

ACURA PHARMACEUTICALS, INC

Form 8-K

October 09, 2018

**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**

**October 5, 2018**

Date of Report (Date of earliest event reported)

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**ACURA PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Charter)

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|   |                          |  |
|---|--------------------------|--|
| State of New York                                 | 1-10113                  | 11-0853640                                 |
| (State of Other Jurisdiction<br>of Incorporation) | (Commission File Number) | (I.R.S. Employer<br>Identification Number) |

**616 N. North Court, Suite 120**

**Palatine, Illinois 60067**

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(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-J(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e-L(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 October 5, 2018 we received a \$1.8 million loan from John Schutte, which combined with earlier loans, total \$4.0 million in loans from Mr. Schutte. In connection with the \$1.8 million loan, we issued a promissory note, or the Schutte Note, in that principal amount to him. The Schutte Note bears interest at prime plus 2%, and matures on January 2, 2020, at which time all principal and interest is due. These terms are the same as the terms for the \$2.2 million loans previously received from Mr. Schutte which are also represented by promissory notes (together with the Schutte Note, the “Schutte Notes”). Events of Default under the Schutte Notes include bankruptcy events and failure to pay interest and principal when due. We used \$1.5 million of the loan proceeds to retire in full our senior secured debt with Oxford Finance. The Schutte Notes provide that they must be secured after our obligations to Oxford Finance have been satisfied in full under the Loan Agreement. As a result of the termination of the Loan Agreement, we are now required to secure payment of all of the Schutte Notes with a security interest in our assets and the Schutte Notes now become our senior secured debt. The Schutte Notes may be prepaid in whole or part at any time.

The funding provided by Mr. Schutte enables us to continue operations into November 2018 while the Company remains focused on licensing its lead asset LTX-03, by which time we hope to have entered into a licensing agreement or raised additional funds.

There can be no assurance we will be successful entering into such a licensing arrangement or receive additional financing. In the absence of closing a licensing agreement upon acceptable terms or securing additional funding, Acura 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 Acura is 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 Acura generates sufficient revenue from its products and product candidates to sustain and grow its operation.

Mr. Schutte is our largest shareholder and directly owns approximately 47.5% of our common stock (after giving effect to the exercise of warrants he holds). Mr. Schutte also controls MainPointe Pharmaceuticals LLC, or MainPointe. 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. MainPointe also has options to expand the territory and for other covered products for additional sums.

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;
- 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;
- 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 deter abuse will be determined sufficient by the FDA to support approval or labelling describing abuse deterrent features;
- whether our Limitx technology can be expanded into extended-release formulations;
- our and our licensee's ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;
- the pricing and price discounting that may be offered by Egalet for Oxaydo;
- the results of our development of our Limitx Technology;
- 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 further studies of our product candidates will be required to support FDA approval;
- 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 abuse discouraging technologies; and
- whether Oxaydo or our Aversion and Limitx product candidates will ultimately deter abuse in commercial settings and whether our Nexafed products and Impede technology product candidates will disrupt the processing of pseudoephedrine into methamphetamine.

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.

A press release regarding our restructured debt obligations is attached as Exhibit 99.1.

### **Item 1.02 Termination of a Material Definitive Agreement**

On September 14, 2018 we filed a Report on Form 8-K with the SEC and reported that we failed to make a required monthly installment payment of approximately \$260,000 due on or about September 4, 2018, under the Loan and Security Agreement (the "Loan Agreement") dated December 27, 2013, as previously amended, with Oxford Finance LLC ("Oxford" or the "Lender"), as collateral agent and as lender,. Such failure constituted an Event of Default under the Loan Agreement and gave Oxford the right to accelerate payment of all principal and interest due thereunder, which was approximately \$1,025,000 million of principal and interest on the loan (the initial principal amount of the loan was \$10,000,000), plus a balloon interest payment of \$795,000. If payment was accelerated by Oxford, a prepayment penalty of approximately \$10,200 would also be due. Such loan was secured by substantially all of Acura's assets, including the stock of Acura Pharmaceutical Technologies, Inc., and the occurrence of the Event of Default gives Oxford the right to foreclose on the collateral as well as all other remedies specified in the Loan Agreement. As a result of the occurrence of the Event of Default, the interest rate on the loan was automatically increased from 8.35% to 13.35%. The Company reported it was in discussions with Oxford to present a plan to remedy the default and forestall acceleration although there could be no assurance that these discussions would result in a plan satisfactory to Oxford.

On October 5, 2018 we negotiated a pay-off of the Loan Agreement with Oxford for \$1.5 million and used proceeds from the Schutte Note to pay-off the Loan Agreement. Pursuant to the pay-off of the Loan Agreement, Oxford will release their security interest in all our existing assets, including our intellectual property assets. Oxford retains the warrants we previously issued to them to purchase an aggregate of up to 59,560 shares of our common stock at an exercise price equal to \$2.52 per share. The warrants are exercisable for cash or by net exercise and will expire December 27, 2020. As a result of the termination of the Loan Agreement, pursuant to the terms of the Schutte Notes we are now required to secure payment of all of the Schutte Notes (with an aggregate principal amount of \$4.0 million) with a security interest in our assets.

**Item 2.01 Completion of Acquisition or Disposition of Assets.**

Item 1.01 is incorporated by reference.

**Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.**

Item 1.01 is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits**

| <b>Exhibit Number</b> | <b>Description</b> |
|-----------------------|--------------------|
|-----------------------|--------------------|

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|-------------|---|
| <u>99.1</u> | <u>Press Release of the Registrant dated October 9, 2018.</u> |
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**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: October 9, 2018



EXHIBIT INDEX

| Exhibit Number | Description |
|----------------|-------------|
|----------------|-------------|

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