

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

July 27, 2006
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 (17CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17CFR240.14d-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 2.02 Results of Operations and Financial Condition

On July 27, 2006, Acura Pharmaceuticals, Inc. (the "Company") issued a press release disclosing the financial results for its second quarter ended June 30, 2006 and OxyADF™ Tablet Development Status. A copy of the Company's press release is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated July 27, 2006 Announcing Financial Results for Second Quarter 2006 and OxyADF™ Tablet Development Status

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.

Date: July 27, 2006

By: /s/ Peter A. Clemens

Peter A. Clemens
Senior Vice President & Chief Financial Officer

Exhibit Index

Exhibit Number

Description

99.1

Press Release dated July 27, 2006 Announcing Financial Results for Second Quarter 2006 and Development Status

OxyADF™ Tablet

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

FOR IMMEDIATE RELEASE

ACURA PHARMACEUTICALS, INC. ANNOUNCES
2ND QUARTER 2006 FINANCIAL RESULTS AND OXYADF™ TABLET DEVELOPMENT STATUS

Palatine, IL, July 27, 2006: Acura Pharmaceuticals, Inc. (OTC:BB-ACUR) today announced a net loss of \$2.6 million or \$0.01 per share for the quarter ending June 30, 2006 compared to a net loss of \$1.4 million or \$0.06 per share for the same period in 2005. Included in the 2006 and 2005 quarterly results is a non cash compensation charge of \$1.3 million and \$0.2 million, respectively, for stock compensation expense pertaining to the Company's issued and outstanding stock options and restricted stock units. For the six months ended June 30, 2006 the Company had a net loss of \$6.8 million or \$0.02 per share compared to a net loss of \$3.3 million or \$0.15 per share in 2005. Included in the 2006 and 2005 six month results is a non cash compensation charge of \$4.0 million and \$0.6 million, respectively, for stock compensation expense pertaining to the Company's issued and outstanding stock options and restricted stock units. The 2006 weighted average number of outstanding common shares reflect the conversion of all outstanding preferred shares into 305.4 million common shares during the fourth quarter of 2005. Highlights of the Company's consolidated balance sheets and statements of operations appear below. Detailed financial statements are included in the Company's Form 10-Q for the quarter ended June 30, 2006 filed with the Securities and Exchange Commission.

Cash Reserves Update

The Company estimates that its current cash reserves, including the net proceeds from the June 2006 Bridge Loan, will fund product development and licensing activities through mid August, 2006. To continue operating thereafter, 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.

OxyADF™ Tablet Development Status

The Company's lead product candidate, OxyADF™ tablets, formulated with the Company's proprietary 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. Product candidates formulated with Aversion® Technology are intended to reduce or discourage misuse of all three common routes of abuse of tablet and capsule pharmaceutical products including (i) intravenous injection of dissolved tablets or capsules, (ii) inhalation/nasal snorting of crushed tablets or capsules and (iii) intentional consumption of excessive numbers of tablets or capsules by oral administration.

OxyADF™ tablets are being developed pursuant to an active investigational new drug application ("IND") on file with the United States Food and Drug Administration ("FDA"). The FDA has confirmed that OxyADF™ is an appropriate product candidate for submission as a 505(b)(2) new drug application ("NDA") and have confirmed in writing to the Company that no additional toxicology studies are required prior to submission of such NDA. To date the Company, in concert with CROs, has completed patient enrollment in one phase I clinical trial (Study AP-ADF-101), one phase II clinical trial (Study AP-ADF-103), a pivotal bioequivalence trial (Study AP-ADF-104) and a pivotal laboratory study relating to the development of OxyADF™. The results from studies AP-ADF-103, AP-ADF-104 and the pivotal laboratory study are summarized below.

OxyADF™ contains a second active ingredient in a sub-therapeutic amount. This second active ingredient has a well established side effect profile in long term administration at doses more than ten-fold greater than the amount contained in the proposed maximum recommended daily dose of OxyADF™ tablets. When OxyADF™ is administered at the intended recommended dose of 1 or 2 tablets every 4-6 hours, then it is expected that legitimate acute pain patients will not feel the effects of this extra active ingredient. However, when either a legitimate acute pain patient or a potential drug abuser consumes excess quantities of OxyADF™ tablets, we anticipate he/she will experience an unpleasant combination of symptoms, including warmth or flushing, itching, sweating and/or chills, headache and a general feeling of discomfort. It is expected that these symptoms will begin approximately 10-15 minutes after the excess dose is consumed and self-resolve approximately 75-90 minutes later. The Company does not expect that the undesirable effects from this extra active ingredient will be "fool-proof" in discouraging excess oral consumption of OxyADF™ tablets but anticipates that it will cause most patients or potential abusers to experience unpleasant effects if excess quantities of OxyADF™ are consumed orally. As described below, the Company is currently evaluating the effects of this second active ingredient in clinical studies involving subjects with no history of opioid abuse as well as in subjects with a history of opioid abuse.

