

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 28, 2005
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 February 28, 2005, Acura Pharmaceuticals, Inc. (the "Company") issued a press release disclosing the financial results for its fourth quarter ended December 31, 2004 and the twelve months ended December 31, 2004. 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 February 28, 2005 Announcing Results for Fourth Quarter and Year ended December 31, 2004.

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
Vice President & Chief Financial Officer

Date: February 28, 2005

EXHIBIT INDEX

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CONTACT: **Acura Pharmaceuticals, Inc.**

Peter A. Clemens, SVP Investor Relations & CFO **847-705-7709**

FOR IMMEDIATE RELEASE

**ACURA PHARMACEUTICALS, INC. REPORTS FINANCIAL RESULTS,
DEVELOPMENT PROGRESS and STRATEGY UPDATE**

Palatine, IL, February 28, 2005: Acura Pharmaceuticals, Inc. (OTC.BB-ACUR) today announced a net loss of \$2.1 million or \$0.09 per share for the three months ending December 31, 2004 compared to a net loss of \$15.3 million or \$0.71 per share for the same period in 2003. For calendar year 2004 the Company had a net loss of \$70.0 million or \$3.20 per share compared to a net loss of \$48.5 million or \$2.28 per share in 2003. Included in results for calendar year 2004 is a non-cash charge of \$72.5 million for amortization of debt discount and private debt offering costs compared to a non-cash charge of \$24.8 million in 2003. Also included in results for calendar year 2004 are gains of \$12.4 million from debt restructuring and \$2.4 million from the divestment of certain non-strategic assets.

Commenting, Andy Reddick, President and CEO said, "In 2004 the Company completed the previously disclosed financial restructuring by converting approximately \$104.6 million of debentures into approximately 218.0 million shares of preferred stock. Completing the financial restructuring eliminates approximately \$5.3 million annually in cash interest expense and leaves the Company with only \$5.0 million in debt in the form of an interest bearing note due June 30, 2007."

"In comparing results of operations for the twelve and three month periods ended December 31, 2004 with those for 2003 it is important to understand that in 2004 the Company focused on proprietary pharmaceutical research and development activities relating to its Aversion™ Technology and, unlike the same periods in 2003, is no longer involved in generic drug manufacturing, sales and distribution except as part of an orderly phase out of these activities in the first quarter of 2004."

Aversion™ Technology: Progress with Product Development

The Company's primary business focus is the research and development of proprietary abuse deterrent formulation technologies (the "Aversion™ Technology") intended to deter the abuse of orally administered opioid analgesic products. To date, the Company has formulated and evaluated two distinct product candidates incorporating the Aversion™ Technology ("Product Candidate #1" and "Product Candidate #2"). Both product candidates are tablet formulations intended for oral administration and contain, among other ingredients, widely prescribed opioid active pharmaceutical ingredients.

In 2004 the Company performed pre-clinical and clinical research and development on its product candidates through a combination of internal activities and external collaborations with contract research organizations ("CROs"). The results of these efforts include the completion of two laboratory studies by CROs demonstrating the advantages of the Aversion™ Technology in deterring potential abuse via intravenous injection when compared to selected, currently marketed, widely prescribed opioid products. Also in 2004, the Company, in concert with a CRO with expertise in regulatory and clinical trial design, evaluated Product Candidate #1 in two clinical studies to assess bioavailability and bioequivalence ("BA/BE") in comparison to frequently prescribed, commercially marketed drug products with the same opioid active ingredient but without abuse deterrent properties. The results of the first BA/BE study indicated that Product Candidate #1 was sufficiently bioavailable but not bioequivalent to the reference commercially marketed opioid product. The Company subsequently developed a revised product formulation ("Product Candidate #1R"). The second BA/BE study confirmed that Product Candidate #1R is both bioavailable and bioequivalent to the commercially marketed product which does not possess abuse deterrent properties.

