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

February 21, 2006Date 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):

- 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 2.02

Results of Operations and Financial Condition

On February 21, 2006, Acura Pharmaceuticals, Inc. (the "Company") issued a press release disclosing the financial results for its fourth quarter ended December 31, 2005 and the twelve months ended December 31, 2005. A copy of the Company's press release is attached as Exhibit 99.1 hereto.

Item 9.01

Financial Statements and Exhibits.

Exhibit

Number <u>Description</u>

99.1 Press Release dated February 21, 2006 Announcing Results for Fourth Quarter and Year ended December 31, 2005.

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: February 21, 2006

EXHIBIT INDEX

Exhibit Number Description 99.1 Press Release dated February 21, 2006 Announcing Results for Fourth Quarter and Year ended December 31, 2005.

FOR IMMEDIATE RELEASE

$\frac{\text{ACURA PHARMACEUTICALS, INC. REPORTS 2005 FINANCIAL RESULTS,}}{\text{and UPDATES OxyADF}^{\text{TM}}} \\ \frac{\text{TABLET DEVELOPMENT, COMMERCIAL}}{\text{STRATEGY and CASH RESERVES}}$

Palatine, IL, February 21, 2006: Acura Pharmaceuticals, Inc. (OTC.BB-ACUR) today announced a net loss of \$7.1 million or \$0.04 per share for the quarter ending December 31, 2005 compared to a net loss of \$2.1 million or \$0.09 per share for the same period in 2004. For calendar year 2005 the Company had a net loss of \$12.1 million or \$0.18 per share compared to a net loss of \$70.0 million or \$3.20 per share in 2004. The 2004 net loss includes a charge of \$72.5 million for amortization of debt discount and private debt offering costs, and a gain of \$14.6 million from debt restructuring and divestment of non-strategic assets. Highlights of the Company's consolidated balance sheet and statements of operation appear below. Detailed financial statements are included in the Company's 2005 Form 10-K filed with the Securities and Exchange Commission.

OxyADF™ Tablets Development Update

The Company's lead product candidate, OxyADFTM tablets (formerly referred to by the Company as Product Candidate #2) is an immediate release tablet under development pursuant to an active IND on file with the U.S. Food and Drug Administration ("FDA"). During the first quarter of 2006, as a routine part of the development process for OxyADFTM tablets, at the Company's written request, the Company and the FDA convened a face-to-face End of Phase 2 meeting ("EOP2 Meeting") for OxyADF tablets. As part of the EOP2 Meeting, the Company and the FDA discussed, among other things, the laboratory and clinical studies completed by the Company to date relating to OxyADFTM tablets and the remaining laboratory and clinical studies anticipated to be completed prior to the submission of a 505(b)(2) NDA for OxyADFTM tablets. The Company believes the guidance provided by FDA at the EOP2 Meeting clarifies the remaining development requirements relating to the Company's proposed indication and contemplated labeling for OxyADFTM tablets. The FDA has confirmed in written correspondence to the Company that OxyADFTM is an appropriate product candidate for submission as a 505(b)(2) NDA.

To date the Company, in concert with its contract research organizations ("CROs") has completed one phase I clinical study and one phase II clinical study relating to development of OxyADFTM tablets. The results from the phase I clinical study were used, among other things, to guide the formulation of the OxyADF tablets used in the phase II clinical study. Results from the phase II clinical study suggest that at the anticipated recommended therapeutic doses in normal subjects, OxyADF tablets will provide a side effects profile similar to the same opioid active ingredient formulated in a tablet without the Company's Aversion® Technology. The Company intends to use the data from such clinical studies in its 505(b)(2) NDA submission for OxyADFTM tablets.

The Company, in concert with an independent clinical CRO, has completed a pilot and a pivotal bioequivalence study for OxyADFTM tablets. The pivotal bioequivalence study used tablets from batches manufactured by the Company at a scale of sufficient size to fulfill the FDA's requirements for a 505(b)(2) NDA submission. The final report from the CRO for the pivotal bioequivalence study confirms that OxyADFTM tablets are bioequivalent to the applicable reference listed drug. The Company intends to use such data in its 505(b)(2) NDA submission for OxyADFTM tablets.

