

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

March 11, 2016
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))
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Item 7.01 Regulation FD Disclosure.

Robert Jones, President and Chief Executive Officer of Acura Pharmaceuticals, Inc. (the “Company”), will present at the 28th Annual ROTH Capital Conference on Monday, March 14, 2016 at 11:30 a.m. Pacific Time at the Ritz-Carlton Laguna Niguel in Dana Point, California. Slides from the presentation are attached hereto as Exhibit 99.1.

On March 11, 2016, it came to the Company’s attention that it previously inadvertently disclosed to an analyst information not previously publicly disclosed by the Company, or disclosed in the same detail by the Company. The slides containing such information are attached as Exhibit 99.2. Each of these slides reflect one of several possible scenarios and were for illustrative purposes only. One of the slides contained information on one possible development timeline and possible costs associated with development activities through NDA submission for LimitX[™]. The Company believes the information contained therein was consistent with but more detailed than its previous disclosure. The Company intends to update the market with a more definitive development plan after a meeting the FDA assuming success from results from study AP-LTX-400. The other slide disclosed the potential market opportunity for a hydromorphone and hydrocodone/acetaminophen LimitX based product, based on an illustrated 10% market share and is not based on the Company’s research or management’s expectations. The information on this slide is not specific to the Company and is available from industry sources. The Company does not intend to update the information on these Extra Slides.

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.

Statements in the attached exhibits 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;
 - our and our licensee’s ability to successfully launch and commercialize our products and technologies, including Oxaydo[®] Tablets and our Nexafed[®] products;
 - the projected timeline and development costs associated with our LimitX technology;
 - the potential pricing, market size, market share or profitability of products or product categories utilizing our LimitX technology;
 - the pricing and price discounting that may be offered by our licensee, Egalet for Oxaydo;
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- whether we can successfully develop a product under our agreement with Bayer;
 - the results of our development of our Limitx technology;
 - 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;
 - the willingness of pharmacies to stock our Nexafed 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;
 - our exposure to product liability and other lawsuits in connection with the commercialization of our products;
 - the increasing cost of insurance and the availability of product liability insurance coverage;
 - 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 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 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;
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- 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 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 9.01 Financial Statements and Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Slides from the Scheduled Presentation on March 14, 2016
99.2	Extra 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: March 11, 2016

<u>Exhibit Number</u>	<u>Description</u>
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99.1	Slides from the Scheduled Presentation on March 14, 2016
99.2	Extra Slides



***Abuse Deterrent
Specialty Pharmaceuticals***

March 2016

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.

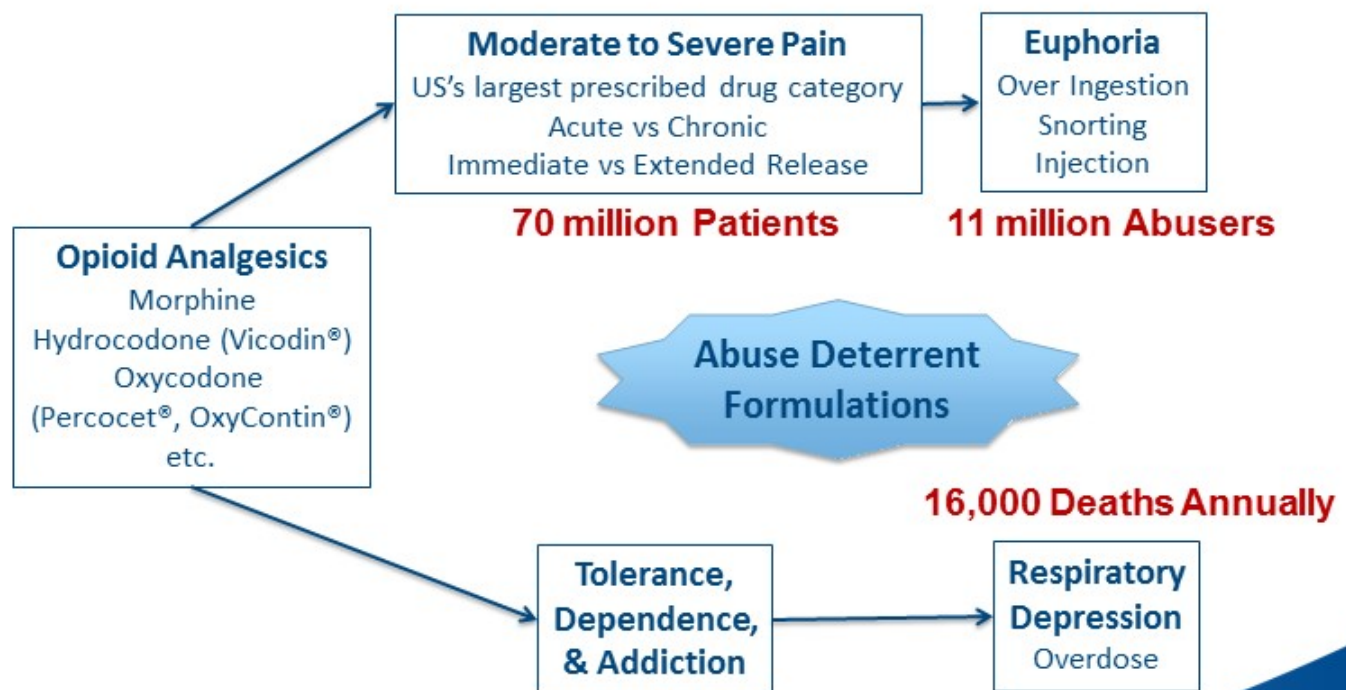
Forward-looking statements may include, but are not limited to:

