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): **May 15, 2025**

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 (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.

Acura Pharmaceuticals, Inc.reported today that on May 15, 2025 the Company and its development partner, Abuse Deterrent Pharma, LLC, had a second meeting with the US Food and Drug Administration (FDA) regarding further development requirements for its drug candidate LTX-03 (hydrocodone bitartrate and acetaminophen) tablets to progress toward a New Drug Application (NDA) submission. LTX-03 uses Acura's LIMITx technology that is designed to provide incrementally lower, non-linear peak drug blood concentrations (Cmax) of hydrocodone as additional tablets are ingested.

Subject to the final FDA meeting minutes and further deliberations and analyses by the Companies, we expect to conduct one additional human pharmacokinetic study of a single tablet dose of LTX-03 compared to a single FDA Reference Standard drug in the fed and fasted state. This study, designated AP-LTX-310, will commence following production of new clinical supplies of LTX-03.

Subject to NDA review, FDA was amenable to describing the unique pharmacokinetic characteristics of LTX-03 in the final approved labeling. FDA advised that a label claim suggesting a lower risk of overdose would not be warranted by pharmacokinetic testing alone. The Company believes a study to support a lower risk safety claim would best be accomplished post-NDA approval, which cannot be assured.

FDA indicated the lower 5/325mg and 7.5/325mg dosage strengths of LTX-03 will require a plan to scientifically support those products in the NDA. We are evaluating whether to conduct such a study for the NDA submission or to study and add these strengths after NDA approval, which cannot be assured.

LTX-03 (hydrocodone with acetaminophen)

The incidence and severity of side effects, such as nausea, vomiting and respiratory depression, associated with opioid pain relievers, such as hydrocodone, increase with increased blood plasma concentration of the opioid. Our goal with LTX-03 is to develop a treatment that delivers hydrocodone into the blood stream at a rate and extent to effectively treat pain at a one or two tablet dose. However, as more tablets are ingested, the rate at which the hydrocodone is absorbed slows providing a non-linear diminishing of peak drug concentration (Cmax). 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 is one of the most prescribed opioid analgesics in the U.S.

Forward-Looking Statements

Statements in this Current Report 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 we will receive FDA acceptance for an NDA for LTX-03 by the agreed target date with licensee;
- whether our licensees will terminate the license prior to commercialization;
- the expected results of clinical studies relating to LTX-03 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 food or other concomitantly ingested drugs or products will adversely impact the safety and/or efficacy our products;
- whether we will develop all possible tablet strengths of our product candidates before NDA submission;
- our ability to get our pharmacokinetic profile or any other feature of our product candidates described in any FDA approved label;
- 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;
- 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.

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/ Robert A. Seiser
Robert A. Seiser
Senior Vice President & CFO

Date: May 21, 2025