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): **January 2, 2020**

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

New York	**1-10113**	**11-0853640**
(State or other jurisdiction of incorporation or organization)	(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)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, $0.01 par value per share	ACUR	OTC – PINK

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):

☐ 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 (17CFR 240.14d-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 2, 2020 Acura Pharmaceuticals, Inc. issued a press release providing an update on the development of LTX-03 (Hydrocodone Bitartrate and Acetaminophen) Tablets using Acura's LIMITx™ technology intended to mitigate risks associated with overdose of the hydrocodone. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and incorporated herein by reference.

Item 9.01 - Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release of Acura Pharmaceuticals, Inc. dated January 2, 2020

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.

Date: January 2, 2020

ACURA PHARMACEUTICALS, INC.

By: /s/ Peter A. Clemens
Peter A. Clemens
Senior Vice President & Chief Financial Officer

Exhibit 99.1

Acura Pharmaceuticals Provides an Update on the Development of LTX-03

PALATINE, IL, January 2, 2020: Acura Pharmaceuticals, Inc. (OTC Pink: ACUR), today provided an update on its development of LTX-03 (Hydrocodone Bitartrate and Acetaminophen) Tablets using Acura's LIMITx™ technology intended to mitigate risks associated with overdose of the hydrocodone. In conjunction with a third party formulation developer, the formulation and manufacturing process for LTX-03 has been optimized for commercial scale. Acura's partnered commercial manufacturer has received hydrocodone quota from the Drug Enforcement Administration and is in the process of acquiring specific auxiliary equipment for the identified manufacturing process. Acura has also completed a non-clinical small animal study to identify the benefits of a reduction in peak plasma drug concentrations (Cmax) on opioid induced respiratory depression (OIRD).

LIMITx™ Technology is designed to retard the release of active drug ingredients when too many tablets are accidentally or purposefully ingested by neutralizing stomach acid with buffer ingredients, but to also deliver efficacious amounts of drug when taken as a single tablet with a nominal buffer dose. Acura's clinical testing to date indicates a reduction in opioid Cmax of up to 65% may be achieved in overdose situations. However, little is known about the influence of Cmax on OIRD particularly at overdose levels.

In study APT-RDR-300 all doses above 100 mg/kg demonstrated with statistical significance ($p<.05$) SpO2 measured OIRD at all time points post-dosing. The 100 mg/kg dose was not statistically significant for OIRD at any time point post-dosing. The mortality rate was correlated with higher doses. In all animals exhibiting OIRD, OIRD was acutely evident within 30 minutes of dosing which was consistent with the Cmax of the hydrocodone dose. Increased Cmax was generally associated with an increased prevalence of acute OIRD (SpO2 ≤70%). Approximately 50% of animals reaching this acute OIRD level resulted in death Due to a high variability in the pharmacokinetics and pharmacodynamics observed in the study, no further associations were possible. Acura believes the results of this study generally support the development of opioid products with a reduction in Cmax in overdose situations. The Company is assessing the results to determine if additional clinical or non-clinical OIRD studies should be performed.

Five groups of 11 Sprague-Dawley rats were orally administered doses of hydrocodone ranging from 100mg of drug per kg of body weight (mg/kg) up to 300 mg/kg. 8 subjects in each group were measured for respiratory depression assessing peripheral oxygen saturation (SpO2) of the blood over a 4 hour observation period. 36 subjects were analyzed as successfully completing the dosing. The additional 3 subjects in each group provided blood samples analyzed for hydrocodone at .5, 1, 2 and 4 hours post-dosing.

About Acura Pharmaceuticals

Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and product candidates intended to mitigate the risk of outcomes associated with product misuse. The Company has three proprietary technologies: LIMITx™ Technology, AVERSION® Technology and IMPEDE® Technology.

LIMITx™ Technology utilizes acid neutralizing ingredients to precisely control gastric acidity, which limits the release of drug from tablets and its subsequent systemic absorption when multiple tablets are ingested. LIMITx™ Technology is useful with products whose side effect risks can be mitigated by limiting exposure to a drug in overdose situations.

AVERSION® Technology, used in the FDA approved drug OXAYDO® (oxycodone HCl) marketed by Zyla Life Sciences, utilizes polymers designed to limit the abuse of the product by nasal snorting and injection. AVERSION® Technology is also licensed to Kempharm for use in certain of their products.

IMPEDE® Technology, used in NEXAFED® (pseudoephedrine HCl) and NEXAFED® Sinus (pseudoephedrine HCl/acetaminophen) marketed by MainPointe Pharmaceuticals, utilizes polymers and other ingredients to disrupt the extraction and processing of pseudoephedrine from the tablets into methamphetamine.

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;
- whether our licensees will terminate the license prior to commercialization;
- the expected results of clinical studies relating to LTX-03, IMPEDE® or any successor product candidate, the date by which such studies will complete and the results will be available and whether any product candidate will ultimately receive FDA approval;
- the ability of LTX-03 single tablets to achieve bioequivalence or to demonstrate efficacy in a clinical study;
- whether our licensing partners will exercise their options to additional products;
- whether LIMITx™ Technology will retard the release of opioid active ingredients as dose levels increase;
- whether the extent to which products formulated with the LIMITx™ Technology mitigate respiratory depression risk will be determined sufficient by the FDA;
- our and our licensee’s ability to successfully launch and commercialize our products and technologies;
- 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 an NDA and FDA approval of our product candidates;
- changes in regulatory requirements;
- adverse safety findings relating to our commercialized products or product candidates in development;
- 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 technologies; and
- whether our product candidates will ultimately perform as intended in commercial settings.

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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