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): **October 16, 2020**

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 (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 1.01 Entry into a Material Definitive Agreement.

On October 16, 2020, Acura Pharmaceuticals, Inc. (“we” “Acura” or the “Company”) entered into an Amendment to the June 28, 2019 License, Development and Commercialization Agreement (the "Amended Agreement") with Abuse Deterrent Pharmaceuticals, LLC, a Kentucky limited liability company (“AD Pharma”), a special purpose company organized by investors that will provide financing, as described below, for Acura’s operations and completion of development of LTX-03 (hydrocodone bitartrate with acetaminophen) immediate-release tablets utilizing Acura’s patented LIMITx™ technology which addresses the consequences of excess oral administration of opioid tablets, the most prevalent route of opioid overdose and abuse.

The Amended Agreement provides for monthly license payments to Acura by AD Pharma of $350 thousand from inception through April 2020 and $200 thousand thereafter until July 31, 2021 or FDA’s acceptance of a New Drug Application (“NDA”) for LTX-03 and reimbursement by AP Pharma of Acura’s LTX-03 outside development expenses. Acura currently expects the submission and FDA acceptance of a new drug application (“NDA”) for LTX-03 to occur in the second quarter of 2021. The Amended Agreement grants AD Pharma exclusive commercialization rights in the United States to two additional products, LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam).

AD Pharma may terminate the Amended Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA by July 31, 2021, 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.

Item 1.01 License, Commercialization and Option Agreement with MainPointe Pharmaceuticals, LLC

On June 28, 2019, we granted authority to MainPointe Pharmaceuticals, LLC (MainPointe) to assign to AD Pharma the option and the right to add, as an Option Product to the Nexafed® Agreement, a Nexafed® 12-hour dosage (an extended-release pseudoephedrine hydrochloride product utilizing the IMPEDE® Technology in 120mg dosage strength) and the Option Product exercise price of $500 thousand was waived if the exercise of the option occurred by June 28, 2024 (five years from the effective date of the License, Development and Commercialization Agreement with AD Pharma). Effective with the Amended Agreement with AD Pharma, this option and right was rescinded. In March 2017, we granted MainPointe an exclusive license to our IMPEDE ® Technology to commercialize our Nexafed® and Nexafed® Sinus Pressure + Pain Products in the United States and Canada.

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

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.

Certain statements in this 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 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 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 deter abuse or overdose will be determined sufficient by the FDA to support approval or labelling describing safety and/or abuse deterrent features;
- whether our LIMITx Technology can be expanded into extended-release formulations;
- 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.

Item 9.01 Financial Statements and Exhibits

Exhibit Number	**Description**
99.1	Press Release of the Registrant dated October 28, 2020

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: October 29, 2020

Exhibit 99.1

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

Amendment Extends NDA Acceptance Date and Expands Agreement

PALATINE, IL, October 28, 2020: 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 Pharmaceuticals, LLC ("AD Pharma") to extend the FDA Acceptance Date for LTX-03 ("NDA Acceptance Date"), expand the product licenses, and revise the license payment schedule. Acura's LIMITx™ technology, when applied to any pharmaceutical product, is designed to mitigate the adverse consequences associated with the overdose of tablets. The amended Agreement extends the NDA Acceptance Date to July 31, 2021, expands AD Pharma's license to the LIMITx™ patents to LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam), and revises the license payments, effective as of May 2020, to $200,000 monthly running through July 2021.

Acura and AD Pharma experienced certain delays in the manufacturing scale-up for LTX-03 including the purchase and installation of auxiliary manufacturing equipment and COVID-19 risk mitigation strategies implemented in the Spring and early Summer at the New Jersey based contract manufacturer that necessitated the amendment of the NDA Acceptance Date as AD Pharma has certain termination rights associated with such date. Development of LTX-02 and/or LTX-09 by Acura on behalf of AD Pharma will be subject to future development agreements, if any.

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;
- 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.

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