

# ACURA PHARMACEUTICALS, INC

## **FORM 8-K** (Current report filing)

Filed 05/19/17 for the Period Ending 05/18/17

Address	616 N. NORTH COURT, SUITE 120 PALATINE, IL 60067
Telephone	847-705-7709
CIK	0000786947
Symbol	ACUR
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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

May 18, 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**  
(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 (17CFR240.14d- 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.

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**Item 2.02 Results of Operations and Financial Condition**

On May 18, 2017 we issued a press release announcing the announced that we completed enrollment and initiated dosing in a second Phase 1 human pharmacokinetic trial of LTX-04, our lead development candidate utilizing our LIMITx™ technology. A copy of our press release is being filed as Exhibit 99.1 hereto.

**Item 9.01 Financial Statements and Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated May 18, 2017

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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: May 18, 2017

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**Exhibit Index**

**Exhibit Number**

**Description**

99.1

Press Release dated May 18, 2017

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### **Acura Pharmaceutical Initiates Second Clinical Study on LTX-04**

PALATINE, Ill, May 18, 2017: Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, today announced that the Company has completed enrollment and initiated dosing in a second Phase 1 human pharmacokinetic trial of LTX-04, its lead development candidate utilizing Acura's novel LIMITx™ technology. The patented LIMITx technology works by neutralizing stomach acid as increasing numbers of tablets are swallowed and relying 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 Company expects dosing to complete by the end of May with topline results announced in June.

Study AP-LTX-401 (Study 401) is a randomized, fasted, crossover design testing Acura's new formulation designated LTX-04P3 in healthy adult subjects. In laboratory dissolution tests LTX-04P3 released drug faster with one tablet but also demonstrated better abuse deterrence with multiple tablets than the Company's initial formulations.

Study 401 enrolled 60 subjects who will be randomly assigned to one of two cohorts. Cohort 1 subjects are taking one LTX-04P3 tablet versus a marketed hydromorphone reference product with the objective to establish efficacious blood levels of the active ingredient and preferably bioequivalence. Cohort 2 subjects will be further assigned to two subgroups. Subgroup A subjects are taking 7 tablets of LTX-04P3 and the marketed hydromorphone reference product with the objective to demonstrate a reduction in peak blood levels of the active ingredient with LTX-04P3. Subgroup B subjects are being dosed in an undisclosed, exploratory protocol.

#### **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:

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- 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 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;
- 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 .

Contact:  
 for Acura Investor Relations  
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 847-705-7709

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