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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): January 12, 2015**

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**ACELRX PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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**DELAWARE**  
(State of incorporation)

**001-35068**  
(Commission File No.)

**41-2193603**  
(IRS Employer Identification No.)

**351 Galveston Drive  
Redwood City, CA 94063**  
(Address of principal executive offices and zip code)

**Registrant's telephone number, including area code: (650) 216-3500**

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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))
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**Item 2.02 Results of Operations and Financial Condition.**

AcelRx Pharmaceuticals, Inc. (the “Company” or “AcelRx”) will be providing financial information about the Company’s cash and investment balances as of December 31, 2014 in the Company’s presentation handout to be utilized in various meetings with securities analysts and investors during the J.P. Morgan Healthcare Conference from January 12, 2015 through January 15, 2015. The aforementioned financial information is included on slides #3, #27 and #29 of the presentation handout, as furnished in Exhibit 99.1 to this Current Report and is incorporated herein by reference.

The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 to this Current Report shall be deemed to be “furnished” and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission under the Securities Act or the Exchange Act made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 7.01. Regulation FD Disclosure.**

AcelRx will participate in various meetings with securities analysts and investors during the J.P. Morgan Healthcare Conference from January 12, 2015 through January 15, 2015 and will utilize a presentation handout during those meetings. The presentation handout, together with a slide setting forth certain cautionary language intended to qualify the forward-looking statements included in the presentation handout, are furnished as Exhibit 99.1 to this Current Report and are incorporated herein by reference. The presentation handout will also be made available in the “Investor Relations” section of AcelRx Pharmaceuticals, Inc.’s website, located at [www.acelrx.com](http://www.acelrx.com).

The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 to this Current Report shall be deemed to be “furnished” and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act. The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission under the Securities Act or the Exchange Act made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Slide presentation entitled, “AcelRx Pharmaceuticals, Inc. January 2015”

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**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 hereunto duly authorized.

Date: January 13, 2015

ACELRX PHARMACEUTICALS, INC.

By: /s/ Timothy E. Morris  
Timothy E. Morris  
Chief Financial Officer

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**INDEX TO EXHIBITS**

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**AcelRx**  
Pharmaceuticals, Inc.

January 2015



## Forward Looking Statements

This presentation contains forward-looking statements, including, but not limited to, statements related to future financial results, potential proceeds under the Grunenthal agreement, the process and timing of anticipated future development of AcelRx's product candidates, including Zalviso, the NDA submission and the CRL, the recent meeting held with the FDA to discuss the CRL, AcelRx's plans to address the issues raised in the CRL, and anticipated resubmission of the Zalviso NDA to the FDA, including the scope of the resubmission and the timing of the resubmission and FDA review time, the impact, if any, of the FDA's review of the amendments to the Zalviso NDA that were not previously reviewed, planned initiation of the Phase 3 clinical trial for ARX-04, and the therapeutic and commercial potential of AcelRx Pharmaceuticals' product candidates, including Zalviso. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: AcelRx Pharmaceuticals' ability to receive regulatory approval for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso, in the United States and Europe; AcelRx's ability to build an effective commercial organization; its ability to receive any milestones or royalty payments under the Grunenthal agreement; its ability to obtain sufficient financing to commercialize Zalviso and proceed with clinical development of ARX-04; the success, cost and timing of all product development activities and clinical trials, including the planned Phase 3 ARX-04 trial; the market potential for its product candidates; the accuracy of AcelRx's estimates regarding expenses, capital requirements and needs for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx Pharmaceuticals' U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on November 10, 2014. AcelRx Pharmaceuticals undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations.

