ACURA PHARMACEUTICALS, INC

FORM 8-K
(Current report filing)

Filed 06/28/17 for the Period Ending 06/28/17

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CIK	0000786947
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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

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	**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 (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 7.01 Regulation FD Disclosure.

On June 29, 2017, we will hold a webcast at 8:30 am ET to discuss the results from clinical study AP-LTX-401, a randomized, fasted, crossover design pharmacokinetic study testing our LIMITx™ formulation LTX-04P3 in healthy adult subjects. The slides to be discussed on the webcast are attached as Exhibit 99.1.

The webcast 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.

Forward-Looking Statements

Certain statements in sides 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 projected period over which funding will be provided from our private placement transaction;
- 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;
- 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 .

Item 9.01 Financial Statements and Exhibits

Exhibit Number	**Description**
99.1	Slides

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.

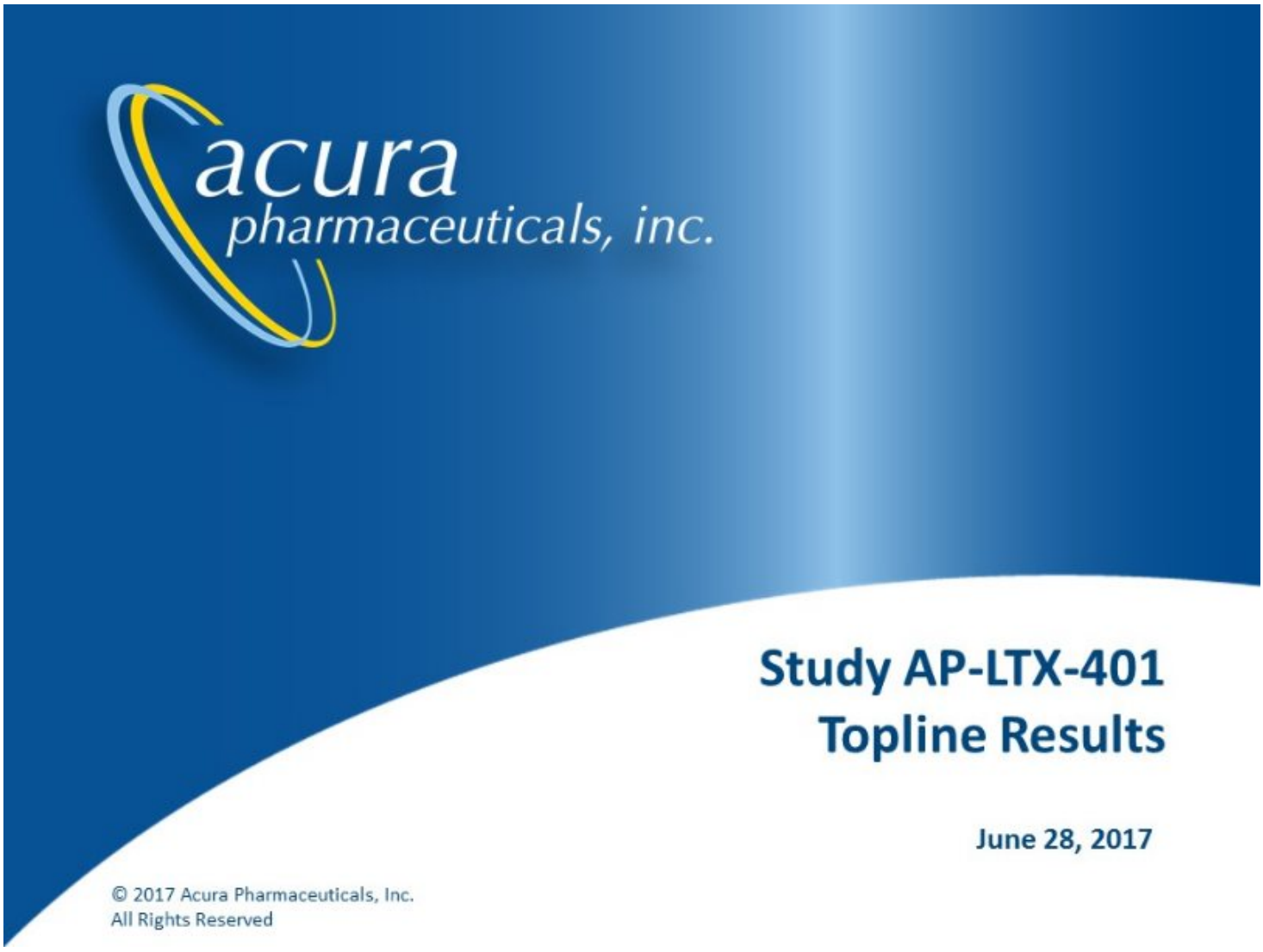
ACURA PHARMACEUTICALS, INC.

