

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 10, 2014
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 B. Jones, our Chief Executive Officer, is scheduled to make a presentation about Acura Pharmaceuticals, Inc. at the 26th Annual ROTH Capital Conference on Tuesday, March 11, 2014 at 4:00 p.m. Pacific Time at the Ritz-Carlton Laguna Niguel in Dana Point, California. 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, the ability of our patents to protect our products from generic competition, our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation, whether private plaintiffs will challenge the Settlement Agreements we entered into with each of Par Pharmaceutical and Impax Laboratories relating to our Oxecta® patent infringement litigation, whether or not additional third parties may seek to market generic versions of Oxecta® and the results of any litigation that we have filed or may file to defend and/or assert our patents against such companies, the possible occurrence of one of the specific events that would result in Par Pharmaceutical or Impax Laboratories marketing a generic Oxecta® earlier than we anticipate, the possible approval by the U.S. Food and Drug Administration (“FDA”) of Sandoz Inc.’s or Ranbaxy Inc.’s generic Oxecta product prior to the expiry of our patents covering Oxecta, our and our licensee’s ability to successfully launch and commercialize our products and technologies including Oxecta® Tablets and Nexafed® Tablets, the price discounting that may be offered by Pfizer for Oxecta, our and our licensee’s ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, the willingness of wholesalers and pharmacies to stock Nexafed® Tablets, expectations regarding potential market share for our products and the timing of first sales, our ability to enter into additional license agreements for our other product candidates, our exposure to product liability and other lawsuits in connection with the commercialization of our products, the increased 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, and 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 to meet over-the-counter, or 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 product candidates, whether the FDA will agree with our analysis of our clinical and laboratory studies and how it may evaluate the results of these studies or 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, whether our product candidates will ultimately deter abuse in commercial settings and whether our Impede technology 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 and beliefs with respect to future events and are based on assumptions and subject to significant risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in the slides may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Forward-looking statements speak only as of the date of this Report, and Acura undertakes no obligation to update or revise these statements.

Item 9.01 Financial Statements and Exhibits.

**Exhibit
Number**

Description

| | |
|------|--|
| 99.1 | Slides from the Scheduled Presentation on March 10, 2014 |
|------|--|

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 10, 2014

| <u>Exhibit Number</u> | <u>Description</u> |
|---------------------------|--------------------|
|---------------------------|--------------------|

| | |
|------|--|
| 99.1 | Slides from the Scheduled Presentation on March 10, 2014 |
|------|--|



Non-Confidential

Roth Capital – March, 2014

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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. Forward-looking statements may include, but are not limited to, our and our licensee's ability to successfully launch and commercialize our products and technologies including Oxecta[®] Tablets and Nexafed[®] Tablets, the price discounting that may be offered by Pfizer for Oxecta[®], the ability of us or our licensee's to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, expectations regarding potential market share for our products and the timing of first sales, our ability to enter into additional license agreements for our other product candidates, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability of our patents to protect our products from generic competition, and the ability to fulfill the U.S. Food and Drug Administration's, or 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 to meet over-the-counter, or 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 product candidates, whether the FDA will agree with our analysis of our clinical and laboratory studies and how it may evaluate the results of these studies or 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, whether our product candidates will ultimately deter abuse in commercial settings and whether our Impede[™] technology 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.

Abuse Deterrent Specialty Pharmaceutical Company

Proprietary Technology Platforms

- Aversion® (Tamper Resistant) Technology
- Impede® (Meth Resistant) Technology

Aversion® Platform

- FDA approved technology
- 1st Aversion® opioid product launched by Pfizer Feb. 2012
- Follow-on products in development

Impede® Platform

- Nexafed® commercially available December 2012
- Follow-on products in development

Addressable Markets

- Opioids are the largest U.S. prescription drug category
- Sizeable non-prescription cough/cold/allergy market

Strong Balance Sheet

- \$26 million of cash and investments (12/31/13)
- Sufficient cash to execute current business plan through at least the next two years