# AcelRx—Working to Improve Acute Pain Management

## Zalviso™ profile from Phase 3 studies

- **Efficacy:** Demonstrated in two placebo controlled studies, 1 active comparator study
- **Adverse events:** Most common related AE's were nausea, vomiting, O<sub>2</sub> desaturation, itching
- **High patient satisfaction and nurse ease of care reported**

## Grünenthal partnership to commercialize Zalviso in EU & Australia established

- **Terms:** \$250M upfront and potential milestones, mid-teens to mid-twenties % royalty
- **Other Territories:** Continue to seek additional partnerships in Asia & South America
- **CE Mark:** Received December 2014
- **MAA filed in Switzerland**

## Upcoming regulatory catalysts in US and EU

- **US:** NDA resubmission targeted Q1 2015
- **EU:** Day 120 submission planned for Q1 2015

**Strong balance sheet with \$75 million cash on hand December 31, 2014  
(unaudited)**

# Zalviso NDA Status-CRL received July 25, 2014

## Major items in CRL:

- **Demonstration of a reduction in the incidence of optical system errors**
  - Optical system errors were noted in the clinical setting at a single digit rate
  - Did not appear to impact Phase 3 safety and efficacy results
  - Improvements have been made to reduce error rate
  - Additional bench testing to be completed to confirm error rate reduction
- **Changes to the Instructions for Use (IFU) to address inadvertent dosing**
  - 15 misplaced tablets of ~30,000 doses
  - IFU modified to address this issue
  - HF studies will be required to confirm IFU/GUI changes are adequate
- **Support for shelf life (not approvability issue)**
  - Data to be provided to support 24 month dating



## Zalviso NDA Resubmission Plan

- Type A meeting with FDA to clarify CRL issues held ✓
- Modifications to dispenser completed ✓
- IFU modifications completed ✓
- Protocols for bench testing and HF study submitted to FDA ✓
- Shelf life data available and to be included in resubmission ✓
- FDA to review and comment on protocols
- Bench testing and HF work to be completed
- Expected to refile by end of Q1 2015
- Type II submission (6 month review)



# Zalviso™

(sufentanil tablets)Ⓒ



**Proposed Indication: Management of  
Moderate to Severe In-Hospital Acute Pain**

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Investigational drug and delivery system not FDA approved for commercial use

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## IV PCA – Current Standard of Care

- In-hospital, post-operative moderate to severe pain control
- Higher Patient satisfaction when patients control their own pain



- Invasive route of delivery
  - IV infiltration causes analgesic gaps
  - IV connection restricts patient mobility
  - Risk of IV site infection
- Programming errors
  - Infusion pumps large source of morbidity / mortality<sup>1</sup>
  - 1/9 harmful hospital errors due to IV PCA<sup>2</sup>

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1. FDA / AAMI Summit Meeting held October 2010; [http://www.aami.org/infusionsummit/AAMI\\_FDA\\_Summit\\_Report.pdf](http://www.aami.org/infusionsummit/AAMI_FDA_Summit_Report.pdf)

2. Calculated from "The rate and costs attributable to intravenous patient-controlled analgesia errors." Brian Meissner et al, Hospital Pharmacy April 2009

# Zalviso: Leveraging Sufentanil

- **High Therapeutic Index Opioid**

- In animal studies

OPIOID	THERAPEUTIC INDEX
Morphine	71 <sup>1</sup>
Hydromorphone	232 <sup>2</sup>
Fentanyl	277 <sup>1</sup>
<b>Sufentanil</b>	<b>26,716<sup>1</sup></b>

- **High Lipophilicity**

- Enables rapid transmucosal uptake
- 6 minute brain:plasma equilibration

- **No active metabolites**

- **Sublingual Sufentanil Delivery**

- May reduce IV peaks & troughs
- Small size may minimize swallowed drug
- May result in high bioavailability
- Helps with goal of consistent dose delivery

- **Supplied in cartridge of 40 Tablets**

- 2 days for average patient



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1. Mather, Clin Exp Pharmacol Physiol 1995; 22:833.

