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 15, 2023**

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 1.01 - Entry into a Material Definitive Agreement.

On June 15, 2023, Acura Pharmaceuticals, Inc. ("we" "Acura" or the "Company"), entered into an agreement to further amend the June 28, 2019 License, Development and Commercialization Agreement ("Agreement") with Abuse Deterrent Pharma, LLC ("AD Pharma"), for the 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 amendment to the Agreement extends the FDA's acceptance date of a New Drug Application ("NDA") for LTX-03 to November 30, 2023 ("NDA Acceptance Date") ("Amended Agreement").

AD Pharma may terminate the Amended Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA by the NDA Acceptance Date, AD Pharma may terminate the Amended Agreement and take ownership of the intellectual property rights of LTX-03 from the Company. Should AD Pharma choose not to exercise this option to terminate the Amended Agreement and the NDA for LTX-03 is subsequently accepted by the FDA, such option to terminate the Amended Agreement 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 acknowledgment that the Amended Agreement is a material agreement not made, or deemed not to be made, in the ordinary course of our business.

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

At April 30, 2023, AD Pharma directly owns approximately 66% of the outstanding common stock of the Company. The ownership percentage of the Company held by AD Pharma does not include their warrant to purchase 10.0 million shares of common stock of the Company. AD Pharma is an entity controlled by Mr. Schutte, of which Mr. Schutte is the managing partner and investor. At April 30, 2023, Mr. Schutte directly owns approximately 14% of our 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.

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 target date, currently November 30, 2023;
- 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	Amendment #6 dated June 15, 2023 to License, Development and Commercialization Agreement with Abuse Deterrent Pharma, LLC
104	Cover Page Interactive Data File (embedded as Inline XBRL document)

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: June 27, 2023

Exhibit 99.1

AMENDMENT #6
TO LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This AMENDMENT #6 (this "**Amendment**") TO LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (the "**Agreement**") dated June 28, 2019 between Acura Pharmaceuticals, Inc. ("**Acura**"), a New York corporation, having a place of business at 616 N. North Court, Suite 120, Palatine, IL 60067, and Abuse Deterrent Pharma, LLC ("**AD Pharma**"), a Kentucky limited liability company, having a place of business at 333 E. Main Street, Suite 220, Louisville, Kentucky 40202, is made as of June 15, 2023.

RECITALS

WHEREAS, Acura and AD Pharma entered into that certain Amendment to the Agreement on October 16, 2020 ("**Amendment #1**");

WHEREAS, Acura and AD Pharma entered into that certain Amendment #2 to the Agreement on June 17, 2021 ("**Amendment #2**"); and

WHEREAS, Acura and AD Pharma entered into that certain Amendment #3 to the Agreement on February 28, 2022 ("**Amendment #3**") and

WHEREAS, Acura and AD Pharma entered into that certain Amendment #4 to the Agreement on November 10, 2022 ("**Amendment #4**" and

WHEREAS, Acura and AD Pharma entered into that certain Amendment #5 to the Agreement on December 8, 2022 ("**Amendment #5**" and together with Amendment #1, Amendment #2, Amendment #3, and Amendment #4 constitute the "**Prior Amendments**"); and

WHEREAS, the Parties desire to amend the Agreement to provide for an extension to the LIMITx™ Regulatory Submission Timeline.

NOW THEREFORE, in consideration of the mutual covenants and promises contained in the Agreement, as amended, and this Amendment and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Acura and AD Pharma agree as follows:

ARTICLE 1
AMENDMENTS TO AGREEMENT

1.1 Item 3 of Schedule 1 "LIMITx™ Regulatory Application Submission Timeline" is hereby amended and replaced in its entirety as follows:

3. By November 30, 2023, Acura must gain filing acceptance by the FDA of a Regulatory Approval Application for the Product.

ARTICLE 2
MISCELLANEOUS

2.1 **Governing Law**. This Amendment shall be governed by the laws of the State of New York without regard to its conflict of laws rules or principles.

2.2 **Amendments**. Except as expressly amended by this Amendment #5 and the "Prior Amendments", the Agreement shall remain unmodified and in full force and effect.

2.3 **Entire Agreement.** The Agreement (including the Schedules attached thereto), as amended by the "Prior Amendments" and this Amendment, constitutes the entire agreement of the Parties with respect to the subject matter hereof and supersede all prior understandings and writings between the Parties relating thereto.

2.4 **Interpretation.** Any capitalized terms used in this Amendment and not otherwise defined herein shall have the meaning provided in the Agreement.

2.5 **Counterparts.** This Amendment may be executed manually or electronically by the Parties, in any number of counterparts, each of which shall be considered one and the same amendment and shall become effective when a counterpart hereof shall have been signed by each of the Parties and delivered to the other Party.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed in their names by their properly and duly authorized officers or representatives as of the date first written above.

ACURA PHARMACEUTICALS, INC.

By: /s/ Peter A. Clemens
Name: Peter A. Clemens
Title: CFO and Vice President

ABUSE DETERRENT PHARMA, LLC

By: /s/ John Schutte
Name: John Schutte
Title: Managing Partner