Product Portfolio Summary

- Broad pipeline of product candidates
- Two proprietary technologies: Aversion® and Impede®

| Product | Area | Technology | Licensee | Status |
|------------------------|--------------|------------|----------|-------------------------------|
| Oxycodone HCL, USP CII | Opioid | Aversion | Pfizer | <i>Marketed in the U.S.</i> |
| Hydrocodone/APAP | Opioid | Aversion | | <i>IND Active (Jan. 2013)</i> |
| 6 Additional Opioids | Opioid | Aversion | | Proof of Concept Complete |
| Nexafed® | Cold/Allergy | Impede | | <i>Marketed in the U.S.</i> |
| Nexafed® Combo #1 | Cold/Allergy | Impede | | <i>In Commercial Scale-up</i> |
| Nexafed® Combo #2 | Cold/Allergy | Impede | | In Development |

Proof of concept = stability and bioavailability (some formulations include niacin)

Aversion[®] Technology

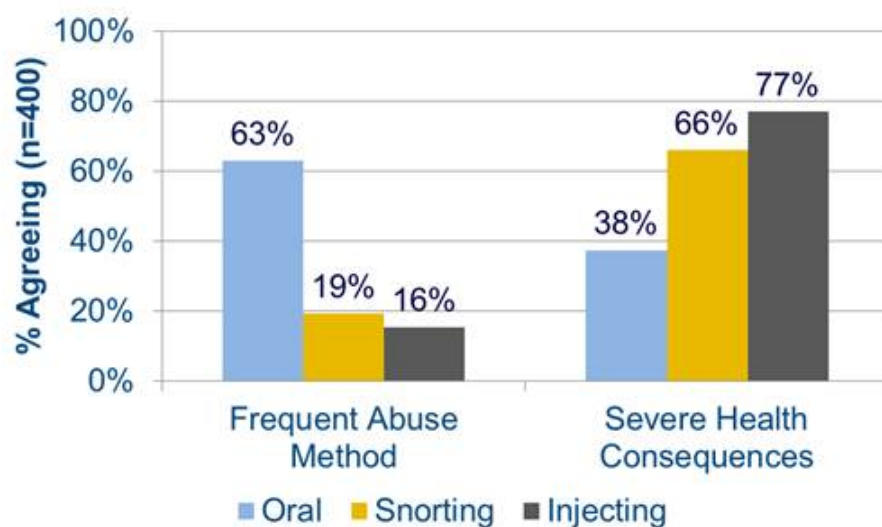
Proprietary mixture of inactive ingredients