2. Kumar, Eur J Pharmacol 2008; 597:39 (ED50) and Purdue Pharma MSDS, 2009 (LD50)

# Zalviso: Delivery Device Design and Feature Set

## Non-invasive (sublingual) delivery

- Eliminates IV infection risk
- May enhance ambulation

## Pre-programmed delivery

- Factory set 20-minute lockout period
- Addresses end-user programming error risk

## Design safety features

- Set-up tablet, RFID cartridge provides full inventory loop tracking of sufentanil tablets
- RFID thumb tag co-located to device helps reduce proxy dosing
- HCP controlled access, device tether reduces risk of product loss
- Battery power ensures 72-hour function even in the event of power outage



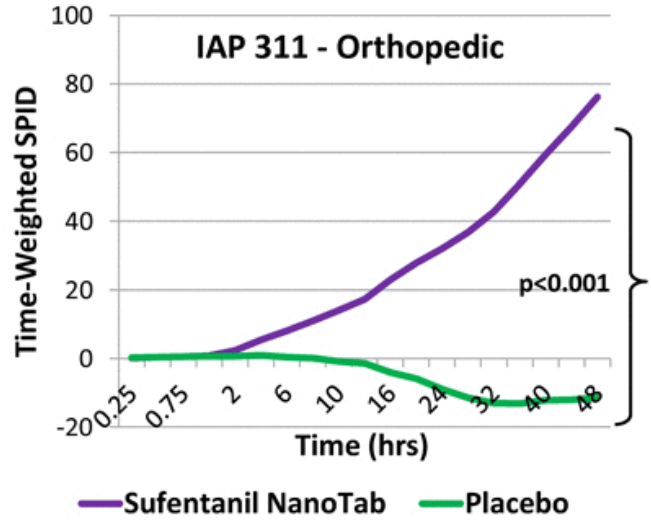
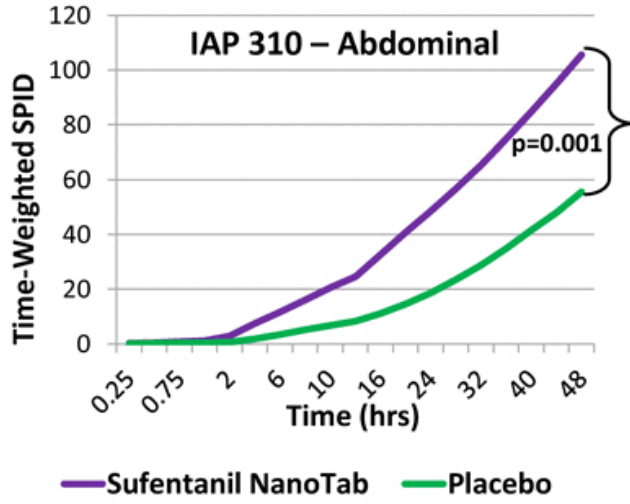
Investigational drug and delivery system not FDA approved for commercial use

## Zalviso Phase 3 Program

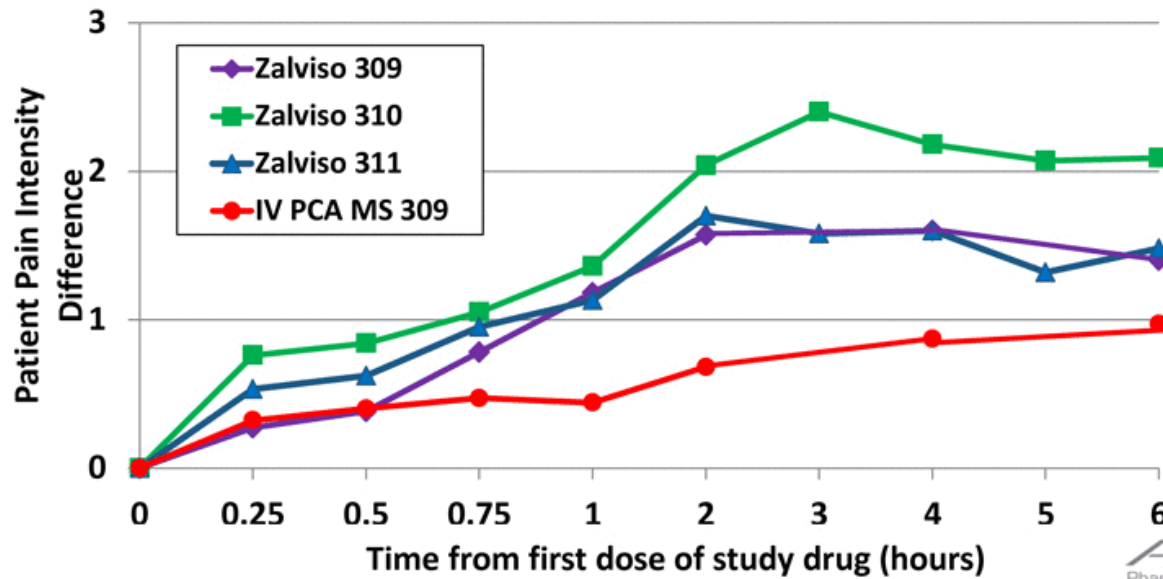
Surgery Type	Study Type	Sites	N	Data	Primary Endpoint Results
Abdominal & Orthopedic Surgery (IAP309)	Open-label, Active-comparator 1° EP: Patient Global Assessment of Method of Pain Control over 48 hrs	26	359 1:1	Nov 2012	Zalviso non-inferior to IV PCA (p<0.001) Zalviso also demonstrates superiority to IV PCA (p=0.007)
Abdominal Surgery (IAP310)	Double-blind, Placebo-controlled 1° EP: Sum of Pain Intensity Difference over 48 hrs	13	178 2:1	Mar 2013	Sufentanil treatment superior to placebo p=0.001
Orthopedic Surgery (IAP311)	Double-blind, Placebo-controlled 1° EP: Sum of Pain Intensity Difference over 48 hrs	34	426 3:1	May 2013	Sufentanil treatment superior to placebo p<0.001



