

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 19, 2007
Date of Report (Date of earliest event reported)

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

State of New York
(State of Other Jurisdiction
of Incorporation)

1-10113
(Commission File Number)

11-0853640
(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):

- ☐ 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 (17CFR 240.13e-4(c))
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Item 8.01 Other Events

On June 19, 2007 the Registrant issued a press release announcing it had reached agreement with the U.S. Food & Drug Administration for a special protocol assessment of a Phase III clinical trial entitled “Study AP-ADF-105: A Phase 3, Randomized, Double-Blinded, Placebo-Controlled, Multicenter, Repeat-Dose Study of the Safety and Efficacy of OxyADF (oxycodone HCl and niacin) Tablets for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Patients”. The press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release announcing agreement with U.S. Food & Drug Administration with respect to a Special Protocol Assessment

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 Financial Officer

Date: June 19, 2007

Exhibit Index

Exhibit Number

Description

99.1

Press Release announcing agreement with U.S. Food & Drug Administration with respect to a Special Protocol Assessment

FOR IMMEDIATE RELEASE

**Acura Pharmaceuticals, Inc. and FDA Reach Agreement on Special Protocol
Assessment for Pivotal Phase 3 Study for OxyADF Tablets**

Palatine, IL, June 19, 2007: Acura Pharmaceuticals, Inc. (OTC:BB-ACUR) (**the Company**) today announced it has reached agreement with the US Food and Drug Administration (**FDA**) on a Special Protocol Assessment (**SPA**) for a pivotal Phase 3 trial of OxyADF Tablets. A SPA is a process in which the FDA provides evaluation and guidance on protocols for Phase 3 clinical trials. The FDA's agreement to the SPA confirms that the design, primary endpoint, and planned statistical analyses of the study adequately addresses the requirements supporting a New Drug Application (**NDA**) submission for OxyADF Tablets. The FDA previously communicated to the Company that only one successful Phase 3 pivotal study will be required prior to NDA submission. While there can be no assurance as to the safety or efficacy results of the Phase 3 trial for OxyADF Tablets, if the Company follows the agreed-upon protocol, then much of the uncertainty associated with the design of this study should be removed. A SPA is binding upon the FDA unless the trial protocol is changed by the Company or a substantial scientific issue essential to determining safety or efficacy is identified after the testing begins.

OxyADF Tablet Pivotal Phase 3 Study Design

The OxyADF Tablet pivotal trial, AP-ADF-105 (**Study 105**), is titled "A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter, Repeat-dose Study of the Safety and Efficacy of OxyADF (oxycodone HCl and niacin) Tablets for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Patients." Study 105 is a 3-arm study comparing two dose levels of OxyADF Tablets to placebo. Study medication in all three study arms will be administered every six hours for 48 hours following the onset of moderate to severe pain following surgery. Study 105 is anticipated to enroll 135 patients per arm (approximately 405 patients in total). In May 2007, in anticipation of receiving FDA agreement to the SPA, the Company executed a Clinical Trial Development Agreement with a leading Contract Research Organization and commenced preliminary start-up activities required prior to beginning patient enrollment. However, enrollment of patients in Study 105 remains dependent upon the Company's ability to secure adequate near-term funding for the study and related operating expenses, of which no assurance can be given. In addition, the completion of Study 105 will be dependent upon the Company's ability to secure adequate longer-term funding or a collaboration agreement with a strategic partner, of which no assurance can be given.

About OxyADF Tablets

OxyADF (oxycodone HCl/niacin) Tablets, the Company's lead product candidate with Aversion® (abuse deterrent) Technology, are orally administered immediate release tablets containing oxycodone HCl as an active analgesic ingredient, a sub therapeutic amount of niacin and several functional inactive ingredients. The Company intends to file a 505(b)(2) NDA for OxyADF Tablets with an anticipated indication for treating moderate to moderately severe pain. OxyADF Tablets are intended to effectively treat moderate to moderately severe pain while also discouraging the three most common methods of misuse and abuse including (i) intravenous injection of dissolved tablets, (ii) nasal snorting of crushed tablets and (iii) intentional swallowing of excessive numbers of tablets. The Company anticipates that OxyADF Tablets will be scheduled as a C-II product by the U.S. Drug Enforcement Administration (**DEA**).

