

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**

Date of Report (Date of earliest event reported): November 12, 2004

ACURA PHARMACEUTICALS, INC.

695 North Perryville Road, Rockford, Illinois 61107

(815-399-2060)

Incorporated under the laws of State of New York

Commission File Number
1-10113

I.R.S. Employer Identification Number
11-0853640

Item 2.02 Results of Operations and Financial Condition

On November 12, 2004, Acura Pharmaceuticals, Inc. (the "Company") issued a press release disclosing the financial results for its third quarter ended September 30, 2004 and the nine months ended September 30, 2004. A copy of the Company's press release is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(b) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated November 12, 2004 Announcing Results for Third Quarter ended September 30, 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.

HALSEY DRUG CO., INC.

Date: November 15, 2004

By: /s/ Peter A. Clemens

Peter A. Clemens

Vice President & Chief Financial
Officer

EXHIBIT INDEX

Exhibit Number

Description

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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 RESULTS FOR THIRD QUARTER 2004,
ACCEPTANCE OF IND FILING BY FDA AND COMMENCEMENT OF CLINICAL TRIALS**

Palatine, IL, November 12, 2004: Acura Pharmaceuticals, Inc. (OTC.BB-ACUR) today announced a net loss of \$(51,480,000) or \$(2.35) per share for the quarter ended September 30, 2004 compared to a net loss of \$(11,590,000) or \$(0.55) per share for the same period in 2003. Included in results for the quarter is a non-cash charge of \$47,836,000 or \$(2.18) per share for amortization of debt discount and private debt offering costs compared to a non-cash charge of \$6,367,000 or \$(0.30) per share in the same three month period in 2003.

For the nine months ended September 30, 2004, the Company had a net loss of \$(67,912,000) or \$(3.12) per share compared to a net loss of \$(33,192,000) or \$(1.57) per share for the same period in 2003. During the nine months ended September 30, 2004, the Company recorded gains of \$12,401,000 from debt restructuring and \$2,388,000 from the divestment of certain non-revenue generating assets. Expenses for the nine month period included, among other things, a non-cash charge for amortization of debt discount and private debt offering costs of \$72,491,000 or \$(3.33) per share compared to a non-cash charge of \$18,050,000 or \$(0.85) per share for the same period in 2003.

Commenting, Andy Reddick, President and CEO said, "In the third quarter the Company completed the previously disclosed financial restructuring by converting approximately \$104.6 million of convertible debentures into approximately 218.0 million shares of preferred stock. Completing the financial restructuring eliminates approximately \$5.3 million in annual 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 three and nine month periods ended September 30, 2004 with those for 2003 it is important to understand that in 2004 the Company has focused its efforts and resources on proprietary research and development activities and, unlike for the same periods in 2003, no longer maintained any generic manufacturing facilities or conducted any activities relating to generic products except as part of an orderly phase out of such activities in the first quarter of 2004."

Developments regarding the Company's Abuse Deterrent Formulation Technologies

The Company's primary business focus is the research and development of proprietary abuse deterrent formulation technologies (the "ADF Technology") intended to deter the abuse of opioid-containing orally administered prescription products. The Company's first product candidate ("Product Candidate #1") incorporating the ADF Technology is a tablet formulation intended for oral administration. The Company received regulatory clearance to initiate a clinical trial program for Product Candidate #1 following the acceptance by the FDA of an investigational new drug application ("IND") in October 2004. The clinical development program for Product Candidate #1 focuses on optimizing the formulation for Product Candidate #1 to most effectively deter the potential for abuse while minimizing any new adverse events compared to non-ADF formulated products.

To date, the Company has performed pre-clinical research and development on Product Candidate #1 through a combination of internal and external collaborative research programs. The Company has and will continue to rely on contract research organizations ("CROs") to perform key components of its product development activities. Such development efforts include the completion of studies demonstrating the effectiveness of the ADF Technology compared to selected currently marketed products in deterring potential intravenous injection.

