

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

April 14, 2016  
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 (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- 4(c))
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## **Item 7.01 Regulation FD Disclosure.**

Robert Jones, President and Chief Executive Officer of Acura Pharmaceuticals, Inc. (the “Company”) is scheduled to make a presentation to analysts today. Slides from the presentation are attached hereto as Exhibit 99.1.

Information in this report furnished pursuant to Item 7.01 shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section. This report will not be deemed an admission as to the materiality or non-public nature of any information in the report that is required to be disclosed solely by Regulation FD.

### **Forward-Looking Statements**

Statements in the attached exhibit 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:

- the expected results of clinical studies relating to LTX-04, the date by which such study results will be available and whether LTX-04 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 to provide an efficacious level of drug when one or two tablets are taken;
  - whether our LIMITX technology can be expanded into extended-release formulations;
  - our ability to fund or obtain funding for our continuing operations, including the development of our products utilizing our LIMITX and Impede® technologies;
  - 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;
  - 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;
  - 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;
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- 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.

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**Item 9.01      Financial Statements and Exhibits.**

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
99.1	Slides from the Scheduled Presentation on April 14, 2016

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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: April 14, 2016

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**Exhibit  
Number**

**Description**

99.1	Slides from the Scheduled Presentation on April 14, 2016
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***Topline Interim Cohort 1 Results  
Study AP-LTX-400 (Study 400)***

**April 13, 2016**

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## General Caution Regarding Forward Looking Statements

Certain statements in this presentation 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. 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. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments.

Forward-looking statements may include, but are not limited to:

- The expected results of clinical studies relating to our LTX-04 formulation, the date by which such study results will be available and whether LTX-04 will ultimately receive FDA approval;
- whether LTX-04 will retard release of the active ingredients as dose levels increase;
- whether we will be able to reformulate LTX-04 to provide increased blood level at a 1 or 2 tablet dose;
- whether our Limitx™ technology can be expanded to extended-release products;
- the ability to fund, or obtain funding, for our continuing operations;
- the ability to enter into future partnerships or maintain our current partnerships;
- the results and timing of future development efforts, whether the FDA will accept those results and completeness of our studies, whether FDA will approve the products for marketing, and whether our technologies will actually reduce abuse if marketed; and
- exposure to infringement of patents, trademarks and other proprietary rights of third parties.



**Nasdaq: ACUR**



# Study 400 Objectives

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## Objectives:

- Demonstrate LIMITX technology can retard the release of the active ingredient as 3 or more doses are administered in humans
- Demonstrate the LTX-04 formulation achieves blood levels of drug with 1 and/or 2 tablets equivalent to DILAUDID

## Observations:

- 3 tablets of LTX-04P demonstrated an approximate 22% proportional reduction in maximum plasma concentration ( $C_{max}$ ) than non-LIMITX tablets
  - LTX-04S had proportional  $C_{max}$  to DILAUDID
- LTX-04S & P did not achieve equivalent peak levels of drug ( $C_{max}$ ) at 1 and 2 tablets compared to DILAUDID
  - $C_{max}$  was ~50% lower than DILAUDID at both doses
  - $T_{max}$  was approximately the same as DILAUDID at both doses
  - $AUC_{0-inf}$  was approximately the same as DILAUDID at both doses