OxyADF Tablet Commercial Manufacturing Site Qualification Plan

In addition to agreement for the SPA, the Company has also received written FDA guidance confirming agreement in all material respects with the Company's proposed commercial manufacturing site qualification plan. The Company is currently in discussions with prospective commercial product suppliers and intends to include relevant data from the selected supplier's commercial manufacturing site in the NDA submission for OxyADF Tablets. OxyADF Tablets utilize a dry blend, direct compression manufacturing process. This process requires commonly utilized blending and tablet compression equipment and, compared to other tablet product formulations, is simple and economical.

About the OxyADF Tablet Market Opportunity

Based on market research data purchased by the Company from IMS Health, for the 12 months ended September 30, 2006, approximately 227 million total prescriptions (brands and generics combined) were dispensed in the U.S. for immediate release and extended release tablet and capsule forms of opioid analgesics. Of these dispensed prescriptions, approximately 13 million were for extended release products (usually administered every 8 to 24 hours) and 214 million were for immediate release products (usually administered every 4 to 6 hours). Extended release products are more commonly prescribed for relief of pain for durations ranging from a few weeks to several months or longer. Immediate release products are more commonly prescribed for relief of pain for durations of generally less than 30 days. According to data published in The National Survey on Drug Use and Health Report, Issue 22, 2006, immediate release opioid containing pain relievers are used non-medically (including through misuse and abuse) approximately ten-fold more often than extended release products. The Company's primary market research (**the Company Market Research**) involving more than 1,000 physicians routinely prescribing opioids, suggests that OxyADF Tablets will be considered by these physicians for use in both the immediate release and extended release market segments. In addition, the Company Market Research indicates that physicians will switch a certain percentage of their prescriptions to OxyADF Tablets from other C-II oxycodone HCl containing products and also from C-III products like hydrocodone with acetaminophen, although there can be no assurance that this will be the case.

Cash Reserves

The Company estimates that its current cash reserves will fund operations, excluding any outlays for Study 105, through mid July 2007. To continue operating thereafter and to initiate patient enrollment in Study 105, the Company must raise additional financing or enter into appropriate collaboration agreements with third parties providing for cash payments to the Company. No assurance can be given that the Company will be successful in obtaining any such financing or in securing collaborative agreements with third parties on acceptable terms, if at all, or if secured, that such financing or collaborative agreements will provide for payments to the Company sufficient to continue funding operations. In the absence of such financing or third-party collaborative agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws.

About Acura Pharmaceuticals, Inc.

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion® (abuse deterrent) Technology and related product candidates.

Forward Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the Company's expectations and projections. The most significant of such risks and uncertainties include, but are not limited to, the Company's ability to secure additional financing to fund continued operations, the Company's ability to enter into contractual arrangements with qualified pharmaceutical partners to license, develop and commercialize the Company's technology and product candidates, the Company's ability to avoid infringement of patents, trademarks and other proprietary rights or trade secrets of third parties, and the Company's ability to fulfill the FDA's requirements for approving the Company's product candidates for commercial distribution in the United States, including, without limitation, the adequacy of the results of the clinical studies completed to date and the results of other clinical studies, to support FDA approval of the Company's product candidates, the adequacy of the development program for the Company's product candidates, changes in regulatory requirements, adverse safety findings relating to the Company's product candidates, the risk that the FDA may not agree with the Company's analysis of its clinical studies and may evaluate the results of these studies by different methods or conclude that the results of the studies are not statistically significant, clinically meaningful or that there were human errors in the conduct of the studies or otherwise, the risk that further studies of the Company's product candidates are not positive, and the uncertainties inherent in scientific research, drug development, clinical trials and the regulatory approval process. You are encouraged to review other important risk factors relating to the Company on our web site at www.acurapharm.com under the link, "Company Risk Factors" and detailed in Company filings with the Securities and Exchange Commission. The Company is at development stage and may never have any products or technologies that generate revenue. Acura Pharmaceuticals, Inc. assumes no obligation to update any forward-looking statements as a result of new information or future events or developments. Acura Pharmaceuticals, Inc. press releases may be reviewed at www.acurapharm.com.