# IAP310 & IAP311 Primary Endpoint: SPID-48 – ITT Population



## Zalviso: Studies Indicate Ability to Control Moderate to Severe Acute Pain





## Adverse Reactions >2% in Placebo Studies

Possibly or Probably Related Adverse Reactions	Zalviso N=429	Placebo N=162
Nausea	29.4%	22.4%
Vomiting	8.9%	4.9%
Oxygen Saturation Decreased	6.1%	2.5%
Itching*	4.7%	0%
Dizziness	4.4%	1.2%
Constipation	3.7%	0.6%
Headache	3.3%	3.7%
Insomnia	3.3%	1.9%
Hypotension	3.0%	1.2%
Confusional State	2.1%	0.6%

\* Significantly Different between Zalviso and Placebo ( $p < 0.05$ )



# Zalviso™ (sufentanil tablets)Ⓒ



**Proposed Indication: Management of  
Moderate to Severe In-Hospital Acute Pain**

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# Moderate-to-Severe Pain in US Hospital Settings<sup>1,2</sup>

## Hospital in-patient, moderate-to-severe acute pain, post-operative

- 12M procedures per annum, Zalviso potentially usable in ~95% cases

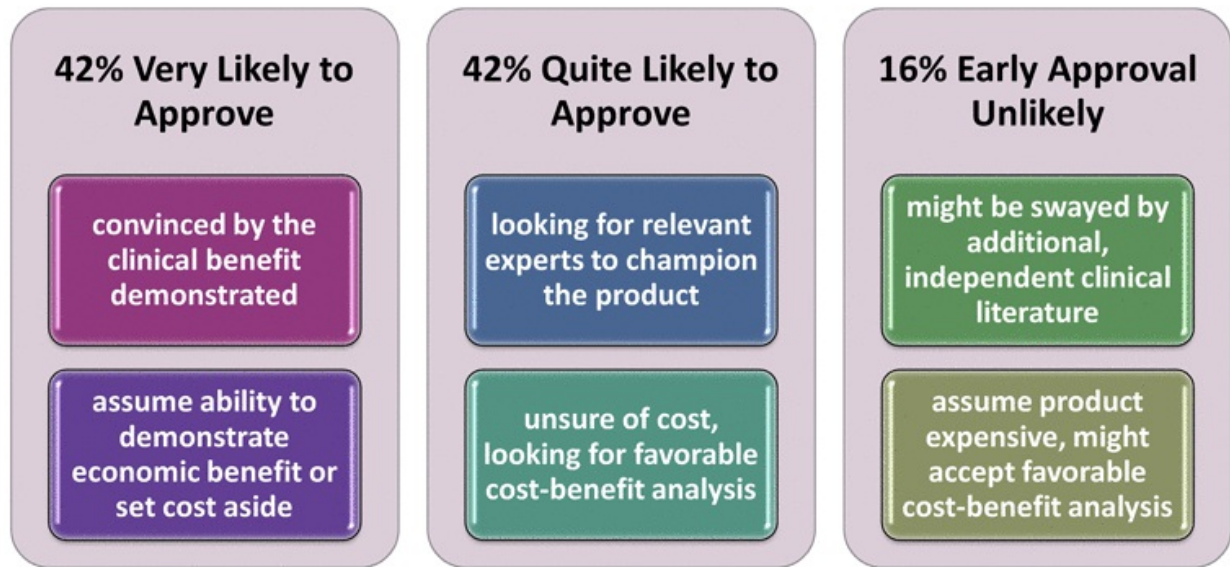
## Hospital in-patient, moderate-to-severe acute pain, not post-operative

