

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

October 3, 2005  
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 (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 8.01

Other Events

On October 3, 2005, Acura Pharmaceuticals, Inc. (the "Company") issued a press release announcing the Company's receipt of communication from the U.S. Food and Drug Administration ("FDA") requesting certain non-clinical studies relating to the Company's Product Candidate #2. A copy of the Company's Press Release is attached hereto as Exhibit 99.1.

Item 9.01

Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release dated October 3, 2005 Announcing Receipt of FDA Communication.

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## **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: October 3, 2005

By: /s/ Peter A. Clemens

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Peter A. Clemens  
Vice President & Chief Financial Officer

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## **EXHIBIT INDEX**

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
99.1	Press Release dated October 3, 2005 Announcing Receipt of FDA Communication.

**FOR IMMEDIATE RELEASE**

**ACURA PHARMACEUTICALS, INC. RECEIVES COMMUNICATION FROM FDA**

**Palatine, IL, October 3, 2005:** Acura Pharmaceuticals, Inc. (OTC:BB-ACUR) today announced that the Company has received correspondence from the United States Food and Drug Administration ("FDA") recommending certain non-clinical studies be conducted prior to conducting further clinical testing of the Company's Product Candidate #2. The Company is therefore suspending the initiation of future clinical trials for Product Candidate #2 until the Company is able to more fully evaluate the basis for, and implications of, the FDA's recommendations. The Company intends to request a meeting with the FDA as quickly as possible to discuss all development requirements for Product Candidate #2. At this time no meeting date with FDA has been established.

**Cash Reserves Update**

The Company estimates that its current cash reserves will fund continued development of Product Candidate #2 and related operating expenses through October, 2005. To continue operating, 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.

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](http://www.acurapharm.com).