Aversive ingredients intended to deter snorting

Physical/chemical properties intended to deter injection

Physician Perception of Opioid Abuse

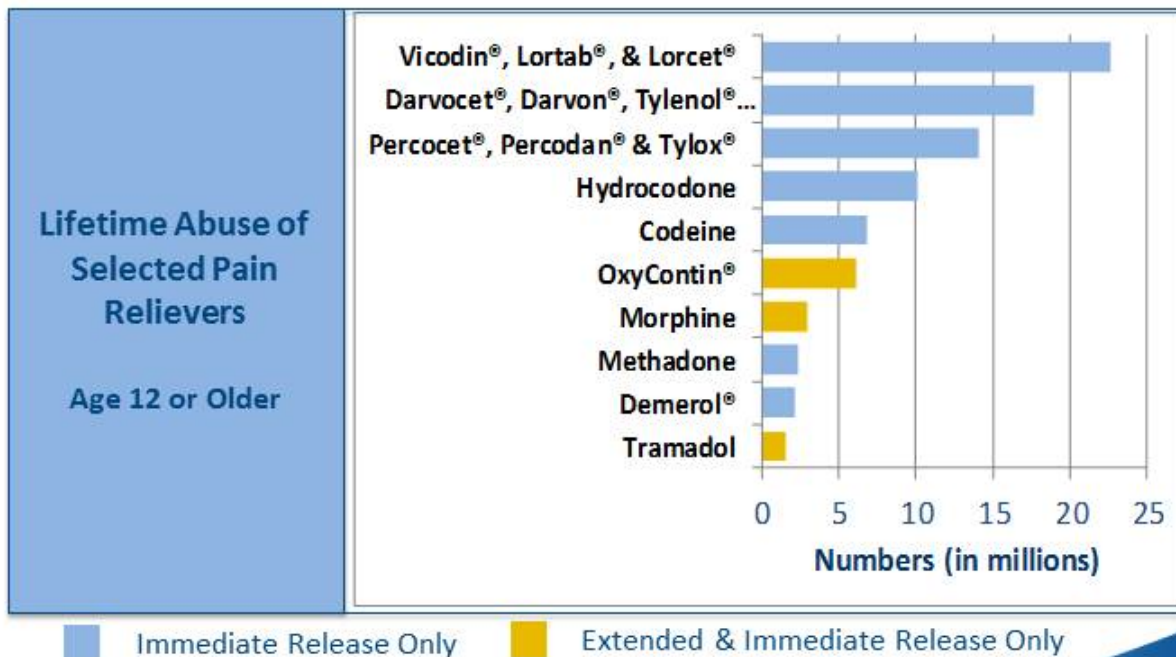
- Snorting and Injecting are the methods with the highest concern for serious adverse health consequences with immediate release opioids



Source: Company Research, 400 Primary Care, Surgeon, Pain Specialists & Emergency Room Physicians, December 2011

Abuse of Opioids is Prevalent

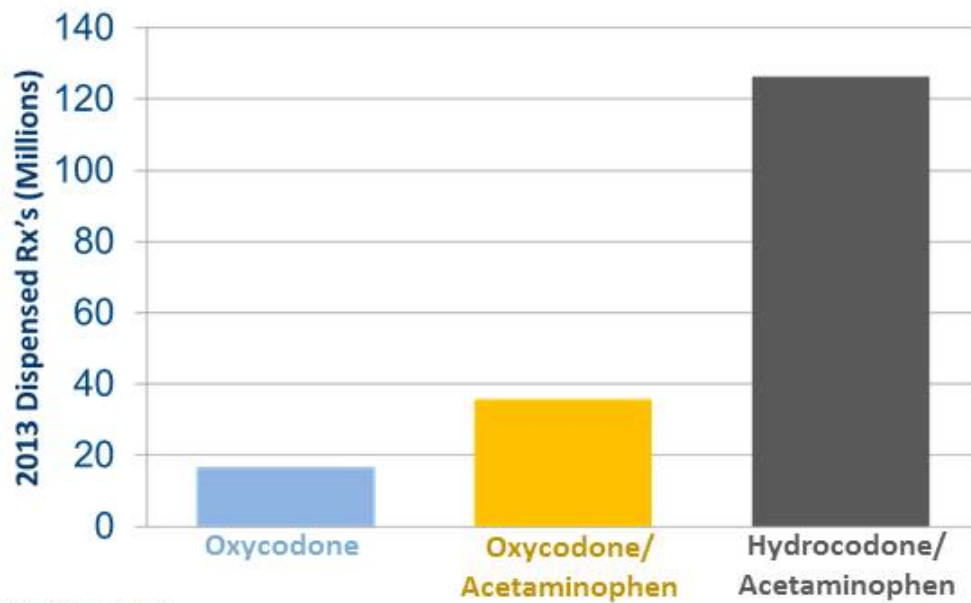
- 37 million people in the United States have used Rx opioids non-medically in their lifetime
- Immediate Release (IR) opioids are more frequently abused than Extended Release (ER) opioids



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

Aversion® IR Product Markets

- 238 million dispensed prescriptions in 2013
- \$2.6 billion in sales (mostly generic prices)



