
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

September 11, 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 (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))

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

**Exhibit
Number**

Description

<u>99.1</u>	<u>Slides from the Scheduled Presentation on September 11, 2017</u>
<u>99.2</u>	<u>Press Release of September 11, 2017</u>



***Rodman & Renshaw
Conference***

September 2017

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General Caution Regarding Forward Looking Statements

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

- 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;
- the ability to reformulate our lead LIMITx product candidate, including to increase blood levels with 1 or 2 tablets while maintaining its abuse deterrent effects;
- the ability of our technologies, if approved, to be successfully marketed, including distribution, market acceptance, market share penetration, and the pricing and price discounts that may be offered;
- exposure to infringement of patents, trademarks and other proprietary rights of third parties; and
- the ability of our patents to protect our products from generic competition.



Symbol: ACUR

Acura's Abuse Deterrent Technology Platforms

LIMITx™

- Opioid Abuse – **Oral Excessive Tablet Abuse**
- Exploratory Stage Development
- Un-partnered
- Issued US Patents to 2033



AVERSION®

- Opioid Abuse – **Snorting and Injection**
- Oxaydo® FDA Approved with labeling
- Licenses to Egalet and Kempharm
- Issued US Patents to 2025

IMPEDE®

- Pseudoephedrine – **Conversion to Meth**
- Two US Marketed Nexafed® Products
- License to MainPointe Pharma
- Issued US Patents to 2032



Symbol: ACUR

A Need for Oral Excessive Tablet Abuse Technologies

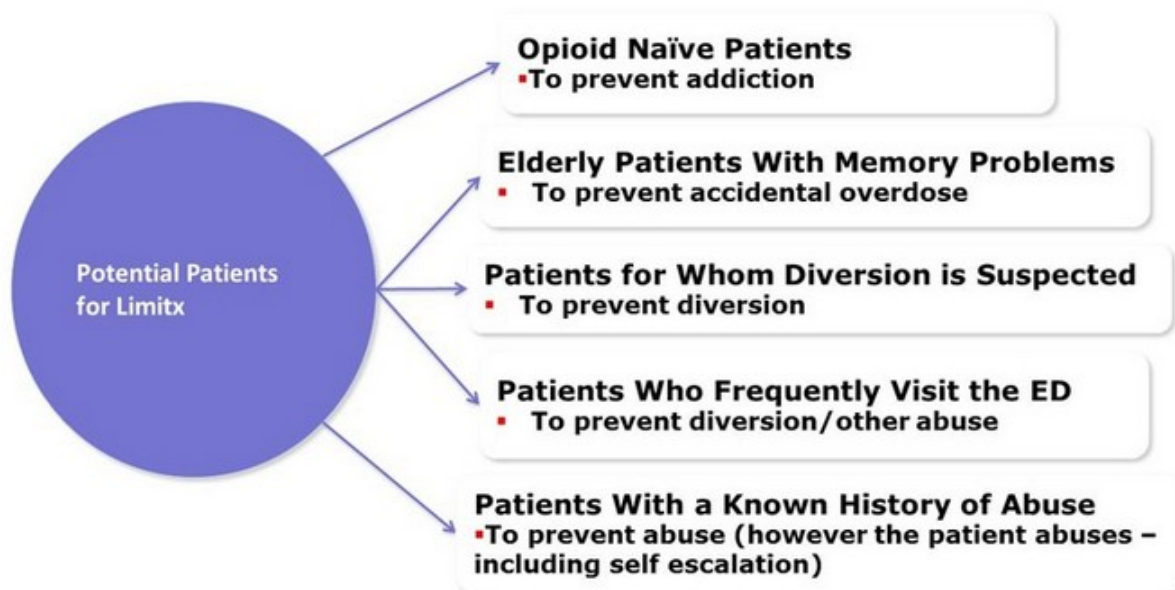
- April 2015 **FDA Guidance “Abuse Deterrent Opioid – Evaluation and Labeling”**
 - Immediate-release opioids containing acetaminophen (APAP)
 - Predominately abused by the oral route
 - Addressing nasal abuse may not meaningfully reduce abuse
- July 2017 **Prime Therapeutics Press Release**
 - “.. we remain concerned about overprescribing of ADF opioids, especially when they can still be used in excess quantities...”
- August 2017 **Investigator for the VA Center for Health Equity Research and Promotion**
 - “These products [current abuse deterrent opioids] do not prevent the most common form of opioid abuse — ingesting pills orally in a way that isn’t consistent with the actual prescription.”
- August 2017 **Dr. Scott Gottlieb, FDA Commissioner**
 - [FDA] wants to focus on reducing the chance people get addicted in the first place



