ACURA PHARMACEUTICALS, INC
Form 8-K
September 11, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

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FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act Of 1934

September 11, 2017

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 of Incorporation)	(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)

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 (17CFR 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-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 7.01 Regulation FD Disclosure.

Robert Jones, our President and Chief Executive Officer, will present at the 19th Annual Rodman & Renshaw Global Investment Conference on Monday, September 11, 2017 at 1:45 p.m. Eastern Time. The conference is being held at the Lotte New York Palace Hotel, New York, New York. Slides from the presentation are attached hereto as Exhibit 99.1.

Statements in the investor slide presentation that are not strictly historical may be "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-04 or any successor product candidate, the date by which such study will complete and the results will be available and whether LTX-04 or any successor product candidate will ultimately receive FDA approval;
- whether LIMITx will retard the release of opioid active ingredients as dose levels increase;
- whether we will be able to reformulate LTX-04 or any successor product candidate to provide an efficacious level of drug when one or two tablets are taken;
- whether a reformulated LIMITx formulation that achieves an efficacious level of drug will continue to demonstrate acceptable abuse deterrent performance;
- whether we will be able to reformulate LTX-04 or any successor product candidate to improve its abuse deterrent performance;
- whether the results from LTX-04 studies will translate into similar results for an immediate release hydrocodone bitartrate acetaminophen product, which is the product we intend to take forward in the near term;
- whether the FDA will accept delays in gastric emptying as a viable component of abuse deterrent methodology;

- 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;

- our and our licensee's ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and Nexafed® products;

- 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 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," "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 8.01 Other Events.

On September 11, 2017 we issued a press release announcing the results of the previously undisclosed exploratory arm of our second LIMITx™ clinical study, study AP-LTX-401 (Study 401). A copy of the press release is attached as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	**Description**
99.1	Slides from the Scheduled Presentation on September 11, 2017
99.2	Press Release of September 11, 2017

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: September 11, 2017

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