- 7.4M patients per annum, Zalviso potentially usable in ~66-80% cases
- IV push opioid is current standard for acute non-post-op pain, not IV PCA
- Physicians reported Zalviso may be supplementary to IV push

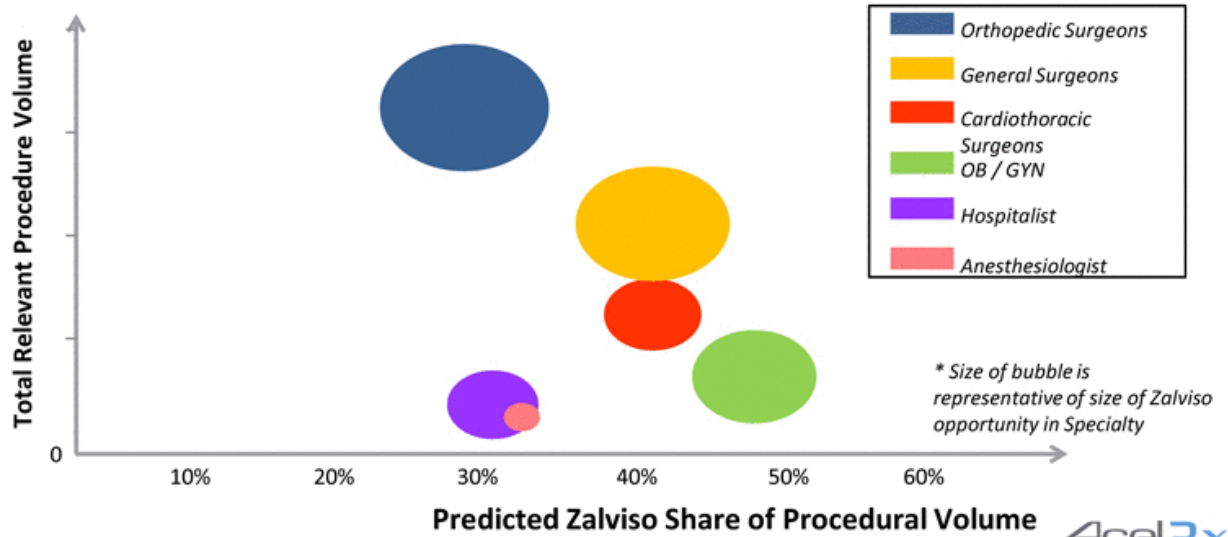
## Hospital Hospice in-patient, moderate-to-severe acute pain

- 300k patients per annum, Zalviso potentially usable in ~40% cases
- Zalviso is a potential replacement for liquid morphine