- the 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, whether approved product labeling will allow for presentation of our technologies’ abuse deterrent features, and whether our technologies will actually reduce abuse if marketed;
- 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.



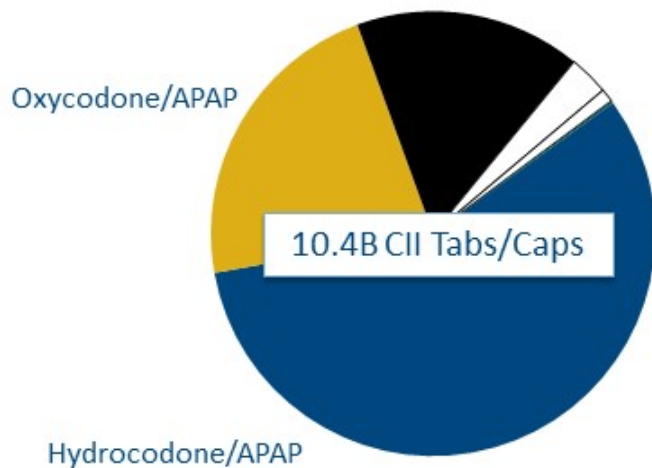
Nasdaq: ACUR

Abuse of Prescription Opioids



FDA Incentivizes Oral Abuse Deterrence in Immediate-release Formulations

- 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



FDA has incentivized industry by holding out the two largest volume Immediate Release CII opioids for those that develop **oral abuse deterrence**

Acura's Abuse Deterrent Technology Platforms

LIMITx™

- Opioid Abuse – **Oral, Snorting and Injection**
- Accidental overdose of NTI drugs
- Immediate-Release Segment
- \$2.9 billion addressable segment with pricing leverage
- Partnership Opportunities
- Issued US Patent to 2033



AVERSION®

- Opioid Abuse – **Snorting and Injection**
- Oxaydo® FDA Approved
- Worldwide license to Egalet
- Abuse Deterrent Labeling
- Issued US Patents to 2025
- \$0.4 billion addressable segment with pricing leverage

IMPEDE®

- Pseudoephedrine – **Convert to Methamphetamine**
- Immediate and Extended Release Tablets
- \$0.3 billion addressable market
- 2 Nexafed® IR products marketed by Acura
- Partnership Opportunities
- Issued US Patents to 2032



Nasdaq: ACUR

The Limitx™ Technology

Product Formulation

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

Oral Abuse Deterrence

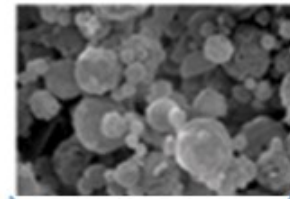
- Tablet matrix acts synergistically with the micro-particle ingredients to retard the release of micro-particle active ingredients when multiple tablets are ingested