Source: IMS NPA, MAT Dec. 2013



Aversion® Opioid Product Portfolio

- Focus on rapid development of Hydrocodone/APAP
- Demonstrated application to multiple opioid formulations
- All are immediate-release tablets

| Product | Area | Technology Licensee | | Status |
|------------------------|--------|---------------------|--------|-------------------------------|
| Oxycodone HCL, USP CII | Opioid | Aversion | Pfizer | <i>Marketed in the U.S.</i> |
| Hydrocodone/APAP | Opioid | Aversion | | <i>IND Active (Jan. 2013)</i> |
| 6 Additional Opioids | Opioid | Aversion | | Proof of Concept Complete |

* Proof of concept = stability and bioavailability (some include niacin)

Aversion® Oxycodone HCl Tablets CII

- Marketed By: **Pfizer Inc.**
- Brand Name: **Oxecta®**
- FDA Approval: **June 17, 2011** (February 2, 2012 1st commercial sale)
- Direct Market Size: **16.7 million annual IR oxycodone Rx's**
+3.2% growth versus 2012
~100 Tabs per Rx
- Royalties: **5% to 25% based on level of sales achieved**
- **Pfizer initiated promotion in late Q4-2013 to national cross section of healthcare providers who treat pain**
- **Pfizer's promotion does not include sales reps**
- **Acura and Pfizer to strategically review the results on-going**

Source: IMS NPA, MAT Dec. 2012
Oxecta is a registered trademark of Pfizer Inc.



