

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 28, 2015
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.

Commencing in October 2015, Robert B. Jones, our Chief Executive Officer, and Peter A. Clemens, our Senior Vice President and Chief Financial Officer, are scheduled to make presentations about Acura Pharmaceuticals, Inc. at meetings with institutional and retail brokers at various locations in the U.S. and Canada. Slides to be used in such presentations are attached hereto as Exhibit 99.1.

Statements in the 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 Aversion®, Impede® and Limitx™ technologies;
 - our and our licensee’s ability to successfully launch and commercialize our products and technologies, including Oxaydo Tablets and our NEXAFED products;
 - the pricing and price discounting that may be offered by Egalet for OXAYDO;
 - whether we can successfully develop a product under our IMPEDE license agreement with a multi-national pharmaceutical company;
 - 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 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 and the timing of first sales;
 - our ability to develop and enter into additional license agreements for our AVERSION Technology 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;
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- 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 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,” “indicates,” “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. 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.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Slides to be used in Acura Presentations

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 28, 2015

**Exhibit
Number**

Description

99.1	Slides to be used in Acura Presentations
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***Abuse Deterrent
Specialty Pharmaceuticals***

Fall 2015

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 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 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

Company Overview

- Specialty Pharmaceuticals – Abuse Deterrence
- Palatine, IL – Corporate Headquarters
- Culver, IN - 28,000 sq. ft. R&D laboratory (Wholly owned)
- Pharmaceutical Formulation Development
- OTC Product Marketing



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Management, Board and Ownership

➤ Key Management

- Bob Jones, President & CEO, Director (30+ years in pharmaceuticals)
- Peter Clemens, Sr. VP & CFO (25+ years in pharmaceuticals)
- Al Brzezko, PhD, Chief Scientific Officer (25+ years in pharmaceuticals)

➤ Board of Directors (non-management)

- William Skelly, CEO of Central Biomedica, Inc.
- George Ross, Consultant to early stage business and financial investor
- Bruce Wesson, former General Partner, Galen Partners
- Immanuel Thangaraj, Mgr. Director, Essex Woodlands Health Ventures

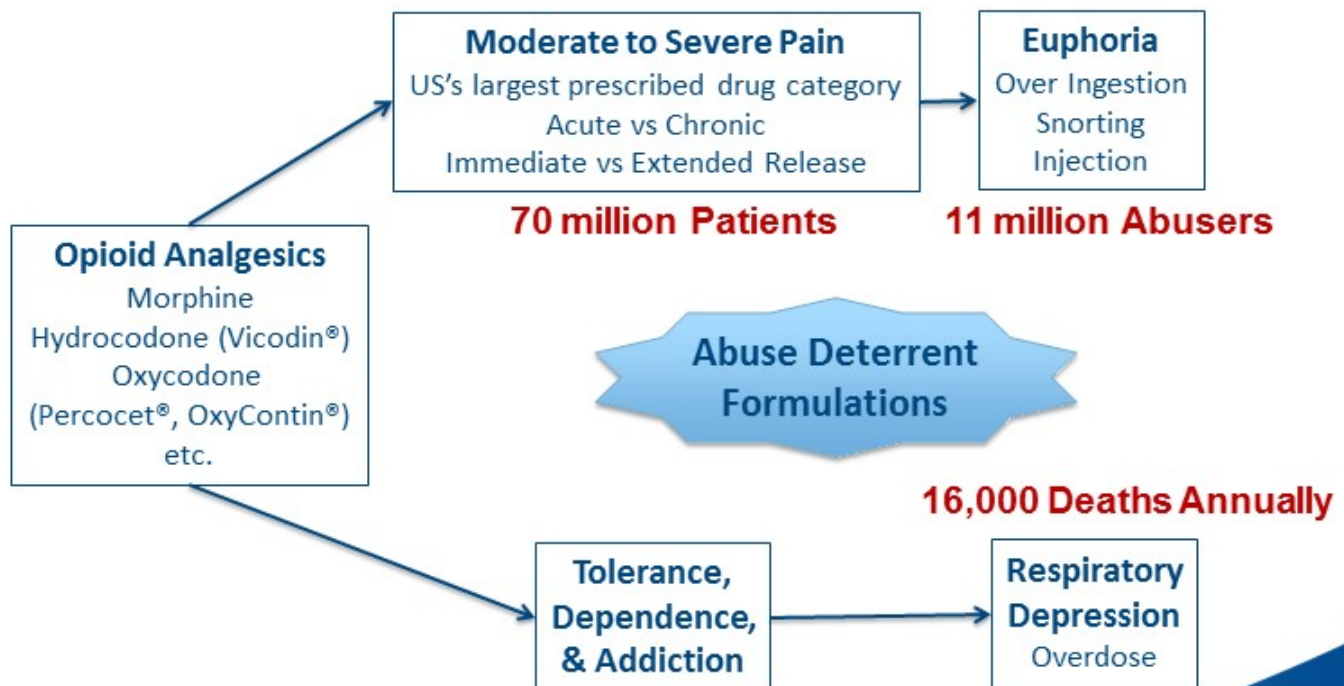
➤ Ownership (11.8 million total common shares outstanding listed on Nasdaq)

