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): **February 14, 2022**

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	OTCQB Market

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 February 14, 2022, Acura Pharmaceuticals, Inc. issued a press release providing an update on the development of LTX-03 (hydrocodone with acetaminophen) Tablets using Acura's LIMITx™ Technology. A copy of that press release is attached as Exhibit 99.1 to this report.

Forward-Looking Statements

Statements in the attached exhibit that are not strictly historical may be "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:

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- our ability to fund or obtain funding for our continuing operations, including the development of our products utilizing our LIMITx and IMPEDE technologies;
- whether we will receive FDA acceptance for an NDA for LTX-03 by the target date;
- whether our licensees will terminate the license prior to commercialization;
- the results of our clinical and other studies relating to LTX-03 or any successor product candidate, the date by which such studies will start and/or complete and the results will be available and whether any product candidate will ultimately receive FDA approval;
- whether our clinical program, as designed, will be sufficient for a successful NDA review;
- the ability of LTX-03 single tablets to achieve bioequivalence or to demonstrate efficacy in a clinical study;
- whether our licensing partners will develop any additional products and utilize Acura for such development;
- whether LIMITx 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.

Item 9.01 - Financial Statements and Exhibits

Exhibit Number	**Description**
99.1	Press Release of the Registrant dated February 14, 2022
104	Cover Page Interactive Data File (embedded as Inline XBRL document)

SIGNATURE

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: February 15, 2022

ACURA PHARMACEUTICALS, INC.

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

Exhibit 99.1

Acura Pharmaceuticals Provides Development Update on LTX-03

PALATINE, IL, February 14, 2022: Acura Pharmaceuticals, Inc. (OTCQB: ACUR) today announced that the LTX-03 (hydrocodone bitartrate and acetaminophen) tablets using Acura's LIMITx technology manufactured in the three New Drug Application ("NDA") required registration batches successfully passed testing at the six month time point in an ongoing shelf life study when stored at normal temperature and humidity conditions, also known as controlled room temperature ("CRT"). The patented LIMITx technology is a composition of inactive ingredients formulated in a manner that reduces the risks of drug overdose by reducing peak drug levels when inappropriate numbers of tablets are ingested.

When stored at high temperature and humidity, also known as accelerated conditions ("AC"), the six month tests revealed the presence of a known derivative of hydrocodone at levels requiring further testing. This known derivative was also detected in the CRT samples and intermediate condition ("IC") samples, those stored at temperatures and humidity between CRT and AC, at levels within normally accepted limits at this stage of development. We intend to continue the shelf life study with the CRT and IC samples as previously planned.

The LTX-03 tablets were produced at the commercial contract manufacturer, in the to-be-marketed formulation, at commercial (equipment and process) scale. The data being generated in the shelf life study is intended to be used to support the manufacturing and shelf life requirements for an NDA.

Acura has completed its review of the Advice Letter received in October 2021 from the Food and Drug Administration ("FDA") regarding our proposed clinical study program for LTX-03. We have updated the three pharmacokinetic study protocols submitted to the FDA and drafted a fourth pharmacokinetic study protocol based on the Advice Letter. These protocols have been provided to our development and commercialization partner, Abuse Deterrent Pharmaceuticals, LLC ("AD Pharma") for comment and determination of the timing of initiation of the studies. The new protocols will require submission to the FDA under the LTX-03 Investigational New Drug ("IND") application before they can commence.

LTX-03 (hydrocodone with acetaminophen)

Recent reports suggest growing numbers of legitimate pain patients are going undertreated as they can no longer find doctors willing to treat them due to new prescribing guidelines associated with the opioid epidemic. Suicide is increasingly seen as the only remedy for some of these patients through opioid overdose. Our goal with LIMITx is to develop a treatment for effective pain relief at a one or two tablet dose while providing overdose protection by limiting high peak levels of drug in the bloodstream (Cmax) that can lead to respiratory depression and death when more than the recommended dose is ingested. LIMITx works by neutralizing stomach acid with buffering ingredients as increasing numbers of tablets are swallowed thereby reducing the stomach acid available to cause the release and subsequent systemic absorption of the active ingredient from micro-particles contained in the LIMITx tablets. In a human clinical study, formulations of LTX-03 demonstrated, under fasted conditions, analgesic levels of hydrocodone in the blood when taken at a recommended one or two tablet dose but reduced the maximum blood level (Cmax) up to 34% when subjects were exposed to higher buffer ingredient levels. Hydrocodone with acetaminophen remains the single largest prescribed opioid in the U.S. with excess oral ingestion as the most prevalent method of misuse. Clinical studies with hydromorphone (LTX-04) demonstrated reductions in Cmax of up to 65% when up to 8 tablets were ingested. Analysis of forensic data associated with hydrocodone overdose death suggests a typical consumption of approximately 16 immediate-release tablets, well within the number of tablets in an average filled opioid prescription. The Company intends to demonstrate that a meaningful reduction in Cmax associated with oral overdose can mitigate the risk of respiratory depression and death. LTX-03 may offer safety advantages over existing opioid therapies consistent with the Food and Drug Administration's (FDA) recently proposed new guidelines for the approval of opioid products.

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™, AVERSION® and IMPEDE®.

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

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

IMPEDE, 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.

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