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LIMITx™ Benefits (Unsolicited)

As identified by opioid prescribers



Source: Company Physician Focus Groups; n=8



Symbol: ACUR

The LIMITx™ Technology

Product Formulation

- Micro-particles containing the opioid active ingredient
- Functional tablet matrix of other ingredients

Oral Abuse Deterrence

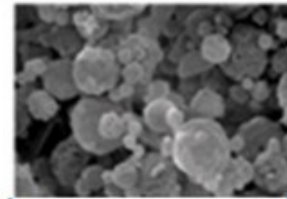
- Tablet matrix acts synergistically with the micro-particle ingredients to retard the release of micro-particle active ingredients when multiple tablets are ingested

Nasal Abuse Deterrence

- Micro-particles can not be reduced/tampered due to size
- Micro-particles designed to be insoluble in the nasal environment

IV Abuse Deterrence

- Multi-step process is expected to be required to extract opioid for syringing



Illustration



Symbol: ACUR

LIMITx™ Technology Objectives

OBJECTIVES

- #1 To provide meaningful analgesic blood levels of drug at the recommended single tablet dose
- #2 To reduce the peak drug levels in the blood when more than the recommended dose is ingested

CHALLENGES

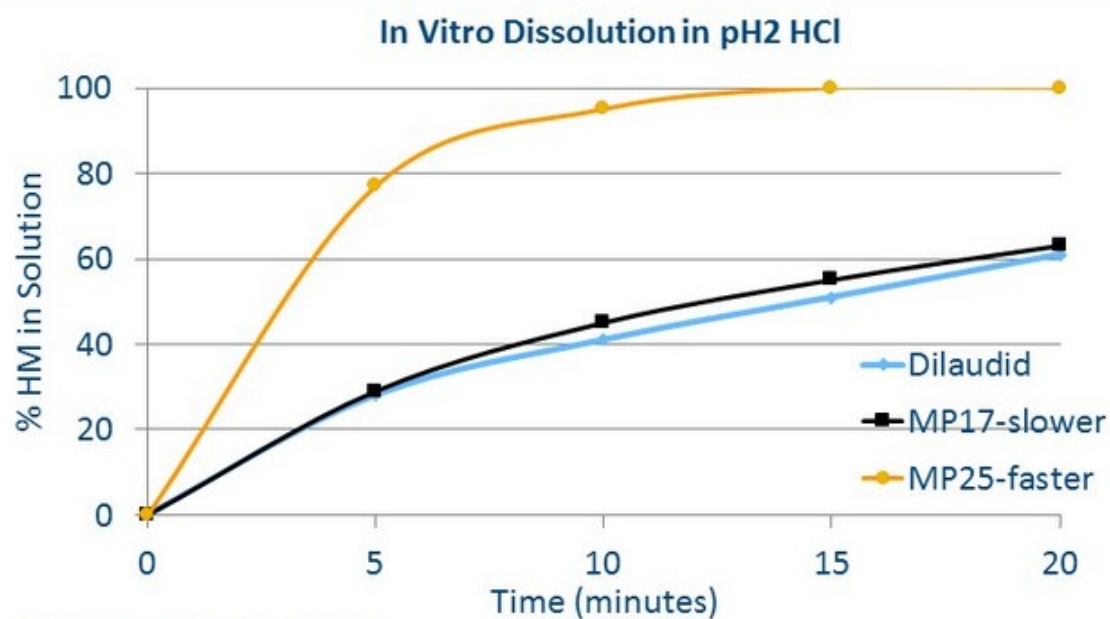
- ? #1: Find the appropriate buffer level that allows for complete release of the drug in the micro-particle with one tablet
- ✓ #2: Design a micro-particle that does not release drug in a non-acidic gastric environment

