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): **August 31, 2023**

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 Market – OTC Expert 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 (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))

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.

Acura Pharmaceuticals, Inc. reported today 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 passed testing at the twenty-four 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 excessive numbers of tablets are ingested.

Two known hydrocodone derivatives continues to be detected in the CRT samples, as well as, unknown impurities. The unknown impurities remain at levels within standards typically accepted by the Food and Drug Administration (FDA) for such impurities but the levels have increased since the eighteen month analysis. We intend to continue the shelf life study with the CRT 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 a NDA. FDA Guidance allows for the use of a minimum of 24 month CRT data to establish shelf life standards for a product.

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 30% 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. 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 FDA's recently proposed new guidelines for the approval of opioid products.

Acura Forward-Looking Statements

Statements in this Current Report constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and these forward-looking statements are made in reliance on the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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:

- whether the FDA will agree with or accept the results of our studies for our product candidates;
- 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;
- whether we can successfully submit a New Drug Application for LTX-03, request a priority review and whether such filings and requests will be accepted by the FDA;
- our ability to obtain funding from Abuse Deterrent Pharma, LLC or other parties for our continuing operations, including the development of our products utilizing our LIMITx™ and Impede® technologies;
- whether we can renegotiate the date by which we are required to obtain FDA acceptance, currently November 30, 2023, for an NDA for LTX-03 by our agreement with Abuse Deterrent Pharma, LLC on which we depend to finance operations;

- whether we can renegotiate the date by which we are required to pay off the promissory notes and accrued interest to Abuse Deterrent Pharma, LLC, currently December 31, 2023;
- whether our licensing partners will develop any additional products and utilize Acura for such development;
- the expected results of clinical studies relating to LTX-03, a LIMITx hydrocodone bitartrate and acetaminophen combination product, or any successor product candidate, the date by which such studies will be complete and the results will be available and whether LTX-03 will ultimately receive FDA approval;
- our business could be adversely affected by health epidemics in regions where third parties for which we rely, as in CROs or CMOs, have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely;
- 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 reduce respiratory depression will be determined sufficient by the FDA to support approval or labelling describing safety features;
- our and our licensee's ability to successfully launch and commercialize our products and technologies;
- the results and timing of our development of our LIMITx Technology, including, but not limited to, the submission of a NDA and/or FDA filing acceptance;
- our or our licensees' 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;
- our exposure to product liability and other lawsuits in connection with the commercialization of our products;
- the increasing cost of insurance and the availability of product liability insurance coverage;
- 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 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 "aim", "anticipate", "believe", "could", "design", "estimate", "expect", "forecast", "goal", "guidance", "imply", "indicate", "intend", "may", "objective", "opportunity", "outlook", "plan", "position", "potential", "predict", "project", "prospective", "pursue", "seek", "should", "strategy", "target", "would", "will", and other words of similar meaning, expressions, derivations of such words and the use of future dates 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 Acura's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC") and in other filings Acura makes with the SEC from time to time. Investors and potential investors are urged not to place undue reliance on forward-looking statements in this communication, which speak only as of this date of the Current Report and are based on the Company's current beliefs, assumptions, and expectations. While Acura may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to update or revise any forward-looking statements contained in this Current Report whether as a result of new information or future events, except as may be required by applicable law.

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: August 31, 2023