

ACURA PHARMACEUTICALS, INC

FORM 8-K (Current report filing)

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Address	616 N. NORTH COURT, SUITE 120 PALATINE, IL 60067
Telephone	847-705-7709
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SIC Code	2834 - Pharmaceutical Preparations
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Sector	Healthcare
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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

January 3, 2017
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 (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01 Other Events

On January 3, 2017 we issued a press release announcing that we are exploring a range of financing and strategic alternatives, including a possible sale of the company and that we retained Roth Capital Partners LLC to assist in this process. A copy of our press release is attached as Exhibit 99.1 hereto and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated January 3, 2017

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: January 3, 2017

Exhibit Index

Exhibit Number

Description

99.1

Press Release dated January 3, 2017

Acura Pharmaceuticals Exploring Strategic Alternatives

****Roth Capital Engaged to Assist in the Process****

PALATINE, IL, January 3, 2017: Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, today announced that it is exploring a full range of financing and strategic alternatives, including a possible sale of the company. The Company has retained Roth Capital Partners to assist in this process. Alternatives to a sale of the company include a capital raising transaction, a licensing transaction and a sale of certain assets. There can be no assurance a transaction will result from this process and the company does not intend to disclose additional details unless and until it has entered into a specific transaction.

About Acura Pharmaceuticals

Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of product candidates intended to address medication abuse and misuse, utilizing its proprietary LIMITX™, AVERSION® and IMPEDE® Technologies. LIMITX contains ingredients that are intended to reduce or limit the rate or extent of opioid release when multiple tablets are ingested. AVERSION contains polymers that cause the drug to gel when dissolved; it also contains compounds that irritate the nasal passages if the product is snorted. IMPEDE is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

OXAYDO® (oxycodone HCl immediate-release tablets) which incorporates the AVERSION Technology, is FDA approved and marketed in the U.S. by our partner Egalet Corporation.

Acura markets NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products that utilize the IMPEDE Technology.

Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to:

- our ability to fund or obtain funding for our continuing operations;
 - the expected results of clinical studies relating to LTX-04 or any successor product candidate, the date by which such study results will be available and whether LTX-04 or any successor product candidate will ultimately receive FDA approval;
 - whether LIMITX will retard the release of opioid active ingredients as dose levels increase;
 - whether we will be able to reformulate LTX-04 or any successor product candidate to provide an efficacious level of drug when one or two tablets are taken;
 - whether we will be able to reformulate LTX-04 or any successor product candidate to improve its abuse deterrent performance;
 - whether the extent to which products formulated with the LIMITX technology deter abuse will be determined sufficient by the FDA to support approval or labelling describing abuse deterrent features;
 - whether our LIMITX technology can be expanded into extended-release formulations;
 - our and our licensee’s ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;
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- our and our licensee’s ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- the market acceptance of, timing of commercial launch and competitive environment for any of our products;
- expectations regarding potential market share for our products;
- our ability to develop and enter into additional license agreements for our product candidates using our technologies;
- the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
- the ability of our patents to protect our products from generic competition and our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation;
- the ability to fulfill the FDA requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development process to meet over-the-counter (“OTC”) Monograph standards, as applicable;
- the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates;
- changes in regulatory requirements;
- adverse safety findings relating to our commercialized products or product candidates in development;
- whether the FDA will agree with our analysis of our clinical and laboratory studies;
- whether further studies of our product candidates will be required to support FDA approval;
- whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and whether we will be able to promote the features of our abuse discouraging technologies;
- whether Oxaydo or our Aversion and LIMITX product candidates will ultimately deter abuse in commercial settings and whether our Nexafed products and Impede technology product candidates will disrupt the processing of pseudoephedrine into methamphetamine; and
- whether we will be able to maintain our listing on the NASDAQ Capital Market.

In some cases, you can identify forward- looking statements by terms such as “may,” “will”, “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “indicates”, “projects,” predicts,” “potential” and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in our filings with the Securities and Exchange Commission.

Contact:
for Acura Investor Relations
investors@acurapharm.com
847-705-7709