LIMITx™ Studies To Date

- **LTX-04** – Immediate-Release Hydromorphone HCl Tablets
 - Fasted Pharmacokinetic Studies AP-LTX-400 and AP-LTX-401
 - Studied 1 tablet up to 8 and 7 tablets, respectively

Formulation Tested	Clinical Study	Micro-particle Release	Buffer Strength
LTX-04S	400	Slower (MP17)	Lower
LTX-04P	400	Slower (MP17)	Higher
LTX-04P3	401	Faster (MP25)	Higher

Study 401 Micro-particles are much faster at pH 2

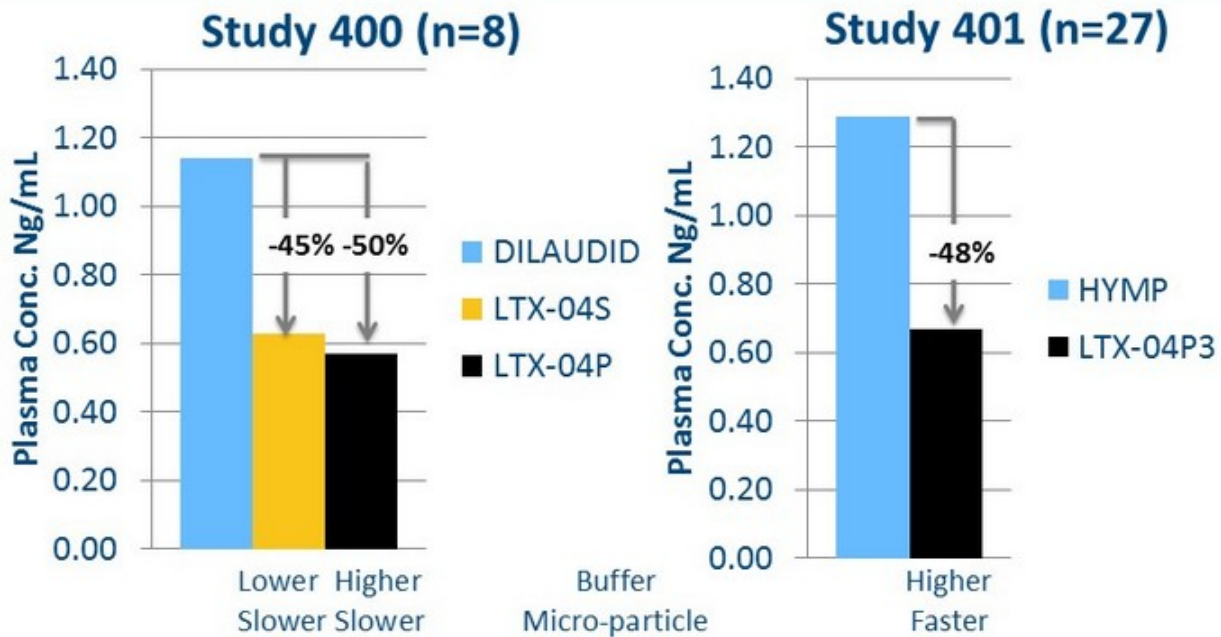


