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

June 28, 2019
Date of Report (Date of earliest event reported)

ACURA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

State of New York	**1-10113**	**11-0853640**
(State of Other Jurisdiction of Incorporation)	(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)

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 (see General Instruction A.2. below):

☐ 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. ☐

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	ACUR	OTC - PINK

Item 1.01 Entry into a Material Definitive Agreement.

On June 28, 2019, Acura Pharmaceuticals, Inc. (“we” “Acura” or the “Company”) entered into a License, Development and Commercialization Agreement (the "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 Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03. The Agreement provides for monthly license payments by AD Pharma to us of $350,000 up to the earlier of 18 months 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. Upon commercialization, as defined, of LTX-03, Acura will receive stepped-up royalties on sales and is eligible for additional payments based upon the achievement of certain milestones.

AD Pharma may terminate the Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA within 18 months, AD Pharma may terminate the Agreement and take ownership of the intellectual property rights of the Company to LTX-03.

The inclusion of a description of the Agreement 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 1.01 Loan Agreement with John Schutte

On June 28, 2019, we entered into a Promissory Note with John Schutte that consolidated existing promissory notes into a single Note for $6.0 million. Terms of the consolidated loan provide for a July 1, 2023 maturity date rather than the previous maturity date of January 2, 2020 for the loan from Mr. Schutte, interest at fixed rate of 7.5% per annum, and deferral of all payments of principal and interest to maturity. We also granted to Mr. Schutte conversion rights of the $6.0 million loan into Acura common stock at $0.16 per share, issued to him a warrant to purchase 10.0 million shares of the Company’s common stock at a price of $0.01 per share and granted a security interest in all Acura assets.

With our consent, Mr. Schutte assigned and transferred to AD Pharma all of his right, title and interest in this Note, Security Agreement and Warrant effective June 28, 2019.

The shares issuable to AD Pharma upon conversion of the Note and exercise of the Warrant represent 69% of the shares of the Company calculated in accordance with Rule 13d-3 promulgated under the Securities Exchange Act.

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). 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.

Mr. Schutte is our largest shareholder and, as of March 15, 2018, to our knowledge beneficially owned approximately 47.5% of our common stock (after giving effect to the exercise of warrants to purchase 1,782,531 shares of Common Stock that he holds). Mr. Schutte also controls MainPointe and, we have been informed by Mr. Schutte, is a member of AD Pharma. The percentage of stock beneficially owned by Mr. Schutte does not include shares beneficially owned by AD Pharma.

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 3.02 Unregistered Sales of Equity

On June 28, 2019, we issued a $6 million note convertible into 37,500,000 shares of our Common Stock (at a conversion price of $.16 per share) and warrants to purchase 10 million shares of common stock at $.01 per share. The note and warrants were issued in reliance upon Section 4(a)(2) of the Securities Act of 1933, as amended. The purchase, nature of the transaction and consideration are described in Item 1.01 which is 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 fund or obtain funding for our continuing operations, including the development of our products utilizing our LIMITx and IMPEDE technologies;
- whether our licensees will terminate the license prior to commercialization;
- the expected results of clinical studies relating to LTX-03, IMPEDE ER 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 exercise their options to additional products;
- 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.

Item 9.01 Financial Statements and Exhibits

Exhibit Number	Description
99.1	Press Release of the Registrant dated July 2, 2019

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: July 5, 2019

Exhibit 99.1

Acura Pharmaceuticals Licenses LIMITx™ LTX-03

Agreement Provides For Completion of Development and Commercialization

Transaction Valued at up to $21.3 Million, not including Royalties

PALATINE, IL, July 2, 2019: Acura Pharmaceuticals, Inc. (OTC Pink: ACUR) today announced a License, Development and Commercialization Agreement (the "Agreement") with Abuse Deterrent Pharmaceuticals, LLC (“AD Pharma”), a special purpose company representing a consortium of investors that will finance 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. AD Pharma retains commercialization rights from which Acura will receive royalties and potential sales related milestones.

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 standards for the approval of opioid products.

Financial Terms

The Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03. Financial arrangements include:

- Monthly license payments by AD Pharma of $350,000 up to the earlier of 18 months or FDA’s acceptance of a New Drug Application (“NDA”) for LTX-03;

- Reimbursement by AP Pharma of Acura's LTX-03 outside development expenses;
- A $6 million loan which consolidates $5.25 million in prior loans from Mr. John Schutte plus an additional $750 thousand loan upon execution of the Agreement. Terms of the consolidated loan are amended to provide for a July 1, 2023 maturity date, interest at 7.5% with all payments of principle and interest deferred to maturity, conversion rights into Acura common stock at $0.16, the issuance of a warrant to AD Pharma to purchase 10 million shares of the Company's common stock at a price of $0.01 per shares and a security interest in all Acura assets;
- Upon commercialization of LTX-03, Acura receives stepped royalties on sales and is eligible for certain sales related milestones; and
- Acura authorizes 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);

AD Pharma may terminate the Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA within 18 months, AD Pharma may terminate the Agreement and take ownership of the intellectual property.

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 Egalet Corporation, 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 our licensees will terminate the license prior to commercialization;
- the expected results of clinical studies relating to LTX-03, IMPEDE ER 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 exercise their options to additional products;
- 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;
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- the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
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- changes in regulatory requirements;
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- 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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