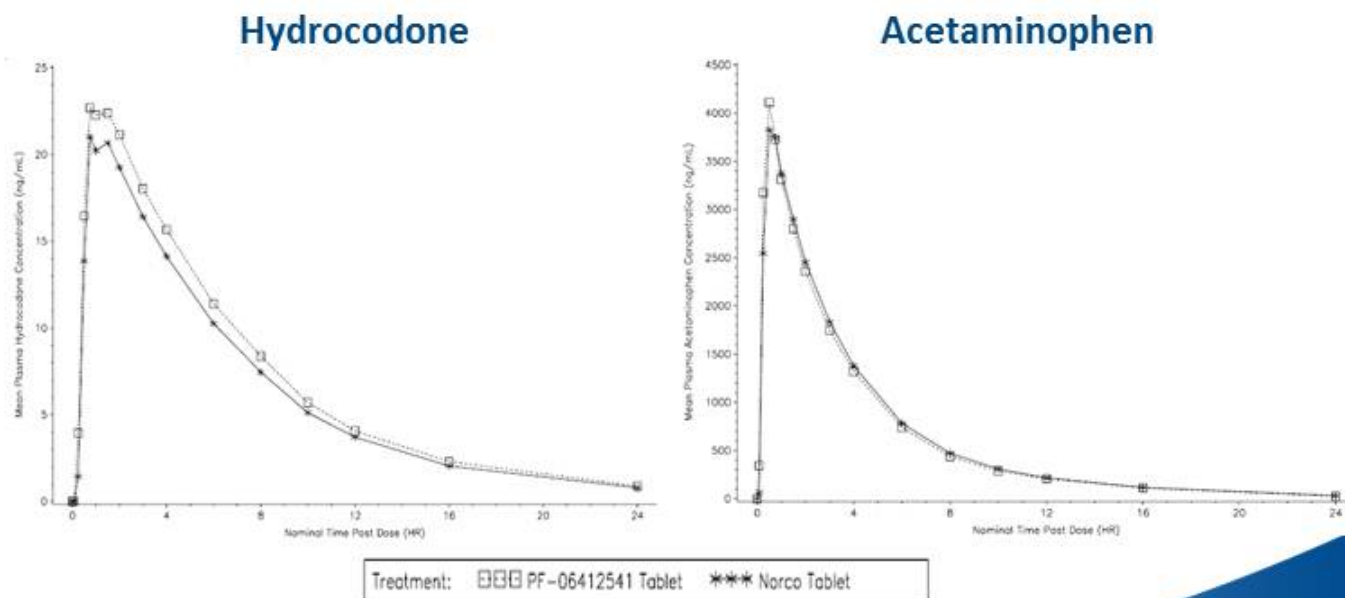
Hydrocodone/APAP Development Program

- IND active Jan. 2013
- Three *In Vitro* Laboratory Studies
 - Syringing Study (Complete)
 - Extraction for Injection Study (Complete)
 - Particle Size Study (Complete)
- Four Clinical Studies with 124 subjects in aggregate
 - 301 – Nasal Abuse Liability Study (n=40) (Complete)
 - 302 – BA/BE – Food Effect PK Study (n=36) (In Progress)
 - 303 – Dose Proportionality PK Study (n=24)
 - 304 – Safety Bridging PK Study (n=24)
- **Status**
 - After 12/5/13 pre-NDA meeting, FDA agreed to re-review the suitability of Study 301 for inclusion in a NDA filing. Awaiting FDA's response.

Aversion[®] Hydrocodone/APAP

Bioequivalent to Norco[®] (hydrocodone bitartrate/APAP)

Single, fasted 10/325mg dose (n=47)



Study AP-ADF-301 (Nasal Snorting)

- 40 completers of recreational drug abusers
- Randomized, cross-over design
- Blinded as to volume, particle size, and visible differences
- 5-arm study: placebo, 2 positive-controls, 2 test articles
- Phases:
 - Drug discrimination/Dose titration
 - Volumetric Testing
 - Treatment
- Primary Endpoint
 - Bi-Polar 100-point Visual Analog Drug Like/Dislike score
 - Mean of the Maximum score (Emax):
Active Comparator vs. Aversion hydrocodone/APAP

Study AP-ADF-301 (Nasal Snorting) Results

- Results consistent with Oxecta® nasal snorting study results
- Small reduction in Emax (maximum drug liking)
- Statistically significant reduction in Take Drug Again
- Statistically significant reduction Emin (maximum drug disliking)
- Subject were able to snort almost all doses

| Endpoint | Aversion | Active Control | Placebo |
|---------------------|----------|------------------|------------------|
| Drug Liking (Emax) | 72.1 | 75.6 p=.22 | 54.5 p<.00001 |
| Drug Dislike (Emin) | 40.2 | 50.4 p=.0042 | 48.8 p=.00003 |
| Time to Emax (hrs) | 1.6 | 0.9 | 1.1 |
| Take Drug Again | 45.1 | 71.0 p<.00001 | 42.2 p=.36 |

Mean scores presented; p-values compared to Aversion®

Carryover effect observed in Emax scores

nexafed[®] ...The Revolution Takes Shape

**“Scott Co. sees drop in meth
labs with new strategy”**



- WBIR Knoxville, TN
NBC Affiliate



Nexafed® is:

The next generation pseudoephedrine hydrochloride

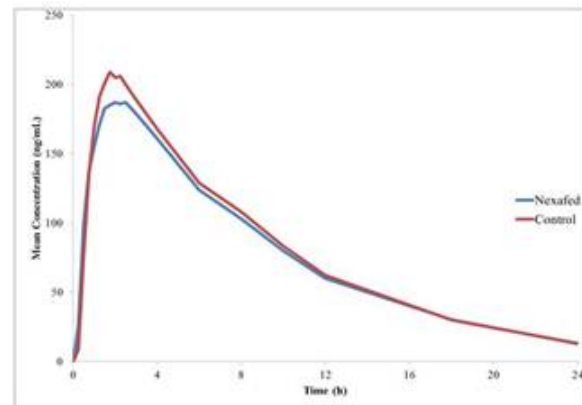
- maximum strength
- non-drowsy
- non-prescription
- effective nasal and sinus congestion relief
- with methamphetamine resistant Impede® technology



Nexafed® - A Unique Selling Proposition

The **only** meth-resistant pseudoephedrine product that meets FDA standards demonstrating therapeutic equivalence to the products consumers currently use, such as Sudafed®