MP17 used in Study 400

MP25 used in Study 401

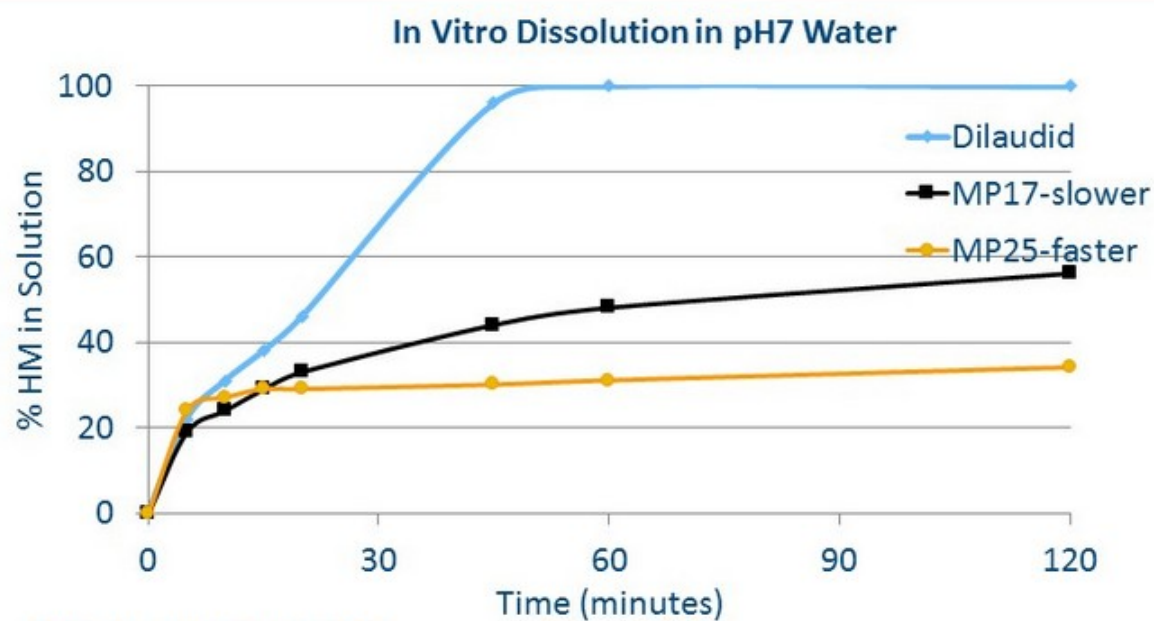
Mean fasted gastric pH is 1.3 to 2.1

One Tablet LTX-04 Dose C_{max} is Consistent



even when the buffer strength and
micro-particle release vary

Study 401 Micro-particles Limit Release at pH 7

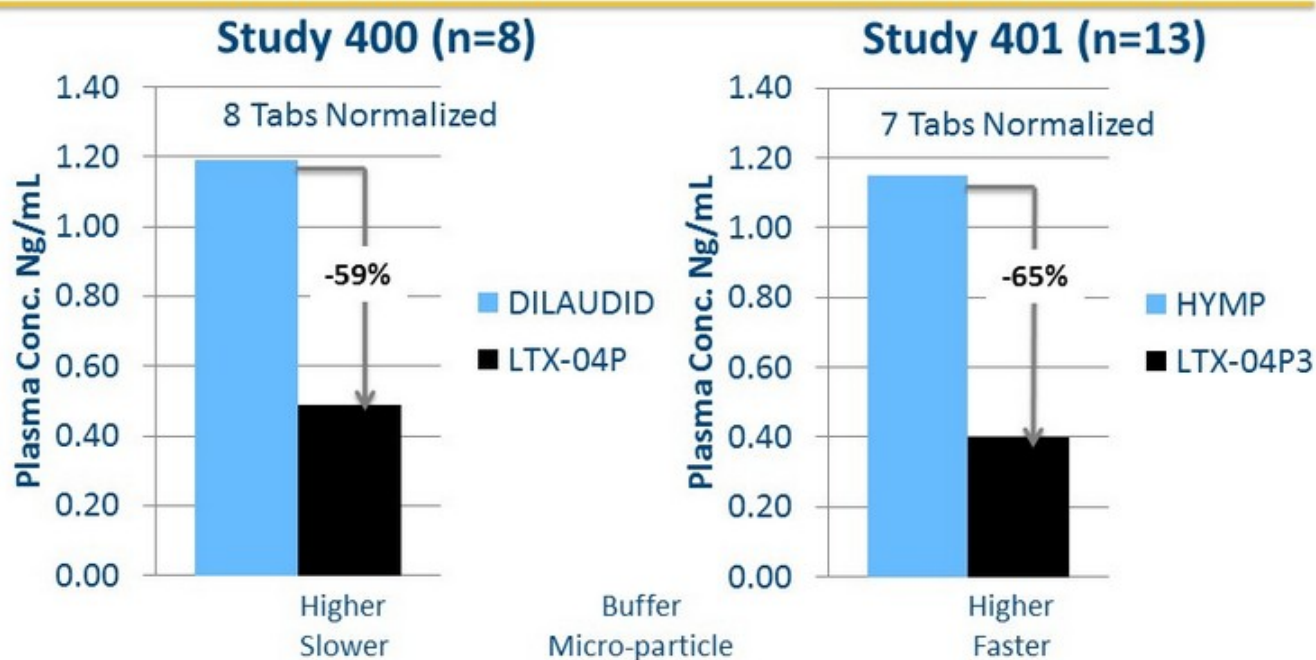


MP17 used in Study 400

MP25 used in Study 401

Mean fasted gastric pH is 1.3 to 2.1

