
**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): **June 7, 2021**

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

New York
(State or other jurisdiction of
incorporation or organization)

1-10113
(Commission File Number)

11-0853640
(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:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
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 June 7, 2021, 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:

- our ability to obtain funding 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 Food and Drug Administration (“FDA”) acceptance, currently July 31, 2021, for an NDA for LTX-03 by our Agreement with Abuse Deterrent Pharmaceuticals, LLC on which we depend to finance operations;
 - 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 with 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;
 - whether LTX-03 will successfully demonstrate suitable shelf life studies;
 - our and our licensee's ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;
 - the results and timing of our development of our LIMITx Technology, including, but not limited to, the submission of a New Drug Application 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;
 - 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;
 - 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 further studies of our product candidates will be required to support FDA approval;
 - 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.
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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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of the Registrant dated June 7, 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: June 7, 2021

ACURA PHARMACEUTICALS, INC.

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



Acura Pharmaceuticals Provides Development Update on LTX-03

PALATINE, IL, June 7, 2021: Acura Pharmaceuticals, Inc. (OTCQB: ACUR) today announced the successful completion of three NDA required registration batches of the to-be-marketed LTX-03 formulation. The LTX-03 tablets were manufactured on commercial scale equipment and passed all requisite quality assurance tests. The LTX-03 tablets from these batches will be used in a six month shelf life stability study, which will commence immediately, and in human clinical studies, which will commence after an update to the Investigation New Drug application on file with the Food and Drug Administration (FDA).

We, along with our Partner, Abuse Deterrent Pharmaceuticals, LLC, intend to conduct 3 clinical studies as was proposed to the FDA in our updated IND submitted in February 2021.

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 an innovative drug delivery company engaged in the research, development and commercialization of technologies and products intended to address safe use of medications. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products: LIMITx™ Technology, AVERSION® Technology and IMPEDE® Technology.

LIMITx™ Technology, a development stage 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 deliver efficacious amounts of drug when taken as a single tablet with a nominal buffer dose. In June 2020, we entered into License, Development and Commercialization Agreement, which was amended in October 2021, with Abuse Deterrent Pharmaceuticals, LLC, ("AD Pharma") a Kentucky limited liability company and a special purpose company representing a consortium of investors that will finance Acura's operations through July 2021 and reimburse us for development of LTX-03. AD Pharma has exclusive commercialization rights in the United States to LTX-03 as well as to LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam).

AVERSION® Technology, 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® 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 obtain funding 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 July 31, 2021, for an NDA for LTX-03 by our Agreement with AD Pharma on which we depend to finance operations;
- 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;
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 - 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;
 - whether the FDA will agree with or accept the results of our studies for our product candidates;
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- 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;
- 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 further studies of our product candidates will be required to support FDA approval;
- 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
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