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	Slides


acura
pharmaceuticals, inc.
Study AP-LTX-401
Topline Results
June 28, 2017
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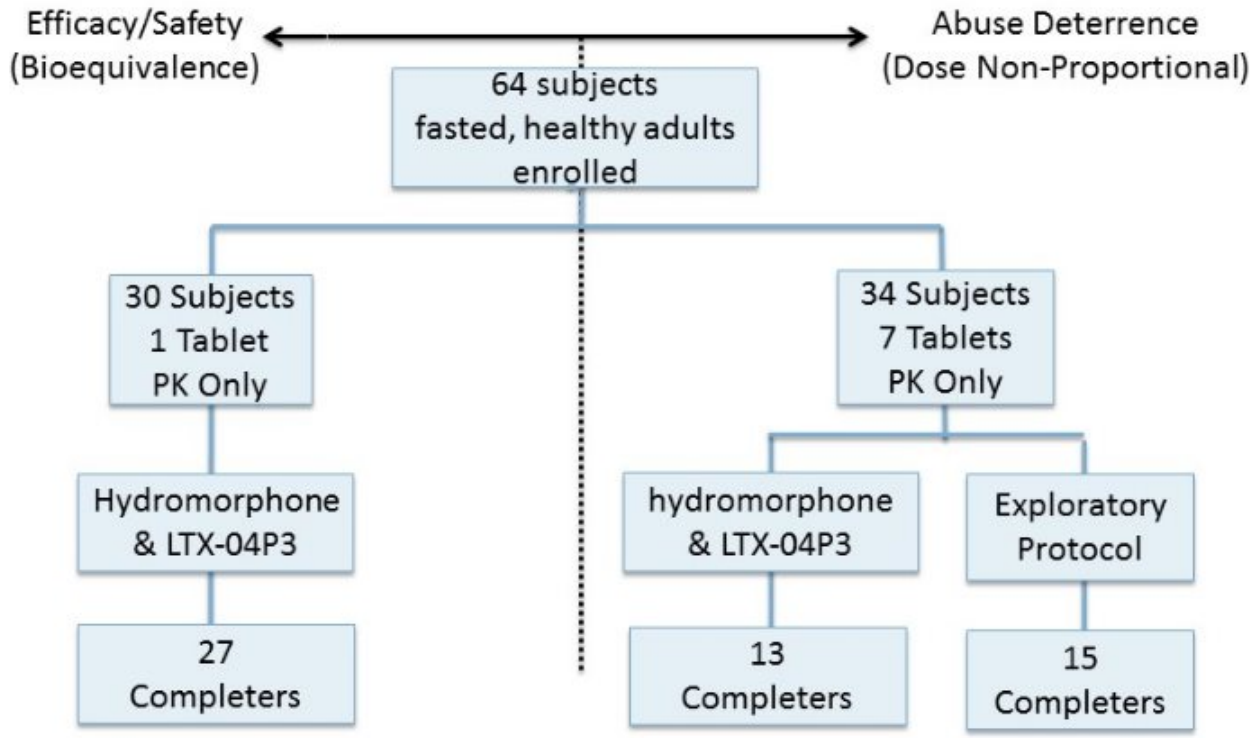
General Caution Regarding Forward Looking Statements

Certain statements in this presentation constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forwarding-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.