Multi-Tablet LTX-04 Dose Cmax is further reduced

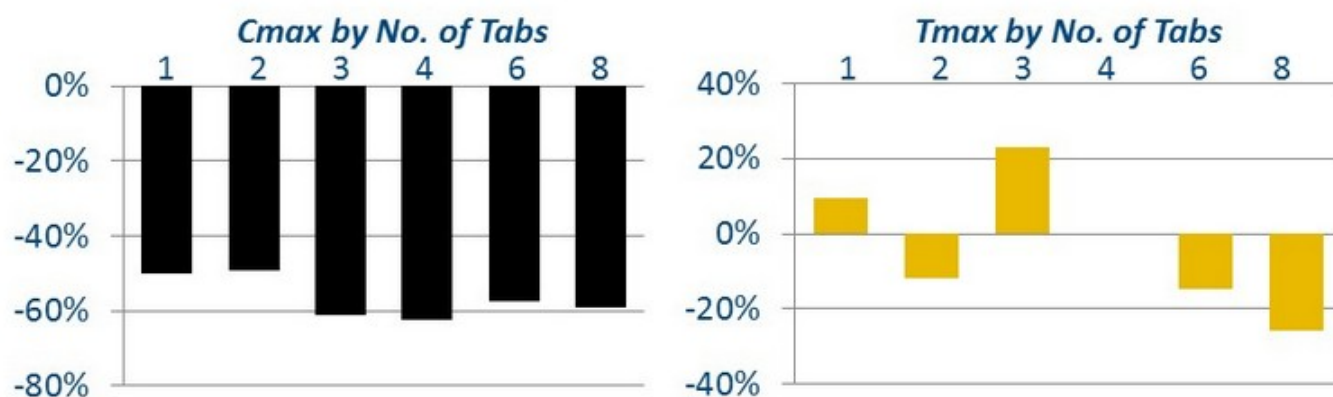


as more buffering agent is
ingested

Increasing Tablets [Buffer] Impact on Cmax/Tmax

Study 400

% Change LTX-04P versus DILAUDID



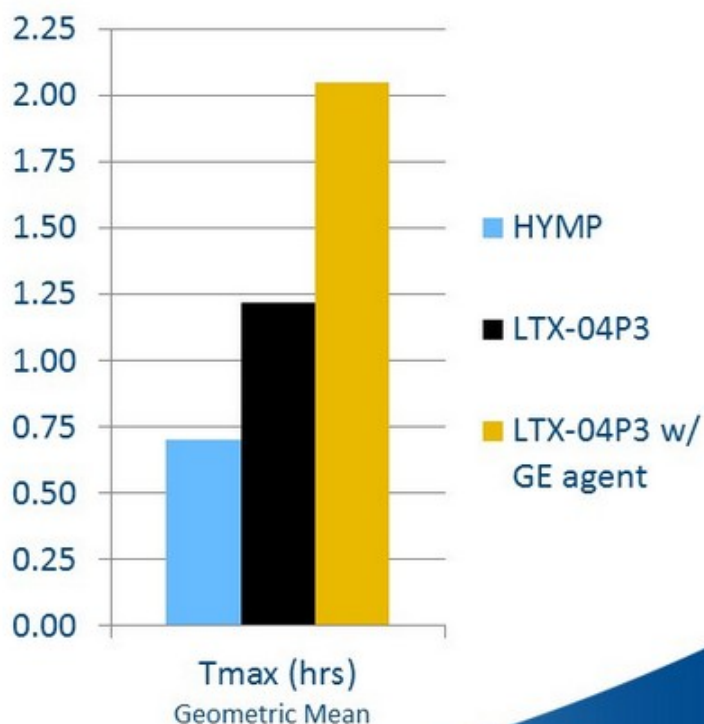
Gastric pH readings in Study 400 provided acid neutralization onset and duration for a 3 tablet dose.

The data indicates the duration of acid neutralization was the same for doses from 3 through 8 tablets.