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

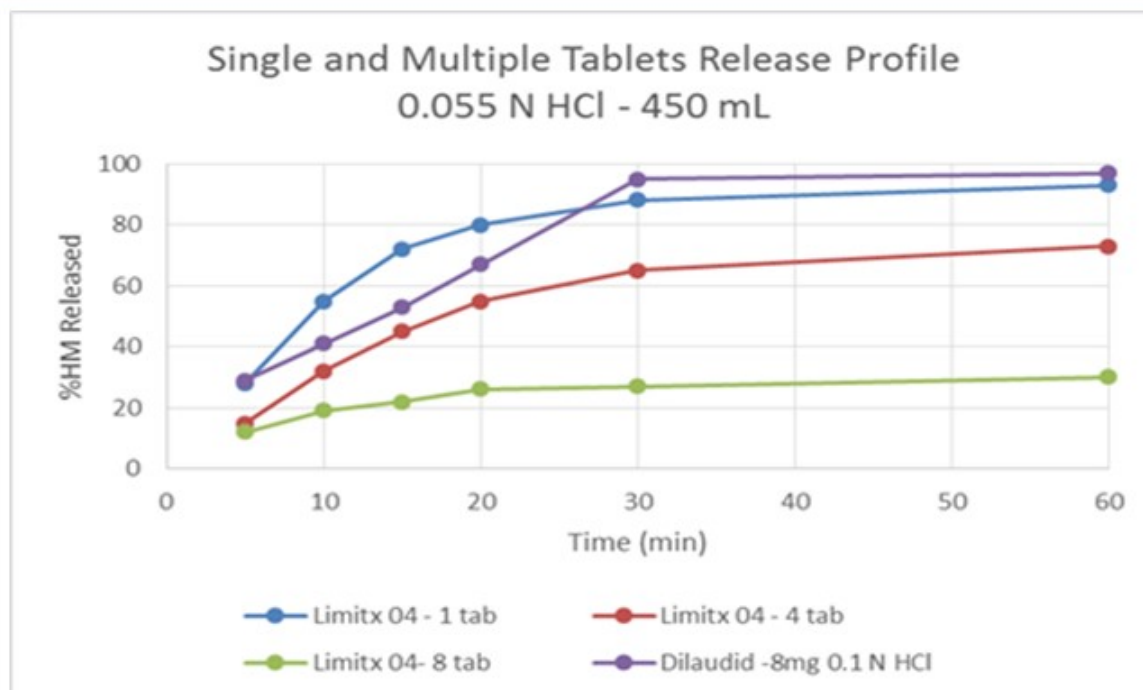


Illustration



Nasdaq: ACUR

LTX-04 (hydromorphone) Tablet Dissolution



LTX-04 research is funded in part by a grant from NIDA who are not responsible for any research or results

Study AP-LTX-400

Objective: Demonstrate therapeutic and safe blood levels for LTX-04 at 1 and/or 2 tabs and diminishing marginal blood absorption (C_{max} and/or AUC) at 3+ tabs

Cohort 1 – efficacious dose levels

- 30 subjects enrolled to target 24 completers
- 1, 2 and 3 tablet sub-groups taking Dilaudid and two LTX-04 formulations
- Dosing started late February
- Cohort 1 results to be analyzed to select Cohort 2's LTX-04 formulation

Cohort 2 – abused dose levels

- 30 subjects enrolled to target 24 completers
- 4, 6 and 8 tablet sub-groups taking Dilaudid and one LTX-04 formulation