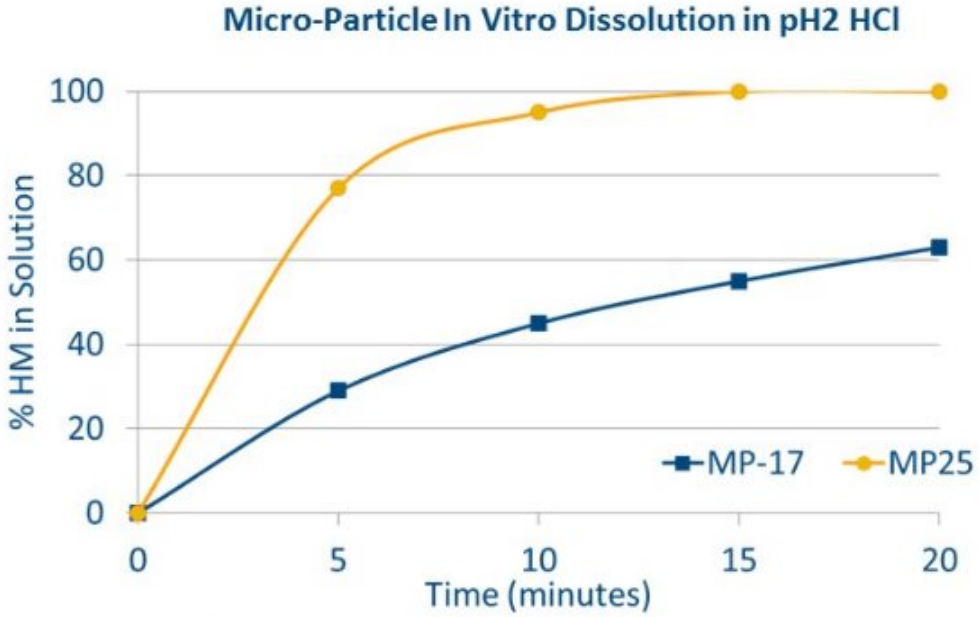
Forward-looking statements may include, but are not limited to:

- 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 a reformulated LTX-04 that achieves an efficacious level of drug will continue to demonstrate abuse deterrent performance;
- whether we will be able to reformulate LTX-04 to provide increased blood level at a 1 or 2 tablet dose or improve its abuse deterrent effects ;
- 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 our development efforts, whether the FDA will agree with or 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.

Study 401 – Design



LTX-04 – Micro-particle single tablet simulation



Micro-particle MP-17 was used in Study 400
Micro-particle MP-25 was used in Study 401

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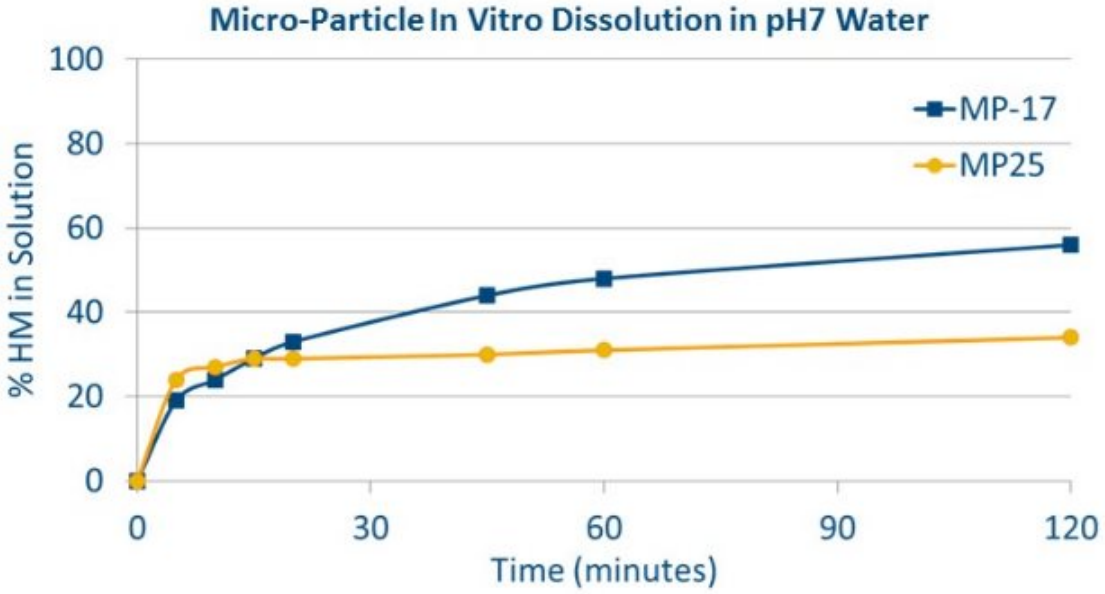
LTX-04 – Micro-particle multiple tablet simulation



Micro-particle MP-17 was used in Study 400
Micro-particle MP-25 was used in Study 401