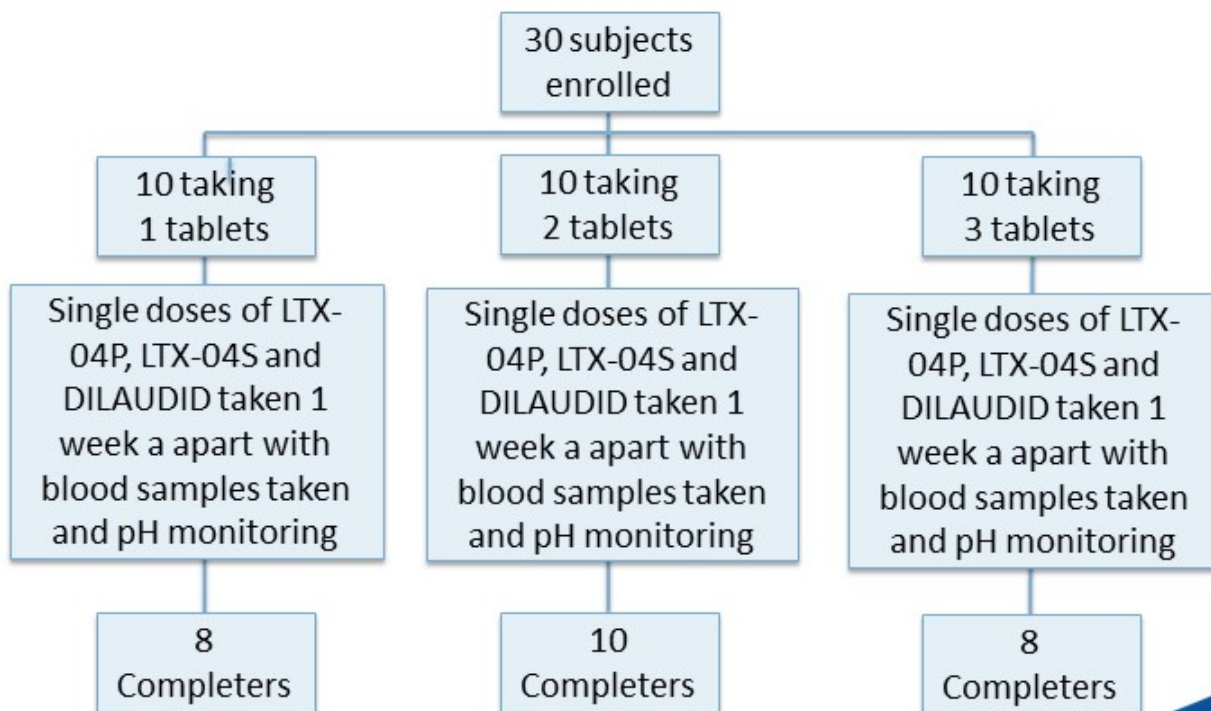
Nasdaq: ACUR

## Study 400 – Cohort 1 Conclusions

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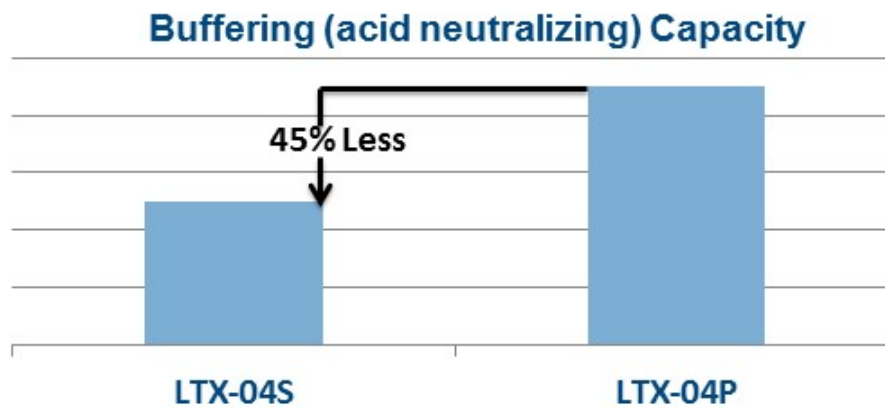
- ✓ The Limitx™ Technology can regulate stomach acid and retard the release of active ingredient at 3 or more tablets
- ✗ The current LTX-04 micro-particle formulation releases drug too slowly for an immediate-release tablet
- ✓ The LTX-04 micro-particle formulation can be adjusted to release drug faster in an acidic environment
- ✓ The current LTX-04 micro-particle formulation exhibits an extended-release profile offering potential to expand the formulation into extended-release products