Through the use of CROs, the Company developed and submitted an IND to the FDA relating to Product Candidate #1. In October 2004, after amending such IND, the Company was cleared by the FDA to begin phase I clinical trials for Product Candidate #1. Also through the use of CROs, the Company has evaluated Product Candidate #1 in a single dose clinical study to assess the bioavailability and bioequivalence ("BA/BE") of such product candidate in comparison to a frequently prescribed, commercially marketed drug product with the same opioid active ingredient but without abuse deterrent properties. The results of the BA/BE study indicate that Product Candidate #1 is sufficiently bio-available but not bio-equivalent to the reference commercially marketed opioid product. The Company has subsequently developed a revised formulation of Product Candidate #1 and plans to test such revised formulation in a pilot BA/BE study to confirm that the revised formulation is both bioavailable and bioequivalent to a commercially marketed product without the abuse deterrent properties. There can be no assurance, however, that Product Candidate #1 will be bioequivalent to the extent required to justify continued clinical testing or that, even if it demonstrates acceptable bioequivalence, it will result in a commercially acceptable drug product.

To receive marketing authorization for commercial distribution in the United States, all drug products formulated with the ADF Technology will require the development, submission and filing of a new drug application ("NDA") and approval of such application by the FDA. In the event that Product Candidate #1 is stable and demonstrates acceptable bioequivalence, then substantial additional clinical and non-clinical testing will be required prior to the submission of an NDA. There can be no assurances that Product Candidate #1 will lead to an NDA submission or that if an NDA is filed, that the FDA will approve such regulatory application for commercial distribution

The Company intends to manufacture additional clinical trial supplies of its product candidates and in this regard has recently completed the construction of a tablet manufacturing suite and installation of related equipment at the Company's Culver, Indiana facility.

Commenting, Andy Reddick, said, "We envision that orally administered opioid containing products incorporating the ADF 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. With the FDA's acceptance of our IND for Product Candidate #1 the Company can continue moving its clinical development program forward and hopefully demonstrate that the ADF Technology is an effective abuse deterrent for commonly prescribed opioid-containing products."

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 of 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 share data)

	(unaudited) Nine Months Ended September 30,		(unaudited) Three Months Ended September 30,	
	2004	2003	2004	2003
Net Product Revenues	\$ 838	\$ 4,210	\$ -	\$ 1,478
Operating Costs				
Cost of Manufacturing	1,437	7,405	-	2,267
Research and Development	3,179	955	1,937	339
Selling, Marketing, General and Administrative	4,236	6,114	1,873	2,197
Loss from Operations	(8,014)	(10,264)	(3,810)	(3,325)
Other Income (Expense)				
Interest Income	40	22	18	1
Interest Expense	(2,839)	(4,436)	(687)	(1,532)
Amortization and Write-off of Deferred				
Debt Discount and Private Debt Offering Costs	(72,491)	(18,050)	(47,836)	(6,367)
Gain on Asset Disposals	2,388	-	633	-
Gain on Debt Restructuring	12,401	-	-	-
Other	603	(464)	202	(367)
Net Loss	<u>\$ (67,912)</u>	<u>\$ (33,192)</u>	<u>\$ (51,480)</u>	<u>\$ (11,590)</u>
Basic and Diluted Loss Per Common Share	<u>\$ (3.12)</u>	<u>\$ (1.57)</u>	<u>\$ (2.35)</u>	<u>\$ (0.55)</u>
Weighted Average Number of Outstanding Shares	<u>21,749,212</u>	<u>21,196,131</u>	<u>21,927,943</u>	<u>21,222,993</u>

ACURA PHARMACEUTICALS, INC.
FINANCIAL HIGHLIGHTS

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	(unaudited) September 2004	(audited) December 31, 2003
ASSETS		
Current Assets	\$ 4,841	\$ 2,122
Property, Plant and Equipment, Net	1,413	3,394
Other Assets	<u>28</u>	<u>1,106</u>
TOTAL ASSETS	<u><u>\$ 6,282</u></u>	<u><u>\$ 6,622</u></u>
LIABILITIES & STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities	1,008	5,892
Long Term Debt, Net	5,071	52,797
Stockholders' Equity (Deficit)	<u>203</u>	<u>(52,067)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	<u><u>\$ 6,282</u></u>	<u><u>\$ 6,622</u></u>