## Anticipated Formulary Adoption after FDA Approval Earliest – 2 Months; Typical – 8-10 Months

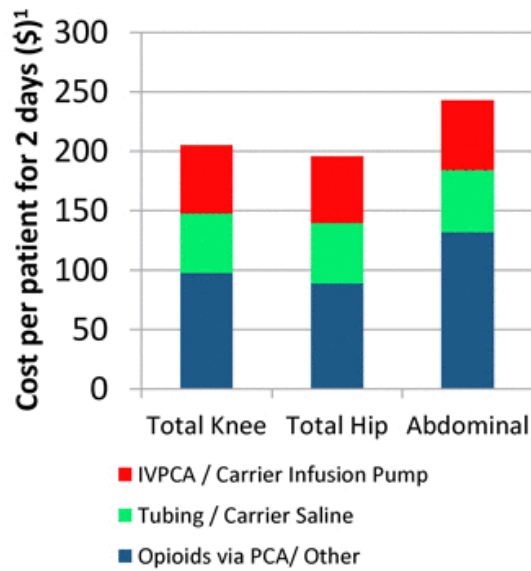


## Strong Positive Reaction to Zalviso Clinical Profile Market Research Among Hospital Specialists (n=244)<sup>1</sup>



\* Size of bubble is representative of size of Zalviso opportunity in Specialty

# Current Cost of IV PCA



## Data from Premier Database, 2010-12

- Data for post surgical pain management involving IV PCA in total knee/hip replacement and abdominal surgery
- Costs for pumps, tubing, carrier saline and drug range from \$200-240 for 2 days

## Zalviso may add value:

- Addresses programming errors
- Elimination of PCA IV site infection risk
- Supports early ambulation
- Enhanced patient satisfaction





# US Customer-focused Organization Planned Build



# Zalviso Publication Strategy

## Peer Reviewed Manuscripts Available

- **Cost of Opioid Intravenous Patient-controlled Analgesia: Results From a Hospital Database Analysis and Literature Assessment.** (Palmer et al.) *Clinicoeconomics and Outcomes Research*  
[www.dovepress.com/getfile.php?fileID=20509](http://www.dovepress.com/getfile.php?fileID=20509)
- **Pharmacokinetics of Sublingual Sufentanil Tablets and Efficacy and Safety in the Management of Postoperative Pain** (Minkowitz et al.) *Reg Anesth Pain Med* 2013;38: 131-139.
- **Sufentanil Sublingual Microtablet System versus Intravenous Patient-Controlled Analgesia with Morphine for Postoperative Pain Control: A Randomized, Controlled Trial** (IAP309 Primary); *Pain Practice*;  
<http://onlinelibrary.wiley.com/doi/10.1111/papr.12238/full>
- **A Phase 3 Study of Sufentanil Sublingual Microtablet System for the Management of Postoperative Pain Following Open Abdominal Surgery** (IAP-310 Primary); *Reg Anesth Pain Med* –  
[http://journals.lww.com/rapm/Abstract/onlinefirst/Sufentanil\\_Sublingual\\_Tablet\\_System\\_for\\_the.99572.aspx](http://journals.lww.com/rapm/Abstract/onlinefirst/Sufentanil_Sublingual_Tablet_System_for_the.99572.aspx)

## Peer Reviewed Manuscripts in Process

- **A Phase 3 Study of a Sufentanil Sublingual Microtablet System for the Management of Postoperative Pain Following Major Orthopedic Surgery** (IAP-311 Primary); *Anesthesiology* - Submitted





# ARX-04 HCP Administered Single 30mcg dose Sufentanil Tablet



Investigating Moderate to Severe acute pain  
treatment in medically supervised settings

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Investigational drug and delivery system not FDA approved for commercial use

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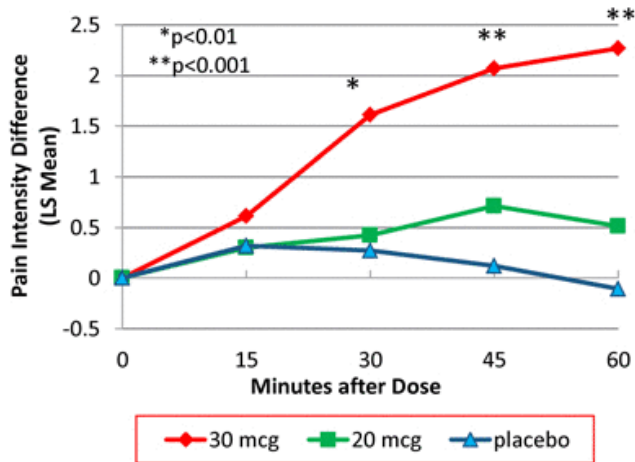
# ARX-04 – Short Term Acute Pain Management