- Galen Partners – 2.2 million
- Essex Woodlands – 2.0 million
- Deerfield Management – 1.0 million (invested in July, 2015)
- Sabby Capital – 0.9 million (invested in July 2015)
- Other investors – 5.7 million (comprised of ~ 1,000 investors)



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Abuse of Prescription Opioids



Abuse Deterrent Opioids – An Unmet Need

2003 - FDA calls for industry to develop abuse deterrent formulations

2005 - Prescription opioid abuse described as “epidemic”

- **Joseph Califano, National Center for Addiction and Substance Abuse**

2015 - Prescription drug abuse is the Nation's fastest-growing drug problem and has been classified as an epidemic by the Centers for Disease Control and Prevention

- **Office of National Drug Control Policy website.**

“We think this [abuse deterrence] is a high priority”

“Oral abuse still remains very challenging in terms of abuse deterrent formulations”

“[Current technologies] still allow abuse through oral, the most common source”

“We need continued innovation”

- **Margaret Hamburg, FDA Commissioner**

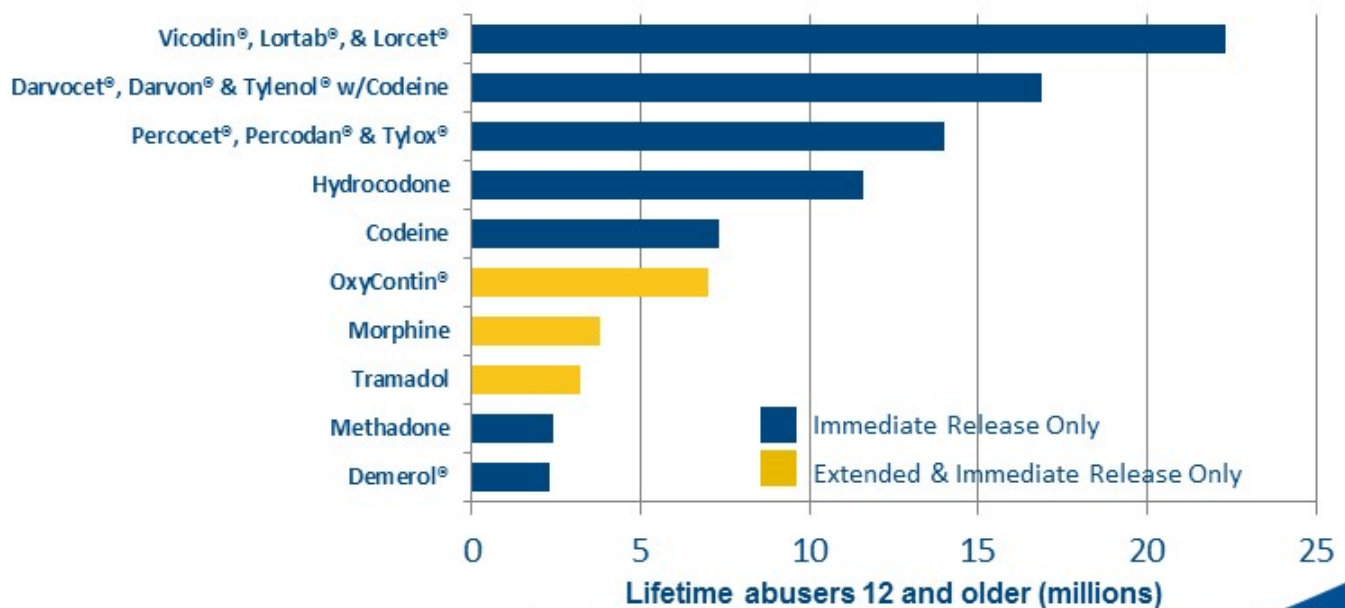
FDA issues final guidance to industry on developing abuse deterrent opioids



