ACURA PHARMACEUTICALS, INC
Form 8-K
November 02, 2007

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

Date of Report (Date of earliest event reported): **November 2, 2007 (October 30, 2007)**

ACURA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

State of New York	**1-10113**	**11-0853640**
(State of Other Jurisdiction of Incorporation)	(Commission File Number)	(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 (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d- 2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e- 4(c))

Item 1.01 Entry into a Material Definitive Agreement.

On October 30, 2007, Acura Pharmaceuticals, Inc. (the "Company") and King Pharmaceuticals Research and Development, Inc. ("King"), a wholly-owned subsidiary of King Pharmaceuticals, Inc., entered into a License, Development and Commercialization Agreement (the "Agreement") to develop and commercialize certain opioid analgesic products utilizing the Company's proprietary Aversion® (abuse deterrent) Technology in the United States, Canada, and Mexico (the "Territory"). The Agreement provides King with an exclusive license in the Territory for Acurox™ (oxycodone HCl and niacin) Tablets (formerly known as OxyADF) and another undisclosed opioid product utilizing Acura's Aversion® Technology (the "Licensed Products"). In addition, the Agreement provides King with an option to license in the Territory all future opioid analgesic products developed utilizing Acura's Aversion® Technology (the "Future Products"). King's right to develop, manufacture and sell such Future Products is subject to King's exercise of its option rights for such Future Product, within 60 days after King's receipt of certain data from the Company demonstrating that such Future Product has achieved Proof of Concept (as defined). The Licensed Products and the Future Products are referred to herein collectively as the Products. The Agreement will become effective upon the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

In accordance with the Agreement, the Company and King will form a joint steering committee to coordinate product development, regulatory and commercialization strategies. The Company will retain responsibility, in consultation with King, for all development and regulatory activities for Acurox™ Tablets through regulatory approval by the FDA of the New Drug Application for such product candidate. With respect to all other products subject to the Agreement, King will be responsible for development and regulatory activities following either acceptance of an Investigational New Drug Application by the U.S. Food and Drug Administration or Acura's demonstration of certain stability and pharmacokinetic characteristics for each product. Assuming King timely exercises its option relating to a Future Product, King thereafter will be responsible for all development and regulatory activities relating to such Future Product. King is responsible for all manufacturing and commercialization activities in the Territory for the Licensed Products and for the Future Products for which it has exercised its option. King will have final decision making authority with respect to all development and commercialization activities for all Products subject to the Agreement.

The Company retains all rights to the Aversion® Technology outside of the Territory and for the development, manufacture and sale in the Territory of products not licensed to King pursuant to the Agreement. Additionally, in the absence of King's timely exercise of its option for Future Product, all rights to such Future Product shall be retained by the Company. King will own all clinical data and results, and regulatory submissions related to all Products developed under the Agreement, provided that the Company will have access to such clinical data and regulatory submissions on a royalty-free basis for use in its retained rights.

Under the terms of the Agreement, the Company will receive a non-refundable cash payment of $30 million upon the satisfaction of closing conditions and the effectiveness of the Agreement. The Company may receive additional non-refundable cash milestone payments based on the successful achievement of certain clinical and regulatory milestones for Acurox™ Tablets and for each other Product developed under the Agreement. The Company may also receive an additional $50 million non-refundable cash milestone payment when the aggregate net sales of all Products developed under the Agreement reach $750 million. In addition, the Company will receive from King royalty payments ranging from 5% to 25% based on the combined annual net sales of all Products developed under the Agreement. King's royalty payment obligations commence on the first anniversary of the first commercial sale of a Product and expire on the later of the expiration of the last to expire valid patent claim covering such product or 15 years from the first commercial sale of such Product in such country.

On a quarterly basis during the term of the Agreement, King will reimburse Acura for its expenses incurred to develop the Licensed Products, consisting of all of the Company's out-of-pocket expenses and internal research and development staff costs allocated to the development of such products. The Company's development expenses to be funded by King include those relating to (i) Acurox™ Tablets commencing September 19, 2007, (ii) qualifying a third-party supplier of the products, (iii) successfully achieving Proof of Concept for any Future Product for which King does not exercise its option to license such Future Product in the Territory, and (iv) product line extensions (as defined) for a Product as agreed to by the parties.

The foregoing provides only a brief summary of selected provisions of the Agreement and is qualified in its entirety by reference to the text of the Agreement attached hereto as Exhibit 10.1 and incorporated herein by reference. A copy of the press release issued in connection with the parties' announcement of the Agreement is attached hereto as Exhibit 99.1 and incorporated by reference herein.

This Report contains forward-looking statements about the Licensed Products, the Future Products, and Agreement between the Company and King. As with any pharmaceutical product under development or proposed to be developed, substantial risks and uncertainties exist in the process of development, regulatory review and commercialization. There can be no assurance that any product developed utilizing Aversion® Technology will receive regulatory approval or prove to be commercially successful. Accordingly, investors in the Company should recognize that there is no assurance that the Company will receive any milestone payment amounts described above for Acurox™ Tablets (formerly OxyADF) or any other product candidate utilizing Aversion® Technology, or even if such milestones are achieved, that the related Products will be successfully commercialized. For further discussion of these and other risks and uncertainties, see the Company's Annual Report on Form 10-K for the year ended December 31, 2006, under the heading "Risks Factors", its most recent quarterly report on Form 10-Q and its other public disclosures filed with the U.S. Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits

Exhibit Number	Description
10.1	License, Development and Commercialization Agreement dated October 30, 2007 between the Company and King Pharmaceuticals Research and Development, Inc.
99.1	Press Release of the Registrant dated October 31, 2007.

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 Clemens

Peter A. Clemens
Senior Vice President & Chief Financial Officer

Date: November 2, 2007

EXHIBIT INDEX

Exhibit Number	Description
10.1	License, Development and Commercialization Agreement dated October 30, 2007 between the Company and King Pharmaceuticals Research and Development, Inc.*
99.1	Press Release of the Registrant dated October 31, 2007.

* Certain information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portion.