

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549

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FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act Of 1934

December 11, 2006  
Date of Report (Date of earliest event reported)

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

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**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 December 11, 2006, the Registrant issued the Press Release attached hereto as Exhibit 99.1.

**Item 9.01                      Financial Statements and Exhibits**

| <b><u>Exhibit Number</u></b> | <b><u>Description</u></b>   |
|------------------------------|---|
| 99.1                         | Press Release dated December 11, 2006 Announcing<br>Notice of Allowance For Issuance of Patent for<br>Deterring Abuse of Opioid Containing Dosage Forms |

## 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

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Peter A. Clemens  
Senior Vice President & Chief Financial Officer

Date: December 11, 2006

**Exhibit Index**

**Exhibit Number**

**Description**

|      |   |
|------|---|
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**CONTACT:** Acura Pharmaceuticals, Inc.,  
Investor Relations, Peter A. Clemens, SVP & CFO 847-705-7709

**FOR IMMEDIATE RELEASE**

**ACURA PHARMACEUTICALS, INC. ANNOUNCES NOTICE OF ALLOWANCE FOR ISSUANCE OF PATENT FOR DETERRING ABUSE OF OPIOID CONTAINING DOSAGE FORMS**

**Palatine, IL, December 11, 2006:** Acura Pharmaceuticals, Inc. (OTC.BB-ACUR), today announced receipt from the United States Patent and Trademark Office of a Notice of Allowance for a non-provisional patent application titled “Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms”. A U.S. patent relating to this Notice of Allowance will be granted after the Company pays the required fees. The patent claims in the Notice of Allowance are directed to pharmaceutical compositions intended to reduce or discourage the three most common routes of prescription opioid analgesic product misuse and abuse (the Company's "**Aversion® Technology**") including; (i) intravenous injection of dissolved tablets or capsules; (ii) snorting of crushed tablets or capsules and; (iii) intentionally swallowing excess quantities of tablets or capsules. The opioid analgesics in the allowed patent claims include oxycodone, hydrocodone, hydromorphone, morphine, codeine, tramadol, propoxyphene and many others. At present, the Company retains ownership of all intellectual property and commercial rights to its Aversion® Technology.

**Potential Market for Opioid Analgesic Products with Aversion® Technology**

According to IMS Health, for the 12 month period ending September 30, 2006, there were more than 225 million dispensed prescriptions in the U.S. for opioid analgesics. The Company believes that healthcare providers generally are unable to predict which, if any, of their opioid analgesic prescriptions will ultimately be abused or diverted to non-medical use. Based on primary market research conducted by the Company, physicians in the U.S. believe that nearly one out of six prescriptions for oxycodone and hydrocodone containing products may be abused. In addition, the results of a survey published in 2006 of over 1,500 adults conducted by Schulman, Ronca and Bucuvalas, Inc., a market research firm, revealed that 37% of those surveyed personally know someone who has abused opioid painkillers. Of those reporting knowing someone who has abused opioid painkillers, ten percent revealed that they personally had abused these products and nearly twenty percent of the abusers were identified as coworkers, with the balance being identified as family members or acquaintances. The uncertainty about which, if any, prescriptions for opioid analgesics will be abused or diverted to non-medical use implies that certain segments of the U.S. market for opioid analgesic prescriptions may represent an attractive opportunity for products formulated with the Company's Aversion® Technology.

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## **OxyADF Tablet Development**

OxyADF Tablets, the Company's lead product candidate utilizing Aversion® Technology, is an orally administered immediate release tablet containing oxycodone HCl as its sole active analgesic ingredient with an anticipated indication for treating acute moderate to moderately severe pain. OxyADF Tablets are being developed pursuant to an active investigational new drug application on file with the United States Food and Drug Administration ("FDA"). To date the Company, in concert with contract research organizations, has completed patient enrollment in two phase I clinical trials (AP-ADF-101 and AP-ADF-107), two phase II clinical trials (AP-ADF-102 and AP-ADF 103), a pivotal bioequivalence trial (AP-ADF-104) and a pivotal laboratory study assessing the relative difficulty of extracting oxycodone HCl from OxyADF Tablets for the purposes of illicit intravenous injection.

The FDA has stated to the Company that successful completion of additional clinical trials and related study reports is required prior to the FDA's acceptance of a 505(b)(2) NDA submission for OxyADF Tablets. These required activities include; (a) unblinding of data, analysis and report writing for study AP-ADF-102, a phase II clinical trial in 24 subjects with a history of opioid abuse; (b) data analysis and a final report for study AP-ADF-107, a phase I clinical trial assessing dose response to a certain ingredient in the OxyADF Tablet composition in 50 healthy normal subjects; (c) successful completion of study AP-ADF-105, a placebo controlled, pivotal phase III clinical trial in approximately 400 acute pain patients and; (d) an additional three or four phase I clinical studies with approximately 25-50 normal subjects per study.

Estimating the dates of initiation and completion of clinical studies and the costs to complete development of the Company's product candidates, including OxyADF Tablets, would be speculative and potentially misleading. The Company expects to reassess its future research and development plans pending review of data received from development activities in progress and the availability of cash resources to fund these activities. The cost and pace of future research and development activities are linked and subject to change. At this stage there can be no assurance that any of the Company's research and development efforts, including those for OxyADF Tablets, will lead to a 505(b)(2) NDA submission or that if NDA submissions are made, that any such submission will be accepted for filing or approved by the FDA.

## **About Acura Pharmaceuticals, Inc.**

Acura Pharmaceuticals, Inc., together with its subsidiary, is a specialty pharmaceutical company primarily engaged in research, development and manufacture of products incorporating Aversion® Technology.

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## 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 product development and 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](http://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. All Acura Pharmaceuticals, Inc. press releases may be reviewed at [www.acurapharm.com](http://www.acurapharm.com).

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