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): **July 26, 2021**

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 1.01 – Entry into a Material Definitive Agreement

On July 26, 2021, Acura Pharmaceuticals, Inc. (“we” “Acura” or the “Company”), entered into a second amendment to the June 28, 2019 License, Development and Commercialization Agreement (the "Second Amended Agreement") with Abuse Deterrent Pharma, LLC (“AD Pharma”). The Second Amended Agreement extends the FDA’s acceptance of a New Drug Application (“NDA”) for LTX-03 from July 31, 2021 to February 28, 2022.

AD Pharma may terminate the Amended Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA by February 28, 2022, AD Pharma may terminate the Amended Agreement and take ownership of the intellectual property rights of the Company to LTX-03. Should AD Pharma choose not to exercise this option to terminate and the NDA for LTX-03 is subsequently accepted by the FDA, such option expires.

The inclusion of a description of the Amended Agreement with AD Pharma under Item 1.01 of this Current Report on Form 8-K shall not be deemed an acknowledgement that the Amended Agreement is a material agreement not made, or deemed not to be made, in the ordinary course of our business.

AD Pharma is our largest shareholder and, as of June 16, 2021, to our knowledge owns approximately 66% of our common stock, which does not include their Warrant to purchase 10.0 million shares of the Company’s common stock.

Item 2.01 – Completion of Acquisition or Disposition of Assets

The contents of Item 1.01 are incorporated herein by reference.

Item 2.03 – Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant

The contents of Item 1.01 are incorporated herein by reference.

Item 8.01 – Other Events

On July 26, 2021, Acura Pharmaceuticals, Inc. issued a press release announcing a second amendment to the License, Development and Commercialization Agreement. A copy of that press release is attached as Exhibit 99.1 to this report. The contents of Item 1.01 are incorporated herein by reference.

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:

- 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 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 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 June 26, 2021

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: July 28, 2021

ACURA PHARMACEUTICALS, INC.

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

Exhibit 99.1

Acura Pharmaceuticals and AD Pharma Amend License to LIMITx™ LTX-03

Amendment Extends NDA Acceptance Date

PALATINE, IL, July 26, 2021: Acura Pharmaceuticals, Inc. (OTCQB: ACUR) today announced an amendment to its License, Development and Commercialization Agreement ("Agreement") regarding Acura's LIMITx™ LTX-03 product candidate with Abuse Deterrent Pharma, LLC ("AD Pharma") to extend the FDA Acceptance Date for LTX-03 ("NDA Acceptance Date") to February 28, 2022.

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.

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 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 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;
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- 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;
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Contact:

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