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Immediate-Release Opioid Abuse is Most Prevalent

"Availability is the mother of abuse".... Joseph A. Califano



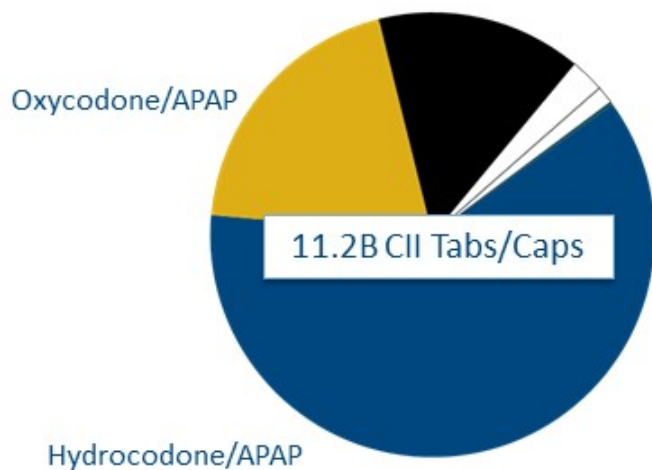
Source: SAMHSA, Office of Applied Studies, 2012 National Survey on Drug Use and Health



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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



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Acura's Abuse Deterrent Technology Platforms

LIMITx™

- Opioid Abuse – **Oral, Snorting and Injection**
- Accidental overdose of NTI drugs
- Immediate-Release Segment
- \$2.7 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 – **Conversion 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



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Limitx™ is at the forefront of ADF Technologies

Limitx™ is being developed in part with a grant from NIDA of the NIH

“In partnership with the NIH, we [FDA] can continue to really move some of the [abuse deterrence] scientific thinking” ... Margaret Hamburg, FDA Commissioner, 2015

Company	Technology	Route of Abuse Addressed		
		Oral*	Nasal	IV
Acura	Limitx™	★	★	★
Acura	Aversion®		★	★
Purdue	unknown		★	★
Grunenthal	Intac™ IR		★	★
Atlantic	SMART/Script™		★	★
KemPharm	Prodrug	1	★	★
Signature	Prodrug		★	★
Pisgah	Acid soluble salts		★	★

* Accidental or intentional over ingestion of tablets

1 Reduced AUC at 12 tabs. No reduction in Cmax or Drug Liking



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The Limitx™ Technology

Product Formulation

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

Oral Abuse Deterrence

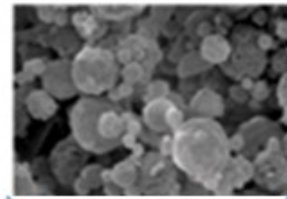
- Tablet matrix acts synergistically with the micro-particle ingredients to retard the release of micro-particle active ingredients when multiple tablets are ingested