## Study 400 Cohort 1 Design



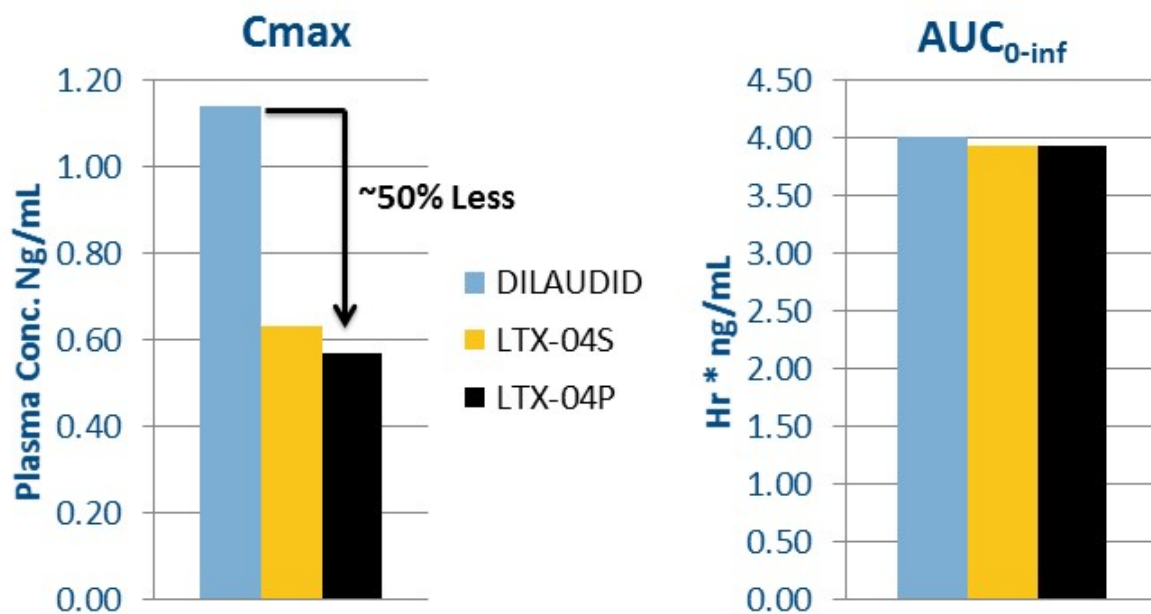
## Study 400 LTX-04P and LTX-04S

- Identical micro-particle formulation in identical amounts in each dose of LTX-04P and LTX-04S
- LTX-04S has 45% less the buffering capacity than LTX-04P



