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 8, 2018
Date of Report (Date of earliest event reported)

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):

☐ 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 (17CFR240.14d-2(b))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On January 8, 2018 we announced topline results from clinical study AP-LTX-301 (Study 301) for our LIMITx™ excess oral abuse deterrent drug LTX-03.

A press release regarding the foregoing is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

Exhibit Number	Description
99.1	Press Release dated January 8, 2018

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: January 8, 2018

Exhibit Index

Exhibit Number	Description
99.1	Press Release dated January 8, 2018

Exhibit 99.1

Acura Pharmaceuticals Announces Successful Results from Study AP-LTX-301

***** LIMITx™ Product LTX-03 Advancing to IND *****

PALATINE, IL, January 8, 2018: Acura Pharmaceuticals, Inc. (OTCQB: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, today announced that topline results from clinical study AP-LTX-301 (Study 301) for its LIMITx™ excess oral abuse deterrent drug LTX-03 identified a formulation that we believe optimizes the balance between providing therapeutic blood levels of drug for pain relief at a single tablet dose while retarding the bioavailability of drug when higher buffer levels are ingested. The Company intends to submit an Investigational New Drug application (IND) for LTX-03 to the US Food and Drug Administration (FDA) in the first quarter of 2018 and advance to clinical development for a New Drug Application (NDA). Current FDA approved abuse deterrent opioid formulations do not address abuse by swallowing excess numbers of tablets.

The patented LIMITx technology works by neutralizing stomach acid with buffering ingredients as increasing numbers of tablets are swallowed and relies on stomach acid to play a role in the release and subsequent systemic absorption of the active ingredient from micro-particles contained in the tablets. Prior clinical studies demonstrated the ability of LIMITx tablets to deliver efficacious levels of drug with no buffering added while reducing the maximum blood level (Cmax) by up to 65% when multiple tablet are ingested. Study 301 was designed to determine the optimal buffer level per tablet.

“With Study 301 we believe we have identified a per tablet buffer level that demonstrated good pharmacokinetics for both the efficacious and abused dose levels”, commented Dr. Al Brzeczko, Acura’s Vice President of Technical Affairs. “We are excited to advance LTX-03 to the IND phase and look forward to beginning the NDA development process.”

Study 301 was an open-label, parallel design pharmacokinetic study testing Acura’s LIMITx formulation LTX-03 in 72 healthy adult subjects randomized into 9 groups (8 subjects per group). One group swallowed a single Norco® 10/325mg tablet, the marketed comparator or reference drug. The remaining 8 groups swallowed a single LTX-03 tablet with increasing buffering amounts starting with no buffer, LTX-03 formulation A through H, respectively. All 72 subjects completed the study and the doses were generally well tolerated with no serious adverse events. One subject in the Formulation E group was not analyzed due to emesis. LTX-03 is a combination of hydrocodone bitartrate and acetaminophen.

In study 301 bioequivalence (BE) was examined to generate information for future registration studies. Results demonstrated a trend toward BE for both active ingredients in LTX-03 formulations A through E, with one at no buffer and four at lower buffer strength tablets. Formulation E had BE ratios (log transformed) for hydrocodone of 0.89 and 0.97 for Cmax and Area Under the Curve (AUC), respectively. In this small sample size study both hydrocodone BE confidence intervals were below the acceptable lower BE range of 0.80 at 0.74 and 0.79 for Cmax and AUC, respectively. For acetaminophen, Formulation E’s BE Ratios were 1.15 and 1.03 for Cmax and AUC, respectively. While the acetaminophen AUC’s met the BE standards, the Cmax upper confidence interval of 1.61 was above the acceptable upper BE range of 1.25. The Company believes that bioequivalence of this formulation may be achieved by reducing data variability that can be achieved through an adequately powered crossover study design with sufficient numbers of subjects in the study.

For LTX-03 Formulations F though H, the higher buffer level tablets, Study 301 demonstrated a progressively increasing reduction in hydrocodone Cmax culminating in a 34% Cmax reduction associated with Formulation H, the highest level evaluated. The Cmax for acetaminophen did not decline in Formulations F through H in Study 301.

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.

NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products that utilize the IMPEDE Technology, are marketed in the U.S. by our partner MainPointe Pharmaceuticals.

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, including the development of our products utilizing our LIMITx and Impede® technologies;
- the expected results of clinical studies relating to LTX-03 or any successor product candidate, the date by which such study will complete and the results will be available and whether LTX-03 or any successor product candidate will ultimately receive FDA approval;
- the ability of LTX-03 single tablets to demonstrate analgesic efficacy in a clinical study;
- the ability of LTX-03 to achieve bioequivalence in future studies;
- our ability to get an effective Investigational New Drug application (IND) for LTX-03 and progress into clinical studies;
- whether LIMITx will retard the release of opioid active ingredients as dose levels increase;
- whether our LIMITx formulation will continue to demonstrate an efficacious level of drug and acceptable 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;
- our and our licensee's ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;
- 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;

- 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 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; and
- 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.

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.

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