Gastric Emptying Plays a Role in Delaying Drug Release

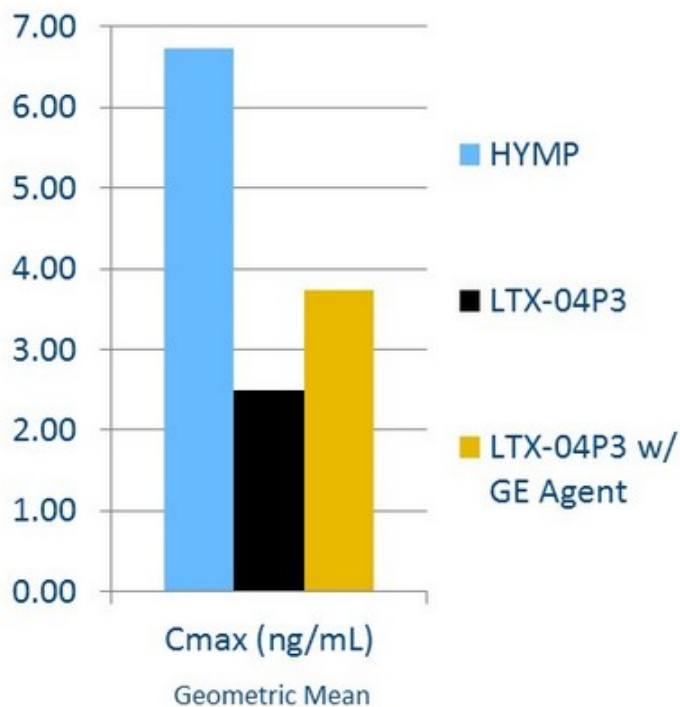
Tmax is significantly increased when gastric emptying is delayed

- Study 401 – 7 tablet dose
- Agent introduced to increase gastric emptying time (Increase gastric retention time)



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Delayed LTX-04 Tmax does not impact Cmax



Despite a lengthened Tmax with the GE Agent, Cmax for LTX-04 remains consistent suggesting micro-particles rapidly and fully released after gastric re-acidification.

- Study 401 – 7 tablet dose
- Agent introduced to increase gastric emptying time (Increase gastric retention time)

LIMITx™ Conclusions and Next Steps

- LTX-04 (Studies 400 and 401 Conclusions)

- We believe the micro-particles are working as designed:

✓ • The clinical data to date indicates we can manipulate the extent and duration of the gastric environment which controls the release and absorption of the active ingredient

? • The rapid release of the micro-particles upon gastric re-acidification suggests that we have excessive buffer strength in the tablets which needs to be fine tuned.

- LTX-03 (Next Steps)

- Hydrocodone Bitartrate with Acetaminophen
- Study AP-ADF-300 Buffer Dose Ranging Study
- Design final tablet formulation with appropriate buffer strength
- Move to commercial supply for NDA clinical work



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Immediate Release Opioids Market Opportunity

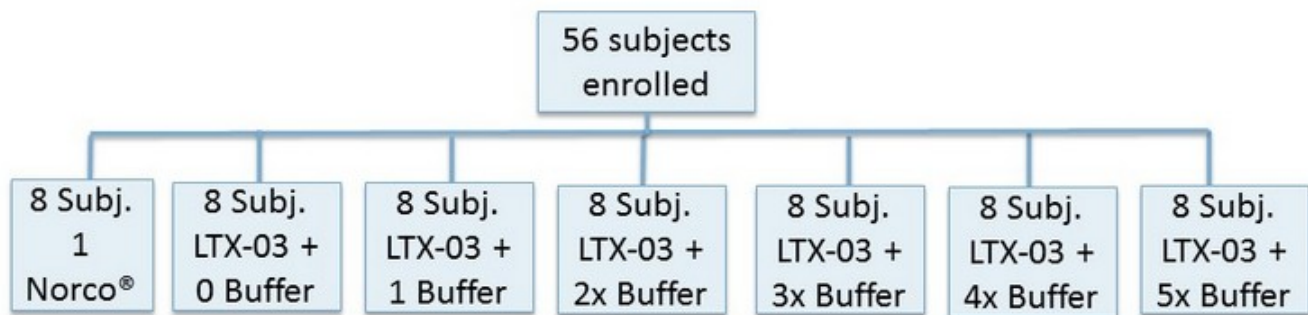
Immediate-release Opioid	Reference Brand(s)	2016 Addressable Market (millions)			
		TRx	Tablets	Dollars	Price/Tab*
Hydrocodone/APAP	Vicodin, Norco	88.7	5,433	888	.16
Oxycodone/APAP	Percocet	35.1	2,224	841	.38
Oxycodone	Roxicodone	20.1	1,775	359	.20
Tramadol	Ultram	41.3	3,068	66	.02
Hydromorphone	Dilaudid	3.2	253	42	.17
Morphine		1.5	129	21	.16
Oxymorphone	Opana	.2	21	45	2.14
Total Addressable Market		190.1	12,903	2,262	