Prospective drug abusers may attempt to dissolve currently marketed oxycodone containing tablets in water or other common solvents, filter the dissolved solution, and then inject the resulting fluid intravenously to obtain a euphoric effect. In addition to its two active ingredients, OxyADF™ tablets also include several inactive ingredients. These inactive ingredients are commonly used pharmaceutical excipients with no therapeutic effect but with specific non-therapeutic functions. When dissolved in water or other common solvents, the functional excipients in OxyADF™ tablets will form a viscous gel that traps the oxycodone ingredient in the OxyADF™ tablet matrix. The Company believes this gel forming feature will substantially limit the ability of prospective I.V. drug abusers to extract oxycodone from an OxyADF™ tablet. The Company has compared (as described below) the relative difficulty of extracting oxycodone from OxyADF™ tablets to several currently marketed oxycodone containing products.

In addition, prospective drug abusers may easily crush or grind currently marketed oxycodone containing products and snort or inhale the crushed powder. The crushed powder may then be snorted and the oxycodone in the powder will be rapidly absorbed through the nasal mucosa often resulting in a euphoric effect. OxyADF™ tablets have three features intended to discourage nasal snorting. First, OxyADF™ tablets are formulated with a functional excipient intended to induce moderate burning and irritation of the nose and nasal mucosal membranes if the tablets are crushed and the prospective drug abuser attempts to snort the crushed tablets. Second, when OxyADF™ tablets are crushed and snorted, the Company expects the moisture in the nasal passages will form a viscous gel with the crushed tablet powder, trapping the oxycodone in the gel and therefore reducing the amount of oxycodone available to be absorbed through the mucosal membranes. Third, the Company expects that the viscous gel formed in the nasal passages will result in a sticky mass producing an unpleasant sensation in the nose of the prospective abuser. Therefore, the Company expects potential nasal abusers of OxyADF™ tablets to experience burning and irritation of the nasal passages, a lower level of oxycodone available for mucosal absorption and a physically unpleasant gelatinous mass in the nose.

Study AP-ADF-103: To assess the safety and tolerability of OxyADF™ tablets in comparison to oxycodone HCl tablets without an ingredient to discourage excess oral consumption, the Company conducted a Phase II single-center, randomized, double-blind, multiple-dose study in 66 healthy adult male and female volunteers (“Study AP-ADF-103”). In Study AP-ADF-103, subjects were randomly assigned to one of three treatment groups (n=22 per treatment group). A run-in phase was conducted on an outpatient basis for five days and included at-home dosing four times daily and adverse event and tolerability assessments. The treatment phase followed the run-in phase and was conducted on an inpatient basis for five days. The treatment phase included dosing with OxyADF™ tablets (with or without the second active ingredient) as well as post-treatment safety and tolerability assessments. Efficacy (the tolerability of OxyADF™) was evaluated with a Side Effects and Symptoms Questionnaire (SESQ) and a OxyADF™ Tolerability Rating Scale. Safety was evaluated by Adverse Events and clinical laboratory and vital signs assessments were conducted periodically during the study. During the run-in phase, comparable tolerability was demonstrated in subjects who took OxyADF™ tablets with and without the second active ingredient. The mean post-dose SESQ total score during the run-in phase was very low in all groups (highest possible score = 33; Group results = 0.84 - 1.6) indicating that OxyADF™ was generally well-tolerated when taken at recommended doses. During the treatment phase, 64% of subjects in Groups 2 and 3 (oxycodone HCl + the second active ingredient) reported side effects and symptoms and 50% of subjects in Group 1 (oxycodone alone) reported side effects and symptoms. Most of the side effects and symptoms observed during the treatment phase were mild or moderate in severity. Irrespective of treatment group, approximately three quarters of subjects reported either “no effect” or “easy to tolerate” on the OxyADF™ Tolerability Rating Scale. Oxycodone HCl administered four times a day, with or without the second active ingredient was determined to be well tolerated. Adverse events were reported by 77% of subjects throughout both phases of the study. The majority of subjects (55%) reported adverse events during the treatment phase that were considered mild in severity. No severe adverse events were reported in any treatment group and no clinically important trends over time were observed in any treatment group for vital signs measurements (blood pressure, heart rate, and respiratory rate). The Company intends to include the data and results from Study AP-ADF-103 in its 505(b)(2) NDA submission for OxyADF™ to the FDA.

Study AP-ADF-104: In addition to Study AP-ADF-101 and Study AP-ADF-103, the Company, in concert with a CRO, has completed a pivotal bioequivalence study for OxyADF™ (Study AP-ADF-104) using tablets from batches manufactured by the Company at its Culver Facility at a scale of sufficient size to fulfill the FDA’s requirements for a 505(b)(2) NDA submission. Study AP-ADF-104 was a pivotal, single-dose, open-label, randomized, two-period crossover bioequivalence study conducted under fasting conditions to compare the pharmacokinetic characteristics of OxyADF™ tablets (oxycodone HCl 5mg) to the FDA reference listed drug, Roxicodone® tablets, 15 mg. Subjects received two separate drug administrations in assigned periods, one treatment per period, according to a randomization schedule. Dosing days were separated by a washout period of at least 7 days. An equal number of subjects were randomly assigned to each possible sequence of treatments. Drug administration consisted of an oral dose of OxyADF™ tablets (3 x 5mg) or Roxicodone® tablets (1 x 15 mg). Thirty-nine (39) of forty (40) healthy adult subjects completed the study. The results demonstrated that OxyADF™ tablets are bioequivalent to Roxicodone® tablets. The 90% confidence intervals for peak exposure based on $\ln(C_{max})$ and overall systemic exposure based on $\ln(AUC_{last})$ and $\ln(AUC_{inf})$ of oxycodone were well within the FDA’s acceptable range for bioequivalence. The Company intends to include the data and results of Study AP-ADF-104 in its 505(b)(2) NDA submission for OxyADF™ to the FDA.

