ACURA PHARMACEUTICALS, INC
Form 8-K
September 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

September 3, 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 September 3, 2009, we announced that on September 2, 2009, King Pharmaceuticals, Inc. and we (the "Companies") met with the U.S. Food and Drug Administration ("FDA") regarding the FDA's June 30, 2009 Complete Response Letter to our New Drug Application ("NDA") for Acurox® (oxycodone hydrochloride and niacin) Tablets. At such meeting the FDA and the Companies agreed to take the NDA to an FDA Advisory Committee to consider the evidence to support the potential opioid abuse deterrent effects of Acurox Tablets. The FDA indicated that no new clinical trials for Acurox® Tablets are required at this time. The FDA has not yet set a meeting date for the Advisory Committee's review of the NDA, however the Companies do not expect the meeting to be convened before the end of this year.

The press release announcing the foregoing is attached hereto as Exhibit 99.1.

We 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 we and King are now jointly developing ACUROX® Tablets and three additional opioid analgesic product candidates utilizing Aversion® Technology.

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Act"). When used in this report, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions are intended to identify forward-looking statements. Examples of forward-looking statements in this press release include statements concerning our expectation of and timing for any such Advisory Committee meeting. We 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® Tablets NDA, and the timing of any such approval, whether additional clinical studies will be required to support FDA approval of the Acurox® Tablets NDA, our ability to gain FDA approval of product labeling for the proposed indication or the abuse deterrent features and benefits of Acurox®, and the benefits of Acurox® and the ability of Acurox® to deter abuse in actual practice. 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and our Quarterly Reports on Form 10-Q for each of the quarters ended March 31 and June 30, 2009, each of which is on file with the U.S. Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release dated September 3, 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: September 3, 2009

Exhibit Number	Description
99.1	Press Release dated September 3, 2009