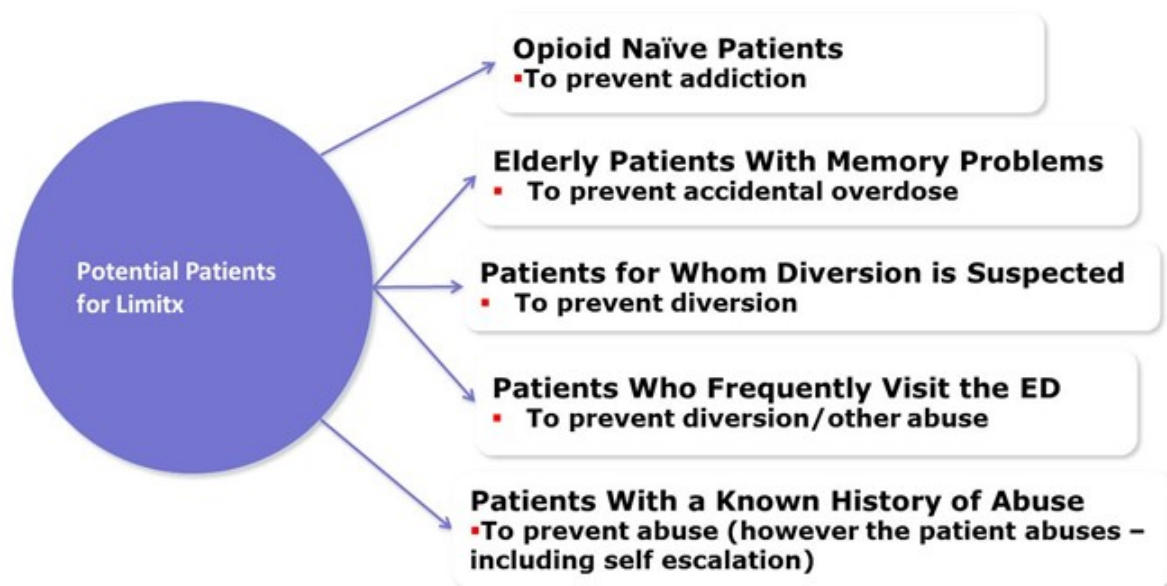
- **Study completion expected 1H 2016**



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As identified by opioid prescribers



Source: Company Research, 8 physicians



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Immediate Release Opioids Market Opportunity

Immediate-release Opioid	Reference Brand(s)	2014 Addressable Market (millions)			
		TRx	Tablets	Dollars	Price/Tab*
Hydrocodone/APAP	Vicodin, Norco	117.5	6,883	984	.14
Oxycodone/APAP	Percocet	35.5	2,206	994	.45
Oxycodone	Roxicodone	14.8	1,672	481	.29
Tramadol	Ultram	42.9	3,324	87	.03
Hydromorphone	Dilaudid	3.5	280	53	.19
Morphine		1.6	143	15	.10
Oxymorphone	Opana	.2	22	61	2.77
Total Addressable Market		216.0	12,324	2,675	

*Principally generic pricing with pricing leverage for differentiated products



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Limitx™ Near Term Activities

- **1H - 2016**

- Announce topline pilot pharmacokinetic study (AP-LTX-400) results
 - Potential to announce interim results
- Complete formulation LTX-03 (Hydrocodone/APAP)
- Evaluate Partnering Opportunities

- **2H - 2016**

- Hold “End of Phase 2” meeting with the FDA for LTX-04
 - Identify remaining LTX-04 development program
- Submit IND for LTX-03



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Marketed Product Opportunities



- **Aversion® Opioids Analgesic**
 - Oxaydo™ FDA approved
 - Licensed worldwide to Egalet Corp.
 - Product launched in the US in September 2015
 - Supported by 50 sales representatives
 - Differentiated abuse deterrent label (snorting)
 - 1.7 billion tablet addressable market

- **Impede® Pseudoephedrine Nasal Decongestant**
 - Acura markets Nexafed® and Nexafed® Sinus
 - Nexafed® Launched December 2012
 - Research collaboration with Bayer Healthcare
 - 12 Hour formulation in development
 - \$0.3 billion addressable market



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Oxaydo® - Egalet Partnership

- Egalet has US and EU Operations
- Extended-release abuse deterrent formulations in development
- Right of first negotiation for a Limitx™ oxycodone product



Financial Terms

- \$5.0 million upfront payment
- \$2.5 million upon first US product shipment
- \$12.5 million one time milestone when worldwide net sales first reach \$150 million in a calendar year
- Royalties on a stepped basis starting at mid-single digits percentage to double digits on net sales worldwide