During the second half of 2004, the Company and the Food and Drug Administration ("FDA") held two scheduled telephonic meetings relating to the Company's Aversion™ Technology. Subsequent to the first meeting the Company received acceptance by the FDA of an Investigational New Drug Application ("IND") for Product Candidate #1 and clearance to initiate a clinical trial program. The clinical development program was designed to optimize the formulation of Product Candidate #1 to effectively deter opioid abuse while minimizing the potential for any new adverse events compared to non-Aversion™ formulated commercially marketed products. After conducting and evaluating a Phase 1 clinical trial for Product Candidate #1 and; (i) following a second teleconference with the FDA, (ii) analysis of proprietary Company-initiated primary market research with physicians and (iii) an assessment of the Company's new patent applications and intellectual property relating to the Aversion™ Technology, a strategic decision was made by the Company to shift its development efforts to Product Candidate #2. This decision was based primarily on the Company's belief that the development expense and timeline for Product Candidate #2 will be reduced and the commercial opportunity for success increased with Product Candidate #2 as compared with Product Candidate #1.

For Product Candidate #2, the Company is currently engaged in pre-clinical studies and manufacturing and release testing of clinical trial supplies and contemplates submitting an IND or an IND amendment with the FDA in the first quarter of 2005. Since the formulation of Product Candidate #2, the Company has temporarily suspended development activities for Product Candidate #1 and Product Candidate #1R and intends to focus future development activities primarily on Product Candidate #2. There can be no assurance, however, that any of the Company's product candidates incorporating the Aversion™ Technology will result in a commercially acceptable drug product.

To receive U.S. marketing authorization for commercial distribution , all drug products formulated with the Aversion™ Technology will require the development, compilation, submission and filing of a new drug application (“NDA”) and approval of such application by the FDA. In the event that Product Candidate #2 is stable and demonstrates acceptable bioequivalence, then additional clinical and non-clinical testing will be required prior to the submission of an NDA. There can be no assurances that Product Candidate #2 will lead to an NDA submission or that if an NDA is filed, that the FDA will approve such regulatory application for commercial distribution of such product candidate.

Commenting, Andy Reddick, said, “We envision that orally administered opioid containing products incorporating the Aversion™ Technology will discourage or deter a pre-existing opioid drug abuser, or a legitimate patient properly using opioid containing analgesics. from abusing an orally administered opioid containing tablet or capsule. The Company is moving its clinical development program forward to hopefully demonstrate that the Aversion™ Technology is an effective abuse deterrent for commonly prescribed opioid active ingredients.”

Commercial Strategy and Cash Reserves Update

The Company plans to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license the Company's Aversion™ Technology and further develop, register and commercialize multiple formulations and strengths of orally administered opioid containing finished dosage products utilizing the Aversion™ Technology. The Company believes that it will derive revenues through licensing fees, milestone payments, profit sharing and/or royalties on net sales of such products and from the contract manufacture and supply of clinical trial and commercial supplies of finished dosage products for distribution and sale by such Partners. To date the Company does not have any such collaborative agreements. The Company can make no assurance that it will be able to negotiate such agreements on favorable terms and, even assuming that such agreements are successfully executed, that the milestones will be achieved and the milestone payments will be subsequently made by our Partners. Accordingly, the Company must rely on its current cash reserves to fund the development of its Aversion™ Technology and related ongoing administrative and operating expenses. The Company estimates that its current cash reserves will be sufficient to fund the development of the Aversion™ Technology and related operating expenses through May, 2005. To fund operations through March 2006, the Company estimates that it must raise additional financing, or enter into collaboration agreements with third parties providing for net proceeds to the Company of approximately \$5 million. 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 to fund 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.

Opioid Synthesis Technologies Strategy Update

The Company is in the process of suspending further development and commercialization efforts relating to its proprietary manufacturing processes for opioid APIs (the “Opioid Synthesis Technologies”). The Company has determined based on, among other factors, the Company’s limited cash balances, the Company’s focus on the AversionTM Technology, the additional funding of at least \$7 million required for facility improvements to scale up the Opioid Synthesis Technologies to commercial scale, and the projected timeline for resolution of the Company’s application to the U.S. Drug Enforcement Administration for a narcotic raw material import registration (the “Import Registration”), that suspending further activities relating to the Opioid Synthesis Technologies is in the Company’s best interest. The Company expects to re-evaluate the development and commercialization of the Opioid Synthesis Technologies after the Administrative Law Judge makes a determination relating to the Company’s Import Registration. No assurance can be given that development and commercialization efforts relating to the Opioid Synthesis Technologies will resume in the future, or even if such activities resume, that the Opioid Synthesis Technologies will be capable of commercial scale up or will be commercialized.