Pivotal Laboratory Study: The Company, in concert with a leading independent laboratory CRO (the “Laboratory CRO”), completed a pivotal study to assess certain properties of OxyADF™ using tablets from batches manufactured by the Company at its Culver Facility at a scale of sufficient size to fulfill the FDA’s requirements for a 505(b)(2) NDA submission. The Laboratory CRO was contracted to quantitatively and qualitatively measure the relative difficulty of extracting oxycodone HCl for purposes of intravenous (IV) injection from various opioid tablet products. The Laboratory CRO was provided with a list of ingredients contained in each product, allotted 80 hours total time to complete the evaluations and allowed to use any methodology desired to extract oxycodone HCl from the tablets. Products tested were OxyADF™ tablets, Oxycontin® Tablets, 40mg, generic oxycodone HCl Tablets, 5 mg and Percocet® Tablets (oxycodone HCl/acetaminophen, 5mg/325 mg). Results were reported as (i) percent of drug extracted, (ii) time to extract drug and (iii) difficulty to extract drug on a scale of 1-10, 1 being easy and 10 being extremely difficult. Oxycontin® and generic oxycodone HCl tablets resulted in 71-92% drug extracted in 3- 6 minutes and were rated 1-2 in relative difficulty. Percocet® tablets resulted in 75% oxycodone HCl extracted in 29 minutes and was rated 3-4 in relative difficulty. OxyADF™ tablets resulted in a “trace” of oxycodone HCl extracted in 355 minutes and was rated 10 in relative difficulty. The Company intends to utilize the data and results from this pivotal laboratory study in its 505(b)(2) NDA submission for OxyADF™ to the FDA.

Development Plan: In written correspondence after the Company's end of Phase II meeting for OxyADF[®] tablets, the U.S. Food and Drug Administration (FDA) has stated that certain additional clinical studies will be required prior to their acceptance of a 505(b)(2) NDA submission for OxyADF[®] tablets. Additional required clinical studies include completion of Study AP-ADF-102, a phase II clinical trial currently in progress in approximately 25 subjects with a history of opioid abuse, Study AP-ADF-105, a placebo controlled, pivotal phase III clinical trial in approximately 300-400 acute pain patients, and four or five 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 current in progress development activities and the availability of cash resources to fund such development 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 with the FDA, that any such submission will be 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 innovative abuse deterrent, abuse resistant and tamper resistant formulations ("Aversion[®] Technology") intended for use in orally administered opioid-containing pharmaceutical products.

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 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.

ACURA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	(unaudited) Six Months Ended June 30		(unaudited) Three Months Ended June 30	
	<u>2006</u>	<u>2005</u>	<u>2006</u>	<u>2005</u>
<u>Operating Costs</u>				
Research and Development	\$ 2,544	\$ 1,682	\$ 1,038	\$ 729
Marketing, General and Administrative	<u>3,724</u>	<u>1,492</u>	<u>1,303</u>	<u>537</u>
Loss from Operations	(6,268)	(3,174)	(2,341)	(1,266)
<u>Other Income (Expense)</u>				
Interest Expense	(495)	(263)	(270)	(137)
Interest Income	10	24	6	9
(Loss) Gain on Asset Disposals	(17)	83	(10)	13
Other	-	-	-	(1)
Net Loss	<u>\$ (6,770)</u>	<u>\$ (3,330)</u>	<u>\$ (2,615)</u>	<u>\$ (1,382)</u>
Basic and Diluted Loss Per Common Share				
	<u>\$ (0.02)</u>	<u>\$ (0.15)</u>	<u>\$ (0.01)</u>	<u>\$ (0.06)</u>
Weighted Average Number of Outstanding Common Shares				
	<u>329,443</u>	<u>22,773</u>	<u>329,577</u>	<u>22,949</u>

ACURA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	(unaudited) At June 30 <u>2006</u>	(audited) At December 31 <u>2005</u>
Current Assets	\$ 900	\$ 444
Property, Plant and Equipment, Net	1,210	1,341
Other Assets	<u>7</u>	<u>7</u>
Total Assets	\$ <u>2,117</u>	\$ <u>1,792</u>
Current Liabilities	10,606	2,922
Long Term Debt	20	5,032
Stockholders' Deficit	<u>(8,509)</u>	<u>(6,162)</u>
Total Liabilities and Stockholders' Deficit	\$ <u>2,117</u>	\$ <u>1,792</u>