*Average - Principally generic pricing with pricing leverage for differentiated products



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Study AP-LTX-300 Design



Norco = Hydrocodone Bitartrate/APAP 10/325mg tablet

LTX-03 = Hydrocodone MP with APAP 10/325mg dose

Buffer = Buffer strength dose at a fraction of that studies in Studies 400 and 401

Doses will be over-encapsulated

Parallel design – one dose visit per subject

Pharmacokinetic outcomes

Topline results – expected Oct. 2017



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Acura's Other Technologies



Aversion® Opioid Analgesic

- FDA approved (Oxaydo®)
- Differentiated abuse deterrent label (snorting)
- Oxaydo® Licensed worldwide to Egalet Corp.
 - Stepped Royalties
- Aversion® licensed to Kempharm for their prodrugs
 - Royalty

Impede® Pseudoephedrine Nasal Decongestant

- Nexafed® licensed to MainPointe Pharma (US/Canada)
 - 7.5% Royalty
- Acura finishing development of PSE/Loratadine with Impede®



Symbol: ACUR

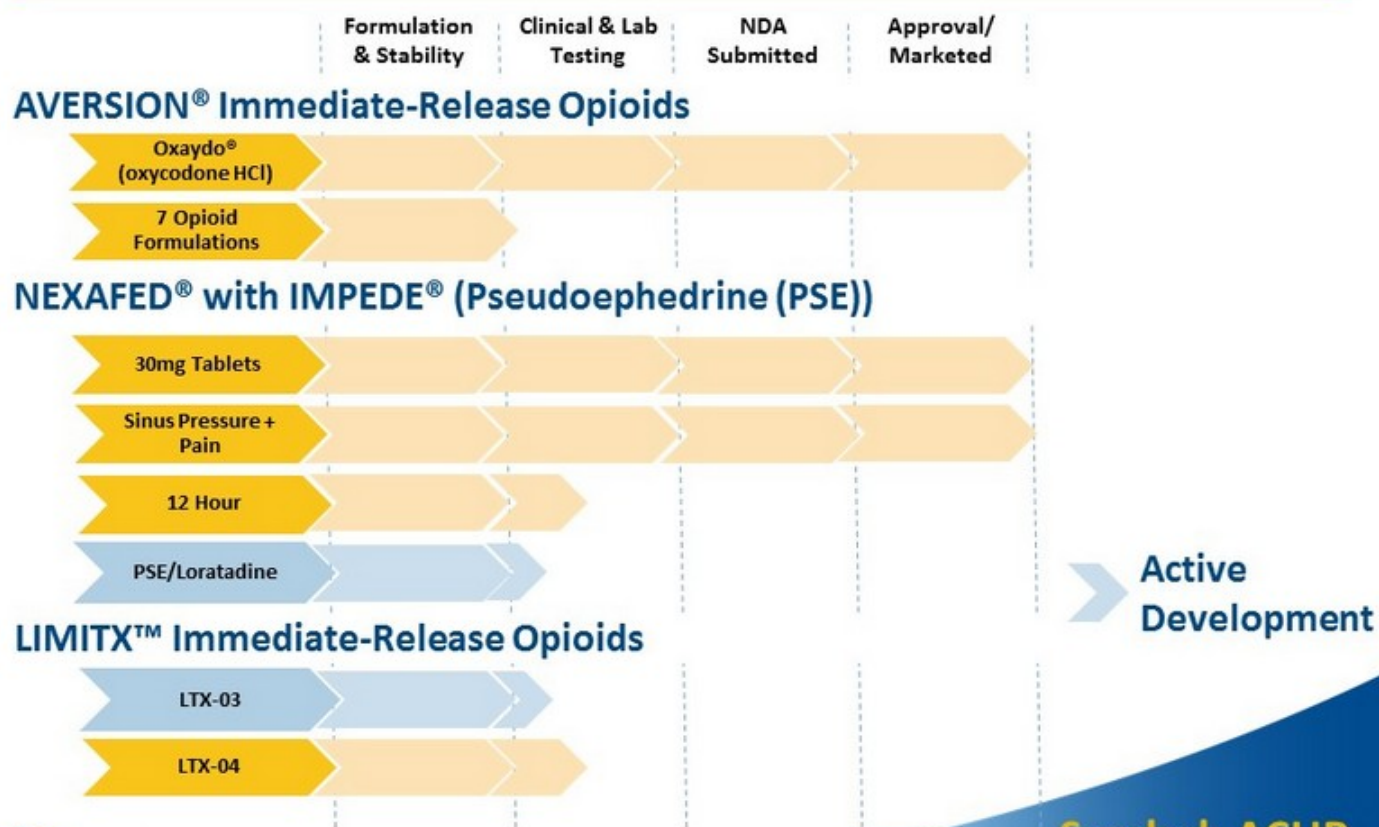
Acura Pharmaceuticals Summary



Symbol: ACUR

20

Acura Product Pipeline Overview



Intellectual Property Position

- **Limitx™ Technology: U.S. issued patents expire 2033**
 - 3 U.S. patents issued
 - 9,101,636 - 9,320,796 - 9,662,393
 - Patents issued in selected foreign jurisdictions
- **Aversion® Technology: U.S. issued patents expire 2023 to 2025**
 - 6 U.S. patents issued
 - US Generic market entry January 2022
 - Patents issued in selected foreign jurisdictions
- **Impede® Technology: U.S. issued patent expires 2032**
 - 1 U.S. patent issued
- **Additional U.S. and foreign patents pending for all technologies**



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Expectations for 2017

- Limitx™ Technology
 - Results from Study AP-LTX-300 expected October 2017
 - Determine commercial LTX-03 formulation
 - Commence LTX-03 NDA studies in 2018
 - Evaluate LIMITx™ for additional drug classes
- Complete formulation work on PSE/Loratadine in first half 2018
- Pursue further licensing/partnering opportunities
- Sufficient cash to execute current business plan through Q1 2018



