ACURA PHARMACEUTICALS, INC
Form 8-K
June 17, 2008

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 17, 2008
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 (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-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 17, 2008 we announced positive top-line results from a pivotal Phase III study, AP-ADF-105 ("Study 105"). Both strengths of Acurox™ Tablets met the primary pain relief endpoint compared to placebo (p=.0001, and p<.0001). The most prevalent reported adverse events in patients receiving Acurox™ Tablets were nausea, vomiting, dizziness, pruritis and flushing. Study 105 was conducted under the U.S. Food and Drug Administration ("FDA") Special Protocol Assessment ("SPA") provision. We have licensed the rights to Acurox™ Tablets to King Pharmaceuticals Research and Development, Inc. ("King"), a wholly-owned subsidiary of King Pharmaceuticals, Inc., pursuant to a License, Development and Commercialization Agreement between King and us, dated as of October 30, 2007. We expect to submit a New Drug Application ("NDA") for Acurox™ Tablets to the FDA by the end of this year with a targeted indication for the relief of moderate to severe pain where the use of an immediate release, orally administered, opioid analgesic tablet is appropriate.

Study 105 was a pivotal Phase III, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of Acurox™ Tablets for relief of moderate to severe pain following bunionectomy surgery. A total of 405 patients were randomized to one of three treatment arms of approximately 135 patients per arm. One treatment arm received a dose of two Acurox™ (oxycodone HCl/niacin) Tablets 5/30mg, a second treatment arm received a dose of two Acurox™ Tablets 7.5/30mg, and the third treatment arm received a dose of two placebo tablets. Study drugs were administered every 6 hours. The primary endpoint was the sum of the difference in pain intensity, measured on a 100mm visual analog scale (VAS), compared to baseline over a 48 hour period ("$SPID_{48}$"). Prior to initiating Study 105, the study design, endpoints and statistical analysis plan were submitted to and agreed by the FDA under a Special Protocol Assessment and the study was conducted accordingly. Both Acurox™ Tablet strengths met the primary endpoint: p=.0001 for Acurox™ Tablets 5mg/30mg and p<.0001 for Acurox™ Tablets 7.5mg/30mg. The most prevalent reported adverse events in patients receiving Acurox™ Tablets were nausea, vomiting, dizziness, pruritis and flushing. Most adverse events were reported as mild or moderate and there were no serious adverse events. Six patients (2.2%) receiving Acurox™ Tablets withdrew from the study due to treatment-emergent adverse events compared with no withdrawals for the placebo group.

A copy of the press release issued by us is being 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 June 17, 2008.

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: June 17, 2008

EXHIBIT INDEX

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