

ACURA PHARMACEUTICALS, INC

FORM 8-K (Current report filing)

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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

June 28, 2017
Date of Report (Date of earliest event reported)

ACURA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

State of New York
(State of Other Jurisdiction
of Incorporation)

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)

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 (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 8.01. Other Events.

On June 28, 2017 we announced results from clinical study AP-LTX-401, a randomized, fasted, crossover design pharmacokinetic study testing our LIMITx™ formulation LTX-04P3 in healthy adult subjects.

A press release regarding the foregoing is attached as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated June 28, 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: June 28, 2017

EXHIBIT INDEX

**Exhibit
Number**

Description

99.1

Press Release dated June 28, 2017

Acura Pharmaceuticals Advances LTX-04 and its LIMITx™ Technology

*** Peak blood levels of abused LIMITx doses can be reduced up to 65% ***

PALATINE, Ill, June 28, 2017: Acura Pharmaceuticals, Inc. (OTCQB: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, today announced that the results from its second clinical study, study AP-LTX-401 (Study 401). Study 401, when considered with the results of its first clinical study (Study AP-LTX-400 or Study 400) demonstrate that the maximum plasma level of drug (C_{max}) following oral excessive tablet abuse (Oral ETA dosing levels are in excess of 2 tablets at a time) of the early development stage product LTX-04P3 are reduced by up to 65% compared to currently marketed products. The single tablet dose of LTX-04P3 in Study 401 achieved a C_{max} that was 52% of the C_{max} of the marketed comparator indicating the current LTX-04 formulation contains excess buffering ingredients resulting in incomplete release of drug. The Company is developing plans for a buffer dose ranging study to guide the reformulation of the tablet buffers to increase the single dose C_{max}, while retaining a reduction in C_{max} in multiple Limitx tablets. A change in development focus is planned from LTX-04, an immediate-release hydromorphone product, to LTX-03, an immediate-release hydrocodone bitartrate product, in subsequent studies. Hydrocodone bitartrate is more likely to be abused by Oral ETA.

The patented LIMITx technology works by neutralizing stomach acid with buffering ingredients as increasing numbers of tablets are swallowed and relies on stomach acid to play a role in the release and subsequent systemic absorption of the active ingredient from micro-particles contained in the tablets.

“The results from Study 401 have allowed for a fuller understanding of the LIMITx Technology as a whole and changed the way we analyze the data such that we now believe the abuse deterrence of LIMITx may achieve up to a 65% reduction in peak blood levels”, commented Dr. Al Brzeczko, the co-inventor of the LIMITx technology. “Following the first study, that data and analysis indicated an abuse deterrence potential of a 20% reduction in peak blood levels. We believe that our current micro-particle formulations are capable of achieving adequate therapeutic blood levels at a single tablet dose once we determine the appropriate buffering level for a single dose.”

Study 401 was a randomized, fasted, crossover design pharmacokinetic study testing Acura’s LIMITx formulation LTX-04P3 in healthy adult subjects. A single dose of LTX-04P3 demonstrated a C_{max} of 52% compared to the marketed comparator. Given that the single tablet C_{max} for LTX-04P3 in Study 401 was consistent with the C_{max} observed in Study 400 (55% for LTX-04S and 50% for LTX-04P compared to the marketed comparator) and the active ingredient in LTX-04P3 in acid media laboratory dissolution tests showed a 2.7x faster release in 5 minutes than the Study 400 formulations, the Company has concluded that the inhibited release at one tablet is due to excessive levels of buffering ingredients in the single tablet that is neutralizing the acidic gastric fluid and retarding the timely release of the active ingredient from that single tablet.

At the seven tablet dose, the C_{max} of LTX-04P3 was 35% of the C_{max} for the marketed comparator. The seven tablet LTX-04P3 dose, on a dose proportionality basis, demonstrated a 32% further reduction in C_{max} when compared to the single tablet dose. Comparatively, in Study 400 there was an approximate 20% further reduction in C_{max} for 8 tablets compared to a single tablet dose based on a dose proportionality analysis.

Study 401 enrolled 64 subjects with 27 completing the single tablet dose and 28 completing the seven tablet dose, divided into two subgroups. There were no severe adverse events in Study 401 and the doses were generally well tolerated.

Conference Call Information

To further discuss these results Acura's management will host a live conference call and webcast at 8:30 am ET on Thursday, June 29, 2017. The presentation will be webcast live and may be accessed by visiting the Company's website, Acurapharm.com and selecting the "News and Events" option under the "Investors" tab. For those wishing to listen only you may dial **1-800-310-1961** with passcode **9489620**. A replay of the webcast will be available for 60 days on the Acura website.

About Acura Pharmaceuticals

Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of product candidates intended to address medication abuse and misuse, utilizing its proprietary LIMITx™, AVERSION® and IMPEDE® Technologies. LIMITx contains ingredients that are intended to reduce or limit the rate or extent of opioid release when multiple tablets are ingested. AVERSION contains polymers that cause the drug to gel when dissolved; it also contains compounds that irritate the nasal passages if the product is snorted. IMPEDE is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

OXAYDO® (oxycodone HCl immediate-release tablets) which incorporates the AVERSION Technology, is FDA approved and marketed in the U.S. by our partner Egalet Corporation.

NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products that utilize the IMPEDE Technology, are marketed in the U.S. by our partner MainPointe Pharmaceuticals.

Forward-Looking Statements

Certain statements in this press release 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-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 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 our Nexafed® products;
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- 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,” “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.

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