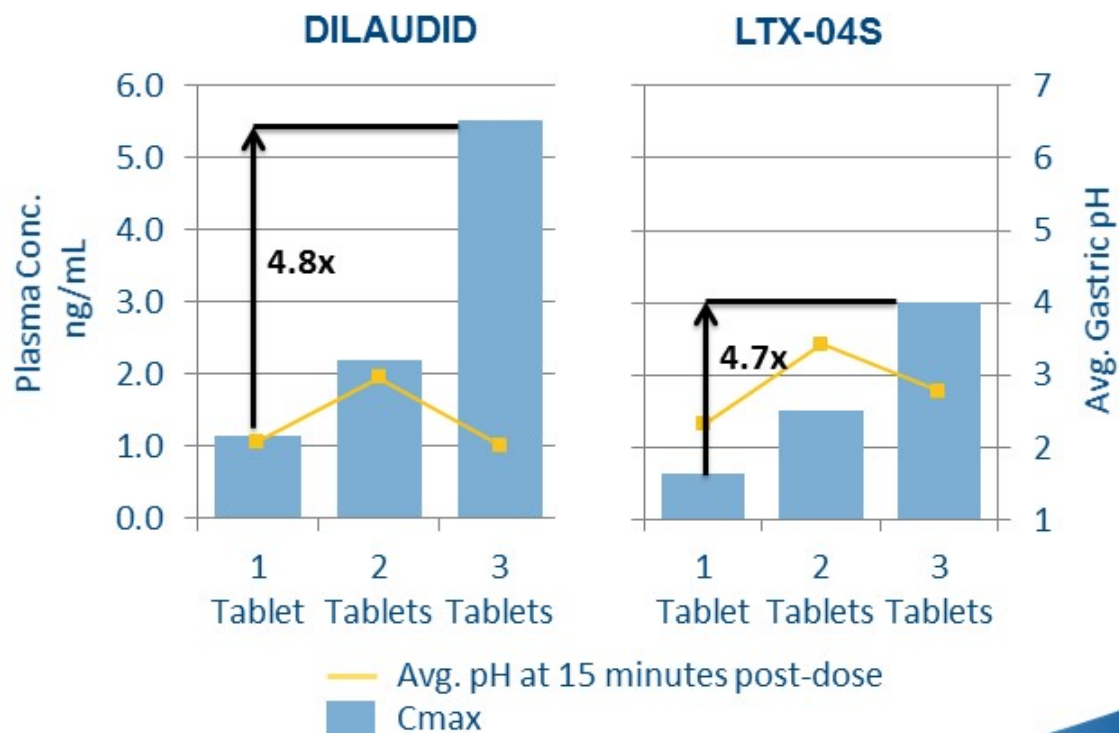
- The LTX-04 test formulations were designed to neutralize different amounts of stomach acid to test the parameters of the oral abuse deterrence of LIMITX

## Study 400 – One Tablet Dose Summary



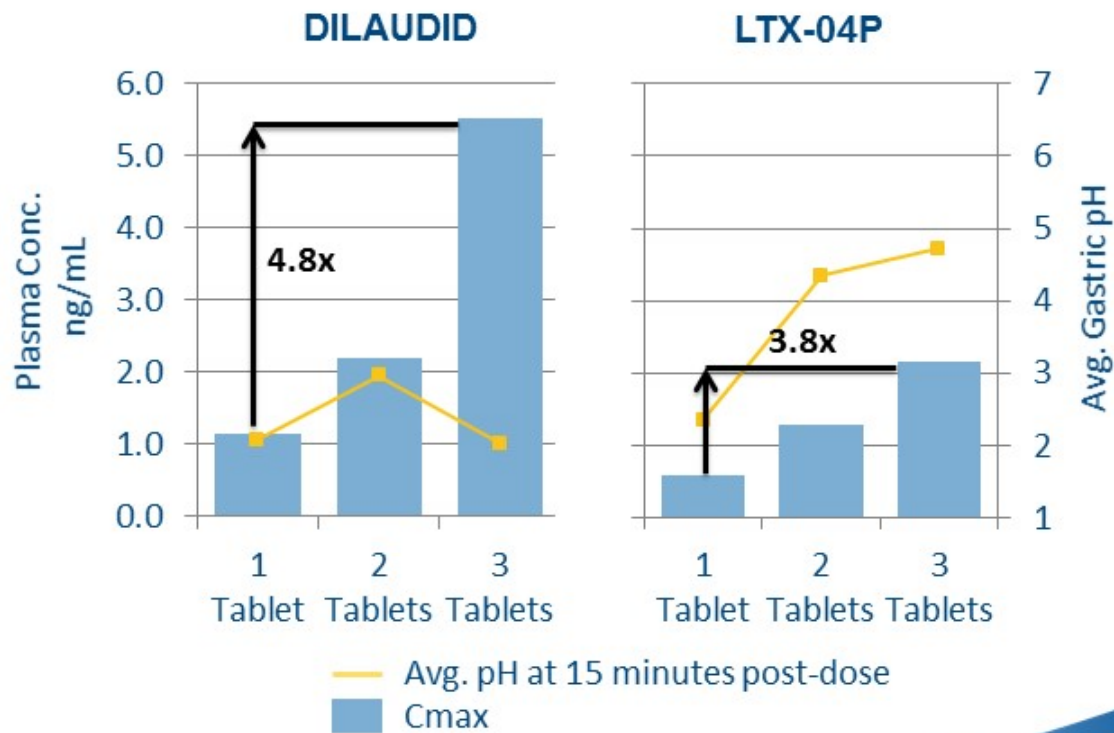
- LTX-04 @ 50% of Comparator Cmax is indicative of a slow release of drug from the micro-particles
- Comparable AUCs coupled with low Cmax is indicative of an extended-release formulation