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

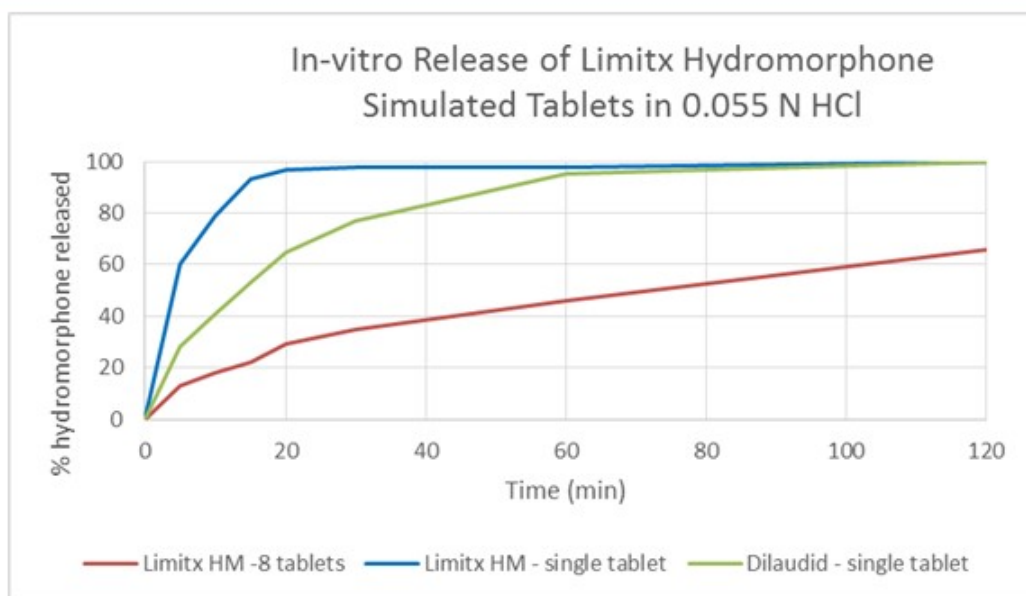


Illustration



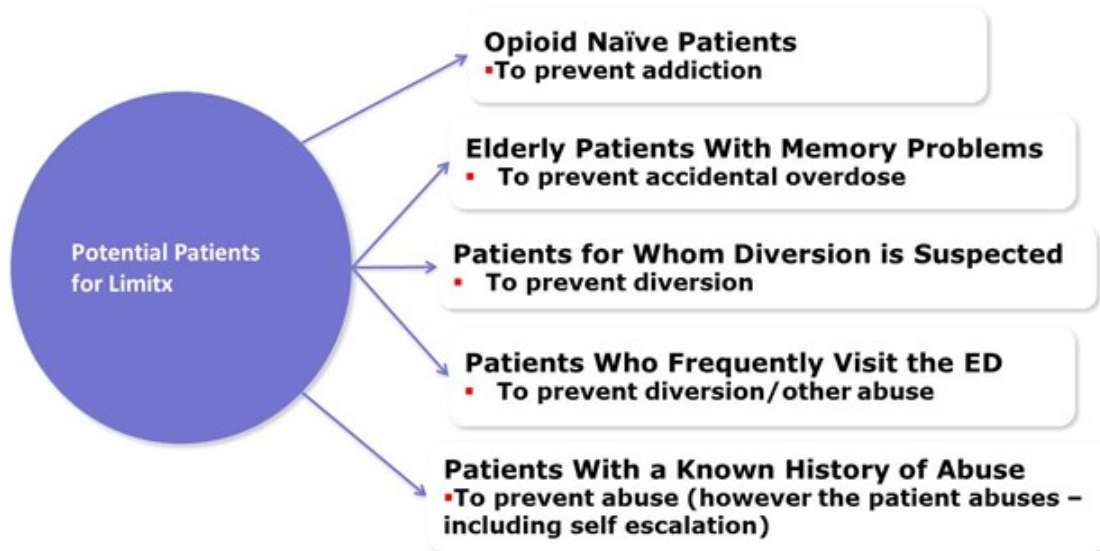
Nasdaq: ACUR

Limitx™ Proof of Concept



- .055N HCl simulated stomach acid
- Blue line - Single Limitx™ tablet releases 100% in ~20 minutes
- Red line – 8 Limitx™ tablets release 66% in ~120 minutes
- Green line – 1 Dilaudid® tablet releases 100% in ~60 minutes

