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): **August 14, 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 (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 1.02 – Termination of a Material Definitive Agreement

On August 14, 2023 the Company and Zyla Life Sciences, LLC (as successor-in-interest to Egalet Corporation) ("Zyla") agreed to terms for the termination of the Collaboration and License Agreement between Acura Pharmaceuticals, Inc. ("Acura") and Zyla dated January 7, 2015 ("Agreement") for OXAYDO (oxycodone HCI tablets) in 5mg and 7.5mg strengths ("Product"). Zyla previously provided a Notice of Termination requesting a termination effective date of September 28, 2023 ("Effective Date") to which Acura has agreed.

At the Effective Date, Zyla's licenses to Acura's AVERSION patents and the trademarks AVERSION and OXAYDO will terminate and Zyla shall have no residual rights to manufacture, market, sell, have sold, distribute and otherwise exploit the Product. Acura does not intend to continue marketing the Product or to actively seek a new marketing partner and has waived its right to transition of the marketing back to Acura. Zyla will retain ownership of the OXAYDO New Drug Application ("NDA"), which it intends to discontinue at the Effective Date, while Acura retains the right to transfer ownership of the NDA back to Acura up until March 16, 2025. Net sales of OXAYDO are approximately $3 million annually and Acura will continue to receive a royalty on net sales through the Effective Date.

OXAYDO (previously known as OXECTA and ACUROX) was initially licensed in 2007 to King Pharmaceuticals Research and Development, Inc. which was subsequently acquired by Pfizer, Inc. in 2011. The NDA for OXAYDO was approved by the US Food and Drug Administration in June 2011 as an early example of an opioid with abuse deterrent features with such features being highlighted in the Product's labeling. Pfizer commenced commercialization of OXAYDO in early 2012 and terminated its license in 2014 and the Product reverted back to Acura. OXAYDO was subsequently licensed to Zyla in early 2015 with a re-launch later that year.

The majority of Acura's U.S. patents covering OXAYDO begin expiring in November 2023 with the last patent expiring March 16, 2025. In 2013, Acura entered into settlement agreements with multiple generic manufacturers following patent infringement suits initiated by Acura against the generic companies, with Par Pharmaceuticals, Inc. being granted a royalty bearing license to Acura's patent to begin marketing a generic after January 1, 2022. To date, Par has not gained approval for a generic to OXAYDO.

Item 2.01 – Completion of Acquisition or Disposition of Assets

The contents of Item 1.02 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 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 November 30, 2023, 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 December 31, 2023;
- 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;
- 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 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: August 16, 2023