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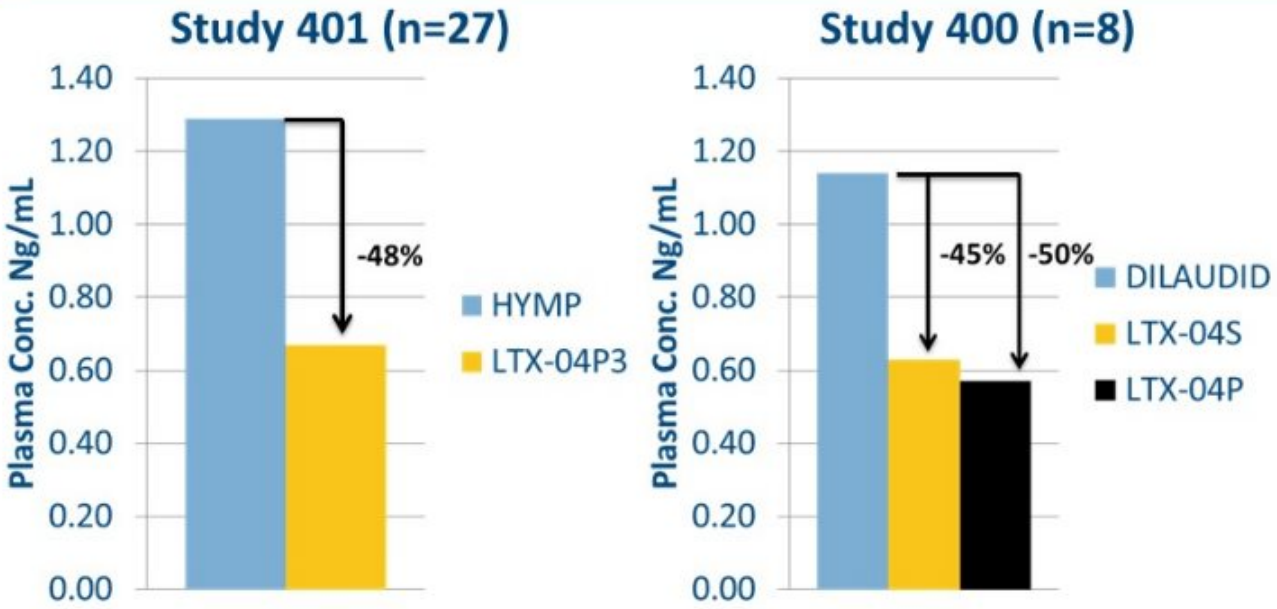
LTX-04 - One Tablet Dose C_{max}



Given the consistent reduction in Cmax and the differences in the tablets formulations, the single tablets appear to be neutralizing the gastric fluid

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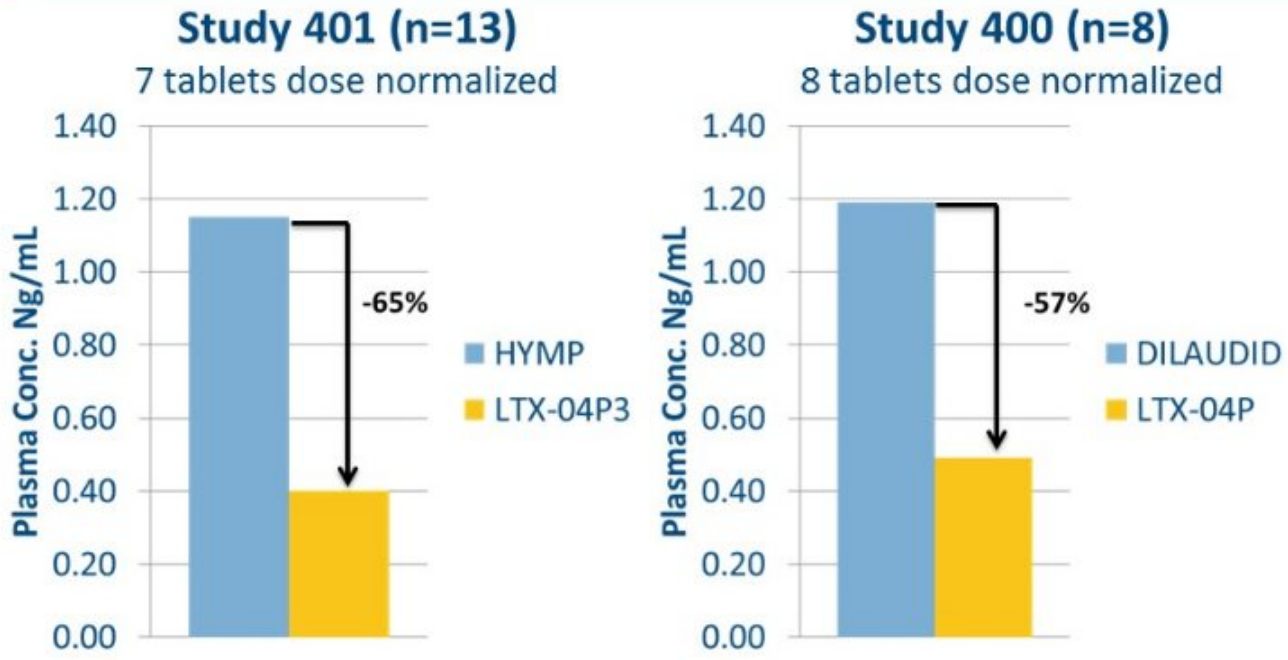
LTX-04 – Multi-Tablet Dose C_{max}



