disclosed in the Company's filings with the Securities and Exchange Commission, no assurance can be given that FDA approval of the NDA for Acurox® Tablets will be received.

The Company is a party to an exclusive License Agreement with King Pharmaceuticals Research and Development, Inc. ("King"), a subsidiary of King Pharmaceuticals, Inc., for the development and commercialization of certain opioid analgesic products utilizing our Aversion® Technology in the United States, Canada and Mexico. The License Agreement provides King with an exclusive license for Acurox® (oxycodone hydrochloride and niacin) Tablets.

On June 23, 2009 we issued a press release relating to the foregoing. A copy of the press release is attached as Exhibit 99.1.

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements which reflect management's current views of future events and operations, including, but not limited to, statements pertaining to the Company's expectations regarding the FDA's review of the Company's NDA for Acurox® (oxycodone hydrochloride and niacin) Tablets. These forward-looking statements involve certain significant risks and uncertainties, and actual results may differ materially from the forward-looking statements. A factor which may cause results to differ is dependence on the unpredictability of the duration and results of the FDA's review of the Company's NDA for Acurox® (oxycodone hydrochloride and niacin) Tablets. 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 the Company's Form 10-K for the year ended December 31, 2008, and Form 10-Q for the first quarter ended March 31, 2009, which are on file with the U.S. Securities and Exchange Commission. The Company does not undertake to publicly update or revise any of its forward-looking statements even if experience or future changes show that the indicated results or events will not be realized.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release dated June 23, 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 A. Clemens
Peter A. Clemens
Senior Vice President & Chief FinancialOfficer

Date: June 23, 2009

Exhibit Number	Description
99.1	Press Release dated June 23, 2009