In addition, the Company, in concert with an independent laboratory CRO, completed a pivotal study to assess certain physical/chemical properties of OxyADFTM using tablets from batches manufactured by the Company at a scale of sufficient size to fulfill the FDA's requirements for a 505(b)(2) NDA submission. The final report from this pivotal laboratory study confirms that extracting the active opioid ingredient from OxyADFTM tablets in a form which may be administered via intravenous injection is substantially more difficult than extracting the active opioid ingredient from several currently marketed opioid-based commercial products. The Company intends to utilize the data from this pivotal laboratory study in its 505(b)(2) NDA submission for OxyADFTM.

To receive marketing authorization for commercial distribution in the United States, OxyADFTM tablets and any drug product formulated with the Aversion® Technology will require the development, compilation, submission and filing of a NDA and approval of such application by the FDA. Estimating the dates of completion of laboratory and clinical development, and the costs to complete development, of the Company's product candidates, including OxyADFTM tablets, would be highly speculative, subjective and potentially misleading. Pharmaceutical products require significant time to research, develop and commercialize. The Company expects to reassess its future research and development plans based on the review of data received from current research and development activities and future guidance from the FDA. 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 OxyADFTM, 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.

Commercial Strategy Update

To generate revenue, the Company plans to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license OxyADFTM tablets and other product candidates utilizing the Aversion® Technology and further develop, register and commercialize multiple formulations and strengths of such product candidates. The Company expects to receive milestone payments and a share of profits and/or royalty payments derived from the Partners' sale of products incorporating the Aversion® Technology. Future revenue, if any, would be derived from licensing fees, milestone payments and a share of profits and/or royalty payments relating to our Partners' sale of products incorporating the Aversion® Technology. To date, the Company does not have any executed collaborative agreements with Partners nor can there be any assurance that the Company will successfully enter into such collaborative agreements in the future.

Cash Reserves Update

As of February 1, 2006, the Company had cash and cash equivalents of approximately \$647,000. The Company estimates its current cash reserves will be sufficient to fund the development of OxyADFTM tablets and related operating expenses through mid-to-late March, 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.

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 challenges inherent in new product development, including obtaining regulatory approvals. 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.

This and past press releases for Acura Pharmaceuticals, Inc. are available at Acura's web site at www.acurapharm.com.

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

Δt	Decemi	hor	21

	2005		2004
Current Assets	\$	444	\$ 3,410
Property, Plant and Equipment, Net	1	341	1,555
Other Assets		7	2
Total Assets	\$ 1	792	\$ 4,967
Current Liabilities	2	922	988
Long Term Debt, Net	5	032	5,064
Stockholders' Deficit	(6	162)	(1,085)
Total Liabilities and Stockholders' Deficit	\$ 1	792	\$ 4,967

ACURA PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)
Three Months Ended
December 31.

Twelve Months Ended December 31.

	December 51,		December 51,		
		2005	2004	2005	2004
Net Product Revenues	\$	_	\$ —	\$ —	\$ 838
Operating Costs					
Cost of Manufacturing		_	_	_	1,435
Research and Development		3,738	951	6,265	4,130
Selling, Marketing, General and Administrative		3,176	1,000	5,296	5,238
Loss from Operations		(6,914)	(1,951)	(11,561)	(9,965)
Other Income (Evmence)					
Other Income (Expense) Interest Expense		(202)	(123)	(636)	(2,962)
Interest Income		6	19	36	59
Amortization and Write-off of Debt Discount					
and Deferred Private Debt Offering Costs		_	_	_	(72,491)
Gain on Debt Restructure		_	_	_	12,401
(Loss) Gain on Asset Disposals		(4)	(29)	81	2,359
Other		4	_	5	603
Net Loss	\$	(7,110)	\$ (2,084)	\$ (12,075)	\$ (69,996)
Basic and Diluted Loss Per Common Share	\$	(0.04)	\$ (0.09)	\$ (0.18)	\$ (3.20)
Weighted Average Number of Outstanding Common Shares		196,149	22,192	66,573	21,861