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www.AcuraPharm.com



**Acura Pharmaceuticals Presenting New LIMITx™ Clinical Data
at the 19th Annual Rodman & Renshaw Conference**

PALATINE, Ill, September 11, 2017: Acura Pharmaceuticals, Inc. (OTCQB: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, today announced the results from the previously undisclosed exploratory arm of its second LIMITx™ clinical study, study AP-LTX-401 (Study 401). Bob Jones, President and Chief Executive Officer, will present the results at the 19th Annual Rodman & Renshaw Global Investment Conference today at 1:45 p.m. Eastern Time. The presentation will be webcast live and may be accessed by visiting Acura's website at www.acurapharm.com.

Study 401 dosed fasted subjects with 7 tablets of LTX-04P3, a test version of Acura's LTX-04 LIMITx oral excessive tablet abuse deterrent technology with a comparison to 7 tablets of commercially available comparable hydromorphone hydrochloride tablets. The exploratory arm added an ingredient, simultaneously dosed with 7 LTX-04P3 Tablets, known to delay gastric emptying and to potentially increase the retention of the LIMITx buffering ingredients in the stomach.

The exploratory arm demonstrated an increase in time to maximum concentration of drug in the bloodstream (lnTmax) to slightly over 2 hours compared to 43 minutes for hydromorphone and 73 minutes for LTX-04P3 alone. Peak concentration of drug in the bloodstream (lnCmax) for the exploratory arm was 3.74 ng/mL compared to 6.73 for hydromorphone and 2.49 for LTX-04P3 alone.

The 7 tablet cohort in Study 401 was a crossover pharmacokinetic design in fasted, healthy adult subjects. 30 subjects completed the hydromorphone arm, 13 subjects completed the LTX-04P3 arm, and 15 subjects completed the LTX-04P3 exploratory arm. There were no serious adverse events with adverse events observed consistent with those known to be associated with hydromorphone.

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.

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.

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