Mean pseudoephedrine plasma concentrations (n=30)
Single, fasted two 30mg tablet dose



Sudafed is a registered trademark and product of Johnson & Johnson

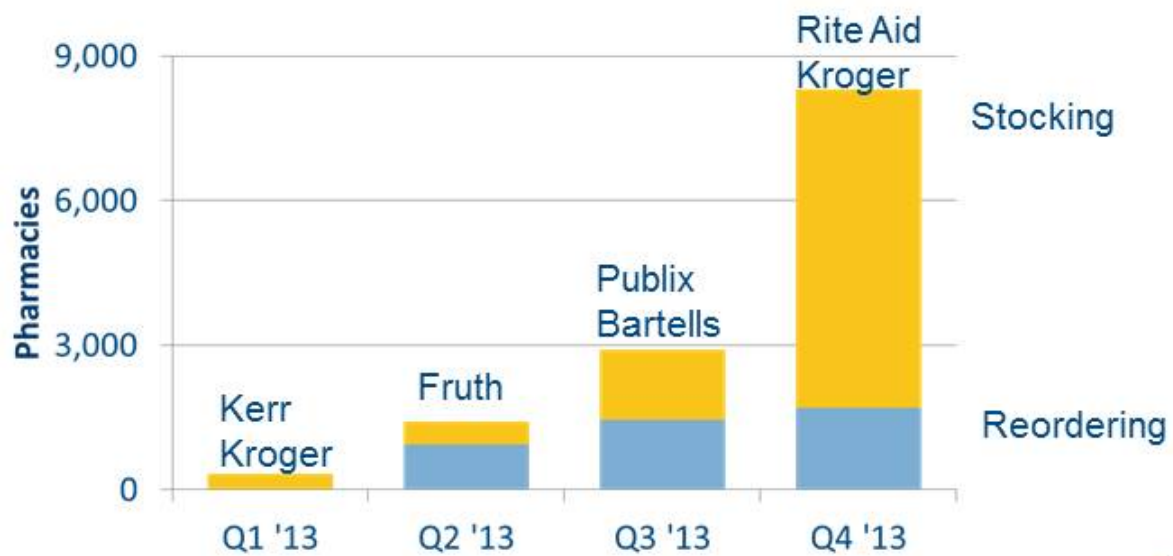


Nexafed® - Strategy

- Establish Nexafed as the new standard of care at the local pharmacy level
 - Drive consumer purchases via pharmacy recommendations.
- Generate public awareness through media outreach
 - Draw attention to the meth problem
 - Establish Nexafed as part of the solution
- Attract chain retail attention
 - Protect access to non-Rx PSE for legitimate patients
 - Offer high quality pharmaceutical products that deliver expected efficacy and convenience
 - Discourage illicit meth activity/traffic in stores and communities
 - Provide win-win for retailers who want to avoid being targeted by media as being part of the problem

Nexafed® - Retail Track Record

- 8,300 pharmacies stock and sell Nexafed®
 - 12% of the estimated 65,000 retail outlets



Nexafed® - A New Standard of Care

**Fruth, Rite Aid and many Independent Pharmacies
are leading the charge in addressing meth**

- Many have replaced all single ingredient pseudoephedrine products with Nexafed®, exclusively.
- Rite Aid replaced all single ingredient pseudoephedrine products in West Virginia with Nexafed®, rolling out Rite Aid branded educational materials on Nexafed® to their nationwide network
- Scott County, TN independent pharmacies all moved to Nexafed® Only
 - 69% drop in meth lab incidents in the first month
 - No meth lab incidents for three straight months

Nexafed® – Success is Contagious

➤ Legislative

- West Virginia legislation considering requiring all pseudoephedrine products to require a prescription; with exemption for meth-resistant products
- Many approaches being discussed in many states

➤ Media

- Investigative reports on the impact of meth-resistant products
- Op Ed's focusing on the proper role for pharmacies and manufacturers in the meth-resistant era