Acura Pharmaceuticals, Inc., together with its subsidiaries, is an emerging pharmaceutical technology development company specializing in proprietary opioid abuse deterrent formulation technology.

This press release contains forward looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Act of 1934, as amended that are based on management's beliefs and assumptions, current expectations, estimates and projections. Investors are cautioned that forward looking statements involve risks, uncertainties and other factors, which could cause actual results to differ materially from future results expressed or implied by such forward looking statements. The most significant of such factors include, but are not limited to, general economic conditions, competitive conditions, technological conditions and governmental legislation. More specifically, important factors that may affect future results include, but are not limited to: changes in laws and regulations, particularly those affecting the Company’s operations; the Company's ability to continue to attract, assimilate and retain highly skilled personnel; its ability to secure and protect its patents, trademarks and proprietary rights; litigation or regulatory action that could require the Company to pay significant damages or change the way it conducts its business; the Company’s ability to successfully develop and market its products; customer responsiveness to new products and distribution channels; its ability to compete successfully against current and future competitors; its dependence on third-party suppliers of raw materials; the availability of controlled substances that constitute the active ingredients of the Company’s products in development; difficulties or delays in clinical trials for Company products or in the manufacture of Company products; and other risks and uncertainties detailed in Company filings with the Securities and Exchange Commission. The Company is at an early stage of development and may not ever have any products that generate significant revenue.

Further, the forward looking statements speak only as of the date such statements are made, and the Company undertakes no obligation to update any forward looking statements to reflect events or circumstances after the date of such statements. Any or all of the forward looking statements whether included in this release or in the Company's filings with the Securities and Exchange Commission, may turn out to be wrong. Readers should remember that no forward looking statement can be guaranteed and other factors besides those listed above could adversely affect the Company, its operating results or financial condition.

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

ACURA PHARMACEUTICALS, INC.
FINANCIAL HIGHLIGHTS

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	(unaudited) Three Months Ended December 31,		Twelve Months Ended December 31,	
	2004	2003	2004	2003
Net Product Revenues	\$ —	\$ 1,540	\$ 838	\$ 5,750
Operating Costs				
Cost of Manufacturing	—	4,300	1,435	11,705
Research and Development	951	505	4,130	1,460
Selling, Marketing, General and Administrative	1,000	1,789	5,238	7,903
Plant Shutdown Costs	—	1,926	—	1,926
Loss from Operations	(1,951)	(6,980)	(9,965)	(17,244)
Other Income (Expense)				
Interest Expense	(123)	(1,565)	(2,962)	(6,001)
Interest Income	19	3	59	25
Amortization and Write-off of Deferred Debt				
Discount and Private Debt Offering Costs	—	(6,721)	(72,491)	(24,771)
Gain on Debt Restructure	—	—	12,401	—
(Loss) Gain on Asset Disposals	(29)	—	2,359	—
Other	—	—	603	(464)
NET LOSS	\$ (2,084)	\$ (15,263)	\$ (69,996)	\$ (48,455)
Basic and Diluted Loss Per Common Share	\$ (0.09)	\$ (0.71)	\$ (3.20)	\$ (2.28)
Weighted Average Number of Outstanding Common Shares	22,192	21,548	21,861	21,227

ACURA PHARMACEUTICALS, INC.
FINANCIAL HIGHLIGHTS

CONDENSED CONSOLIDATED BALANCE SHEETS
At December 31,
(in thousands)

	<u>2004</u>	<u>2003</u>
ASSETS		
Current Assets	\$ 3,410	\$ 2,122
Property, Plant and Equipment, Net	1,555	3,394
Other Assets	<u>2</u>	<u>1,106</u>
	<u>\$ 4,967</u>	<u>\$ 6,622</u>
LIABILITIES & STOCKHOLDERS' DEFICIT		
Current Liabilities	988	5,892
Long Term Debt, Net	5,064	52,797
Stockholders' Deficit	<u>(1,085)</u>	<u>(52,067)</u>
	<u>\$ 4,967</u>	<u>\$ 6,622</u>