
**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): **January 19, 2023**

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	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 (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 1.01 - Entry into a Material Definitive Agreement.

On January 19, 2023 we received a \$250,000 loan from Abuse Deterrent Pharma, LLC (“AD Pharma”). This loan combined with a previous loan and with the \$2,319,279 under the November 10, 2022 Amended Consolidated and Restated Secured Promissory Note, now totals \$2,819,279, bears interest at 5.25% and matures on December 31, 2023, at which time all principal and interest is due. 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 funding provided by AD Pharma will be used for operations over the course of the next month. There can be no assurance we will be successful in receiving additional financing. In the absence of the receipt of additional financing by the end of February 2023, we will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. This could result in a complete loss of shareholder value in the Company. Even assuming we are successful in securing additional sources of financing to fund continued operations, there can be no assurance that the proceeds of such financing will be sufficient to fund operations until such time, if at all, that we generate sufficient revenue from our products and product candidates to sustain and grow our operation.

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 January 15, 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 January 15, 2023, 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 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 June 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.

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: January 20, 2023