Market Opportunity-2015

- 1.7 billion tablets dispensed
- \$.23/tablet generic market pricing
- Egalet responsible for Oxaydo pricing



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Impede® Technology/Nexafed® Franchise

- **Chemical conversion of pseudoephedrine (PSE) from cold products into methamphetamine**
 - Dangerous, toxic process requires costly clean-up and creates child endangerment
 - Highly addictive – no pharmaceutical treatment
- **1.2 million people in the US used methamphetamine at least once in 2014**
- **The 2006 Combat Methamphetamine Epidemic Act**
 - Pseudoephedrine (PSE) products secured “behind the counter” / limits consumers purchases
 - 83% increase in labs incidents between 2007 and 2012 (49 states at least 1 incident)
- **State Legislative Initiatives Imposing Further Restrictions on Legitimate Consumers**
 - Oregon, Mississippi and parts of Missouri require dispensing with a physician’s prescription
 - Pseudoephedrine is subject to ongoing Rx-only legislative activity
- **Nexafed® has been associated with reduction of meth-labs of up to 90% in select regions**



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Impede® - Expansion/Partnering Opportunities

2014 US ex-Factory¹ Sales (\$340 Million)



- Higher value targets in extended-release segment
- Move to behind-the-counter generated ~50% value loss
- Continued legislative pressure on pseudoephedrine product sales
- Potential for sole source upside against generics with issued patent to 2032
- Creates strong partnering potential

¹ Assumes a 28% mark-up to retail pricing



Nasdaq: ACUR

Intellectual Property



Nasdaq: ACUR

Intellectual Property Position

- **Limitx™ Technology:** U.S. issued patent expires 2033
 - 1 U.S. patent issued
 - 1 Canadian notice of allowance
- **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**
 - Multiple patent applications are pending in the United States and internationally for all our technologies



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17

Expectations for 2016

- Sufficient cash to execute current business plan through 2016
- Limitx™ Technology
 - Final Topline results from Study AP-LTX-400 in 1H 2016
 - If successful, FDA End of phase 2 meeting on LTX-04 and outline development program and timelines to NDA
 - Initial LTX-03 Formulation and submission of an IND in H2 2016
- Aversion® Technology – Advancement of Oxaydo® by Egalet
- Impede® Technology
 - Submit IND for 12-hour product and advance commercial scale-up
 - Further recognition of public health benefits in state jurisdictions
- Further licensing/partnering opportunities
- Analyst coverage
 - Roth Capital (Michael Higgins)
 - FBR (Vernon Bernardino)



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www.AcuraPharm.com
www.Nexafed.com
www.Oxaydo.com

Limitx™ Tablets

General Development Timeline(s)

Critical Path Activities	Cost	Hydromorphone	Other Formulation
	\$MM	Months to Develop	
Formulation/Methods Development	.3	--	3
Transfer to Commercial Supply	.3	3	3
Fasted Oral PK Study (BE/abuse deterrent)	.5	3	3
Fed Oral PK Study	.5	3	3
Nasal PK/Liking Study	5.0	6	6
NDA Preparation/Submission	2.0	4	4
Total	8.6	19	22

Assumes Category 2 Oral Abuse Deterrent Labeling
 Category 3 Oral Abuse Deterrent Supplement Not Included



Limitx™¹

Limitx™ Sales Potential - Illustrative

- 10% market share
- Market volume (tabs) remain at 2014 levels
- Avg. Price/Tab = total sales divided by extended units (IMS NPA data)
- Brand price: Dilaudid (hydromorphone) and Vicodin+Norco (hydrocodone/APAP)

	Hydromorphone	Hydrocodone/APAP
Market Tabs (MM)	280	6,883
Generic Price/Tab	0.19	0.14
Sales Value (MM)	\$5.3	\$96.4
Brand Price/Tab	2.31	1.38
Sales Value (MM)	\$64.7	\$949.9
50% of Brand Price	1.16	0.69
Sales Value (MM)	\$32.3	\$474.9

Abuse Deterrent Product Pricing Research Available Under CDA