Phase 2: 30mcg sufentanil tablet

End of Phase 2 Meeting held Dec. '13

Rapid onset of effect demonstrated

Proposed Clinical Development Pathway



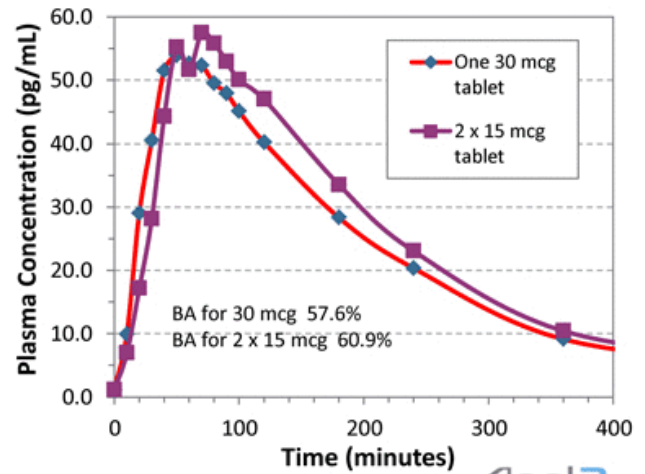
- 505(b)(2) submission
- 500 patient safety database , 100 multiple dose, 400 single dose
- Phase 3 placebo controlled study
  - Abdominal surgery, SPID-12 primary, follow for 48 hours
  - Results expected H2 2015
- Single & repeat dose pk study
- In addition, a small ER study is planned
  - Results expected H2 2015

## ARX-04 – PK Study Results

### Demonstration of Bioequivalence of 2x15mcg and 1x30mcg sublingual sufentanil tablets

- Bioavailability:
  - 30 mcg 57.6%
  - 2 x 15 mcg 60.9%
- Proposed to FDA that demonstration of bioequivalence for 2 x 15mcg dosed 20 mins apart and single 30mcg dose would enable use of Zalviso database to support ARX-04
- In Phase 3 Zalviso studies, 323 patients dosed at t=0 and between t=20-25mins later

### Bioavailability of 1x30mcg and 2x15mcg sublingual sufentanil tablets



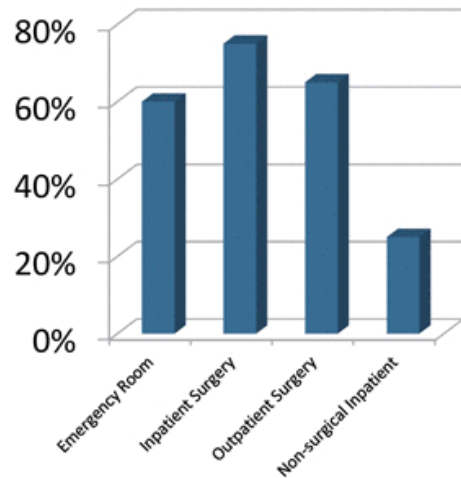
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# ARX-04 – Commercial Opportunity