## Study 400 – Cmax of Three LTX-04S Tablets Proportionally Equal DILAUDID

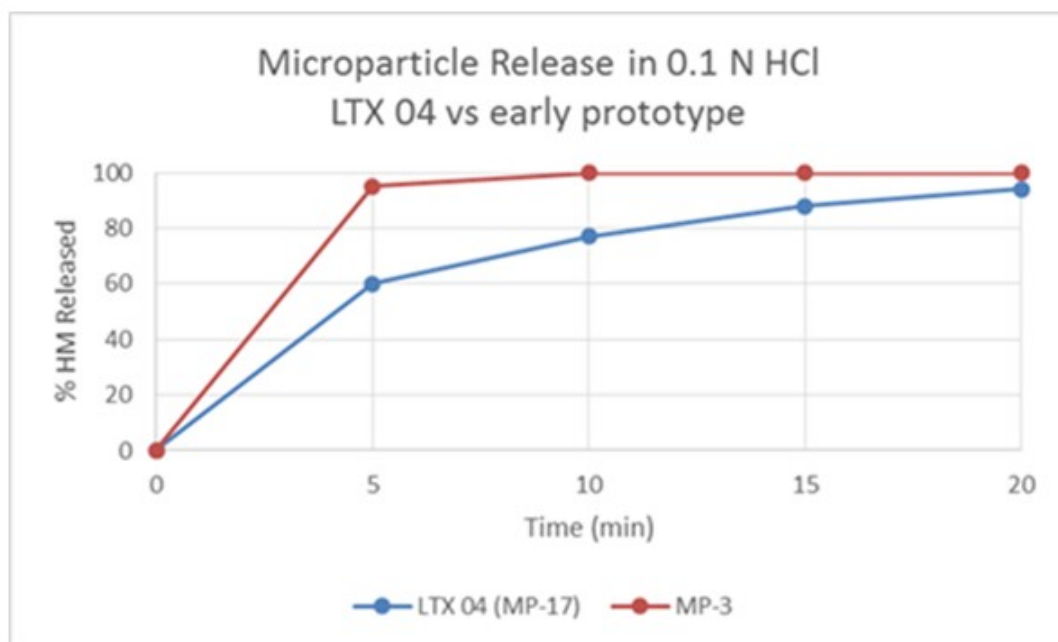




## Study 400 – Cmax ~22% Lower at 3 Tablets for LTX-04P than expected



## LTX-04 - Micro-particle Dissolution versus an earlier prototype (MP-3)





## Study 400 - Cohort 1 Conclusions

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- ✓ The Limitx™ Technology can regulate stomach acid and retard the release of active ingredient at 3 or more tablets
- ✗ The current LTX-04 micro-particle formulation releases drug too slowly for an immediate-release tablet
- ✓ The LTX-04 micro-particle formulation can be adjusted to release drug faster in an acidic environment
- ✓ The current LTX-04 micro-particle formulation exhibits an extended-release profile offering potential to expand the formulation into extended-release products

## LTX-04 Development Next Steps

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- Complete Study AP-LTX-400 Cohort #2 to confirm results for oral abuse deterrence
  - Results expected end of June 2016
- Fine tune LTX-04 micro-particle formulation
- Use additional insights from Cohort #1 to assess tablet formulation
- Discuss Study AP-LTX-400 results with FDA under FAST TRACK designation
  - Commence 1 and/or 2 tablet pharmacokinetic study for bioequivalence in the 2<sup>nd</sup> half 2016



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12



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