➤ Law Enforcement/Others

- Supported by the TN State Troopers Association
- Recognized by District Attorney Lori Phillips-Jones
- Supported by the TN Chapter of the NAACP
- Partnership with The Meth Project

Nexafed® – Market Opportunities

30mg Market Estimate*

372M Tablets

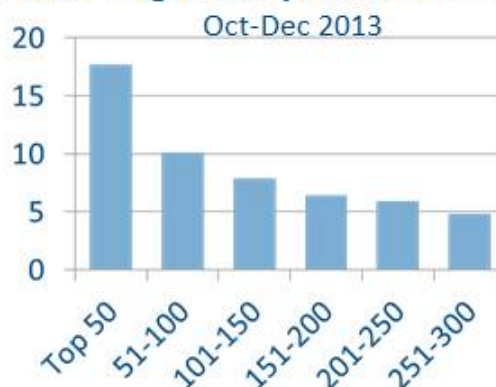
15.5M Boxes of 24

~20 Boxes per outlet per month

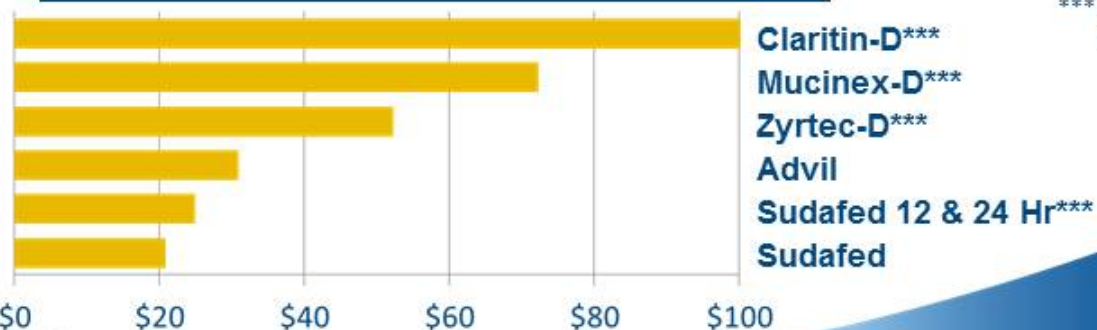
* 2009 AC Nielsen

** Based on store wholesale purchases

Nexafed® Avg. Boxes per Store Per Month**



2009 Branded Product Retail Sales in Millions*



*** Sustained Release formulation

Nexafed® - 2014 Plans

- Continue to raise awareness among pharmacists, pharmacies, consumers, law enforcement, and legislators via public relations, advertising and social media
- Build the franchise
 - Nexafed® Line Extension #1 – expected launch 2nd half 2014
 - Nexafed® Line Extension #2 – In development
 - Improved formulation for enhanced meth resistance
 - Seek international franchising opportunities
 - Assess US partnering opportunities as presented

Intellectual Property and Financial Information

Intellectual Property Position

- **Aversion® Technology patents expire in 2023 to 2025**
 - 6 U.S. patents issued covering compositions of opioids and certain other abused drugs with functional inactive ingredients
 - 1 U.S. Patent issued covering an extended release opioid dosage form
- **Impede® Technology patents pending**
- **Additional U.S. and foreign patents**
 - Multiple patent applications pending in the United States and internationally

Financial and Share Summary @ 12/31/2013

- Sufficient cash to execute current business plan through at least the next two years
- Projected to use ~ \$11 - \$12 million of Net Cash for Operations in 2014

| Selected Financial Information | \$ Millions |
|--|-------------|
| Cash, Cash Equivalents and Marketable Securities | \$26.1 |
| Debt (60 month term @ 8.35% with interest only thru March, 2015 and principal & interest to December 2018) | \$10.0 |
| Shares Outstanding | Millions |
| Total Common Shares Outstanding | 48.848 |
| Shares Held by 2 Largest Shareholders (42%) | 20.913 |



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