## Market Research Suggests Broad Opportunity in Moderate to Severe Acute Pain\*

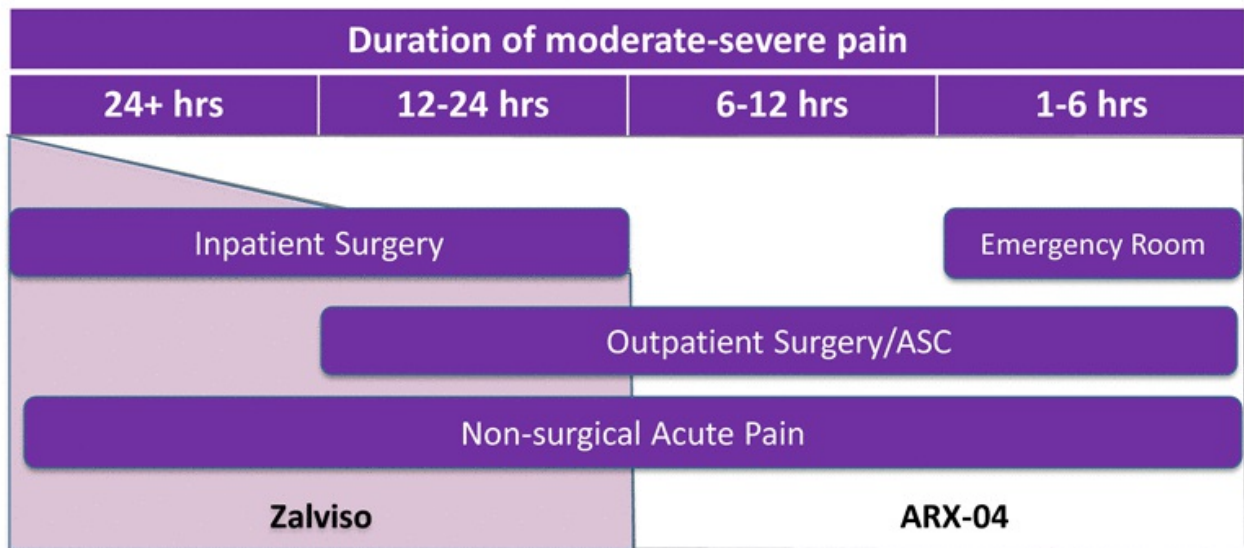
- ER Department
  - 51MM patients annually
  - 2 doses per patient on average
- Inpatient Surgery
  - 8MM patients annually
  - 2-9 doses per patient
- Outpatient Surgery
  - 13MM patients annually
  - 3 doses per patient on average
- Non-surgical Acute Pain
  - 4MM patients annually
  - 8 doses per patient on average

Physician Stated Share



ZS Associates US Opportunity Sizing, September 2014; Includes only patients 18+ years of age.  
Sponsored by AcclRx Pharmaceuticals, Inc.

# Zalviso – ARX-04 Commercial Synergy



## Scientific Conference Schedule - 2015

- **Minimally Invasive Surgery Symposium (MISS)**  
February 25-28; Las Vegas, NV – poster presentation (ARX-04)
- **American Academy of Orthopedic Surgeons (AAOS)**  
March 24-28; Las Vegas, NV – Booth & Symposium
- **American Society of Peri-Anesthesia Nurses (ASPAN)**  
April 26-30; San Antonio, TX – Booth & Symposium
- **American Congress of Obstetricians (ACOG)**  
May 2-6; San Francisco – Booth & Symposium
- **International Conference on Emergency Medicine (ICEM)**  
May 11-12; Montreal, Quebec – Podium Presentation (ARX-04)
- **American Society of Pain Management Nursing (ASPMN)**  
September 16-19; Atlanta, GA – Booth & Symposium
- **American College of Surgeons (ACS)**  
October 4-8; Chicago, IL – Booth & Symposium
- **American Society of Anesthesiologists (ASA)**  
October 24-28; San Diego, CA – Booth & Symposium
- **American Society of Regional Anesthesia and Pain Management (ASRA)**  
November 19-21; Miami, FL – 1 Booth & Symposium
- **American Society of Health System Pharmacists (ASHP)**  
December 6-10; New Orleans, LA – Booth & Symposium

## Financial Summary

### Cash position at September 30, 2014: \$85 million

- \$10 million drawn June 2014 under debt facility
- \$5 million received August 2014 from Grünenthal for MAA submission

### Currently available cash resources fund operations through launch

- Assumes timely regulatory approval of Zalviso in the US in 2015
- Supports execution of all planned US pre-commercial launch efforts

### Q3 2014 cash usage of ~\$12 million

### Headcount at December 31, 2014: 50

### Cash balance December 31, 2014 \$75 million (unaudited)

### 44 million shares outstanding at December 31, 2014



## Future Catalysts

Event	Timing
120 day question response to Zalviso MAA review	Q1 2015
Zalviso NDA resubmission (pending protocol approval)	Q1 2015
ARX-04 DOD contract finalized	Q1 2015
Zalviso NDA decision	Q3 2015
Zalviso MAA decision	Q3 2015
ARX-04 Phase 3 data	H2 2015



# AcelRx–Working to Improve Acute Pain Management

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(unaudited)**