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): **March 25, 2024**

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 (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 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 March 25, 2024, Acura Pharmaceuticals, Inc. ("we" "Acura" or the "Company"), received the executed 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 June 30, 2024 ("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.

Item 1.01 - Entry into a Material Definitive Agreement.

On March 25, 2024, Acura Pharmaceuticals, Inc. ("we" "Acura" or the "Company"), received the executed agreement to further amend the November 10, 2022 Amended, Consolidated and Restated Secured Promissory Note (the "Note") with Abuse Deterrent Pharma, LLC ("AD Pharma"). Amendment #2 has an effective date of March 15, 2024 and changes the maturity date of the Note from March 31, 2024 to June 30, 2024, at which time all principal and interest is due. As of March 15, 2024, the Note's principal balance was $5,419,279, bears interest at 5.25%, and had an accrued interest balance of approximately $265,000. Events of default under the Note include, among other items, bankruptcy events, failure to pay interest and principal when due and such failure continues for 5 days, and if Acura is generally not, or is unable to, or admits in writing its inability to, pay its debts as they become due. If any amount payable hereunder is not paid when due (without regard to any applicable grace periods), whether at stated maturity, by acceleration, or otherwise, including upon an event of default, such overdue amount shall bear interest at the rate per annum of 7.5% from the date of such non-payment until such amount is paid in full.

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 March 15, 2024, AD Pharma directly owns approximately 65% 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. John Schutte, of which Mr. Schutte is the managing partner and investor. At March 15, 2024, Mr. Schutte directly owns approximately 14% of the outstanding common stock of the Company.

Item 2.01 – Completion of Acquisition or Disposition of Assets

The contents of both Items 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 both Items 1.01 are incorporated herein by reference.

Acura Forward-Looking Statements

Statements in this Current Report constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and these forward-looking statements are made in reliance on the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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:

- 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;
- whether we can successfully submit a New Drug Application for LTX-03, request a priority review and whether such filings and requests will be accepted by the FDA;
- our ability to obtain funding from Abuse Deterrent Pharma, LLC or other parties 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 June 30, 2024, for an NDA for LTX-03 by our agreement with Abuse Deterrent Pharma, LLC on which we depend to finance operations;
- whether we can renegotiate the date by which we are required to pay off the promissory notes and accrued interest to Abuse Deterrent Pharma, LLC, currently June 30, 2024;
- 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 reduce respiratory depression will be determined sufficient by the FDA to support approval or labelling describing safety features;
- our and our licensee's ability to successfully launch and commercialize our products and technologies;
- the results and timing of our development of our LIMITx Technology, including, but not limited to, the submission of a NDA 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;
- 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 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 “aim”, "anticipate", "believe", "could", "design", "estimate", "expect", "forecast", "goal", "guidance", "imply", “indicate”, "intend", "may", "objective", "opportunity", "outlook", "plan", "position", "potential", "predict", "project", "prospective", "pursue", "seek", "should", "strategy", "target", "would", "will", and other words of similar meaning, expressions, derivations of such words and the use of future dates 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 Acura’s Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC") and in other filings Acura makes with the SEC from time to time. Investors and potential investors are urged not to place undue reliance on forward-looking statements in this communication, which speak only as of this date of the Current Report and are based on the Company’s current beliefs, assumptions, and expectations. While Acura may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to update or revise any forward-looking statements contained in this Current Report whether as a result of new information or future events, except as may be required by applicable law.

Item 9.01 - Financial Statements and Exhibits

Exhibit Number	**Description**
99.2	Amendment #8 to the License, Development and Commercialization Agreement with Abuse Deterrent Pharma, LLC
99.3	Amendment #2 to the November 10, 2022 Amended, Consolidated and Restated Secured Promissory Note
104	Cover Page Interactive Data File (embedded within 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: March 26, 2024

Exhibit 99.2

AMENDMENT #8
TO LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This AMENDMENT #8 (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 March 15, 2024.

RECITALS

WHEREAS, Acura and AD Pharma have entered into certain Amendments to the Agreement (the **"Prior Amendments"**) as follows: Amendment #1 on October 16, 2020,
Amendment #2 on June 17, 2021,
Amendment #3 on February 28, 2022,
Amendment #4 on November 10, 2022,
Amendment #5 on December 8, 2022,
Amendment #6 on June 15, 2023, and
Amendment #7 on November 13, 2023**; 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 June 30, 2024, 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 #8 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.

/s/ Robert Jones
Name: Robert Jones
Title: President and CEO

ABUSE DETERRENT PHARMA, LLC

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

Exhibit 99.3

AMENDMENT #2
AMENDED, CONSOLIDATED AND RESTATED
SECURED PROMISSORY NOTE

This AMENDMENT #2 (this "**Amendment**") TO AMENDED, CONSOLIDATED AND RESTATED SECURED PROMISSSORY NOTE (the "**Note**") dated November 10, 2022 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 March 15, 2024.

RECITALS

WHEREAS, the Parties desire to amend the Note to change the Maturity Date of this Note.

NOW THEREFORE, in consideration of the mutual covenants and promises contained in the Note, 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
AMENDMENT TO AGREEMENT

1.1 Item 2.1 "Maturity Date" is hereby amended and replaced in its entirety as follows:

The Company agrees to pay the principal sum of this Note and interest on the unpaid principal sum of this Note on June 30, 2024 (the "**Maturity Date**"). Time shall be of the essence with respect to all of the Company's obligations under this Note.

2.1 **Amendments**. Except as expressly amended by this Amendment #1, the Note shall remain unmodified and in full force and effect.

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: SVP and CFO

ABUSE DETERRENT PHARMA, LLC

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