As identified by opioid prescribers



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Immediate Release Opioids Market Opportunity

		2014 Addressable Market (millions)			
Immediate-release Opioid	Reference Brand(s)	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

- **4Q-2015**

- Submit an Investigational New Drug application to the FDA for Hydromorphone
- Initiate a pilot pharmacokinetic study for Hydromorphone
- Initiate development Hydrocodone micro-particle

- **1H-2016**

- Pilot pharmacokinetic study for Hydromorphone topline results
- Complete formulation of Hydrocodone tablets
- Evaluate Partnering Opportunities



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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)
 - 1.6 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

- 1.6 billion tablets dispensed
- \$.29/tablet generic market pricing
- Egalet will set pricing for Oxaydo



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Impede® Technology/Nexafed® Franchise

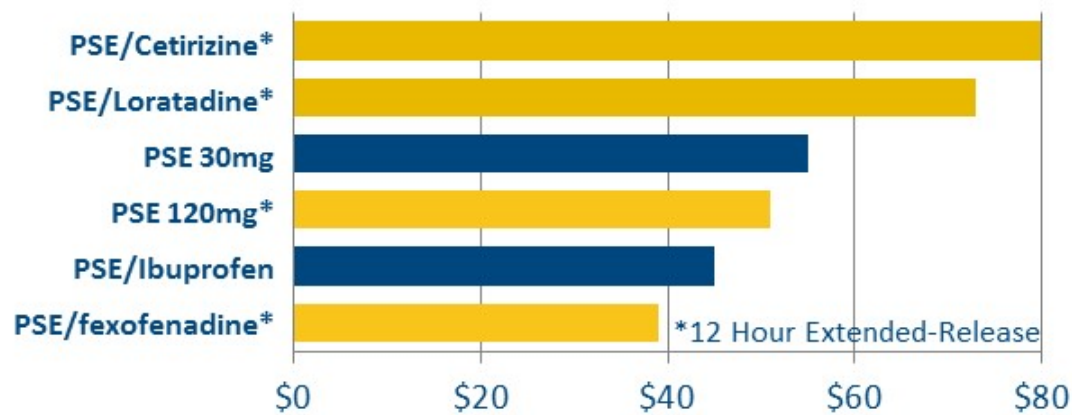
- **Chemical conversion of pseudoephedrine (PSE) from cold products into methamphetamine**
 - Dangerous, toxic process requires costly clean-up and creates child endangerment
 - Highly addictive – no pharmaceutical treatment
- **1.2 million people in the US used methamphetamine at least once in 2014**
- **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%**



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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



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Intellectual Property and Financial Information



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Intellectual Property Position

- **Limitx™ Technology US issued patent expires 2033**
 - 1 U.S. patent issued
- **Aversion® Technology US 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 US issued patent expires 2032**
 - 1 U.S. patent issued
- **Additional U.S. and foreign patents**
 - Multiple patent applications pending in the United States and internationally



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Financial and Share Summary @ 10/1/2015

- Sufficient cash to execute current business plan through 2016
- Projected to have ~ \$13.5 million of cash at 12/31/2015

Selected Financial Information	\$ Millions
Cash, Cash Equivalents and Marketable Securities	\$15.2
Debt (60 month term @ 8.35% with interest only thru March, 2015 and principal & interest to December 2018)	\$8.7
Shares Outstanding	Millions
Total Common Shares Outstanding	11.801
Shares Held by 4 Largest Shareholders (52%)	6.110



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