Improved reduction in Cmax reduction in Study 401 may be the result of the MP-25 micro-particle

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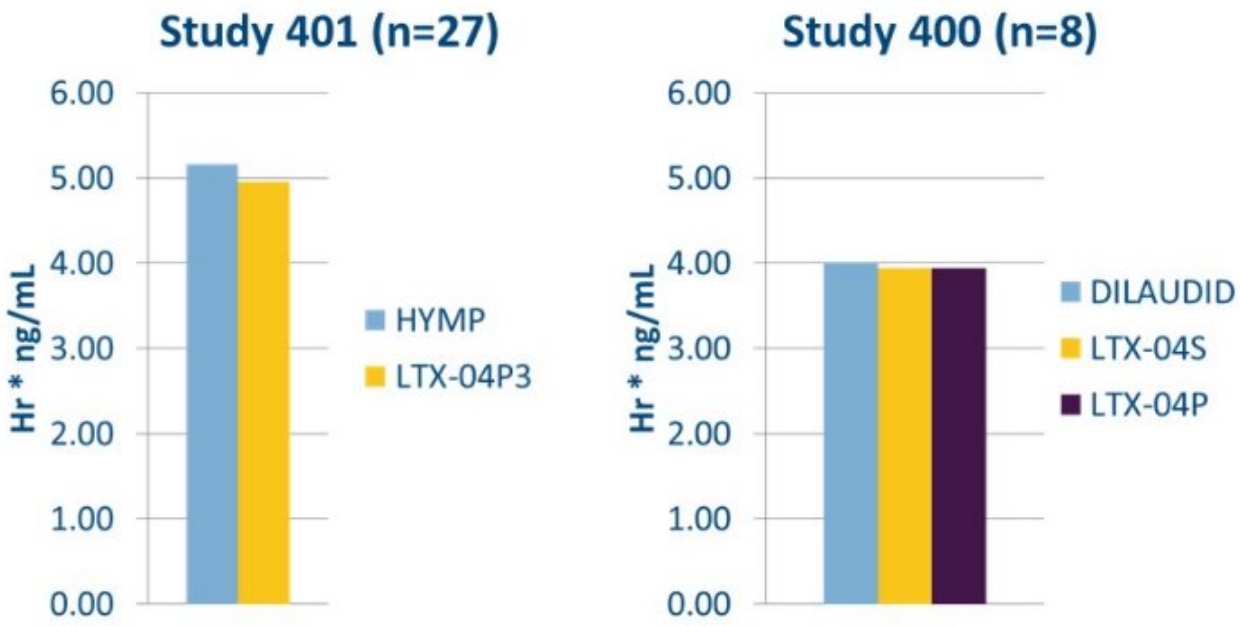
LTX-04 – One Tablet Dose $AUC_{(0\text{-}inf)}$



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Study 401 – Conclusions

- ✓ New micro-particle developed with potentially greater abuse deterrent potential and faster release at 1 tablet.
- ✓ New interpretation of the data suggested much more compelling abuse deterrent potential of up to 65% reduction in Cmax.
- ✓ Opportunity to switch to hydrocodone bitartrate which is a larger market and believed to have greater abuse by Oral ETA

LIMITx™ - Path Forward

- Better understanding of the LIMITx™ Technology
- Better understanding of the gastric environment and acidity
- Potential for the enhanced abuse deterrent properties for LIMITx
- Need to determine the correct level of buffering ingredients to use for a single table through the execution of a dose ranging study

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