

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

Date of Report (Date of earliest event reported): February 24, 2015

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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**

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))
-

Item 7.01. Regulation FD Disclosure.

AcelRx Pharmaceuticals, Inc. (the “Company” or “AcelRx”) will participate in various meetings with securities analysts and investors and will utilize a presentation handout during those meetings. The presentation handout has been updated to include confirmation of completion of the Zalviso system bench test evaluating the rate of optical system and total system errors. This test was designed to respond to issues identified in the Complete Response Letter (CRL) issued by the U.S. Food and Drug Administration, (FDA) relating to Zalviso in July 2014. Results from the Zalviso system bench test will be submitted to the FDA as part of the resubmission of the Zalviso New Drug Application, or NDA. The bench testing included 700 Zalviso systems. The actual error rate observed during the bench testing was lower than the target error rate discussed with the FDA and included in the bench test protocol submitted to and reviewed by the FDA. While the testing met the pre-specified endpoint, the results of the bench testing are subject to FDA test review. We have also received feedback from the FDA on the protocols submitted for the proposed Human Factor (HF) studies to review modifications to the Instructions For Use and system training screens to address misplaced tablets. The FDA had no additional comments on the HF protocols submitted in November 2014, and stated that “the proposed protocols are acceptable.” The presentation handout confirms completion of the first of these HF studies, in healthy volunteers, which demonstrated that patients were able to follow and implement the revised instructions. The presentation handout also confirms completion of the second HF study in post-operative patients. We are waiting for the results from the second HF study. The results of both HF studies are subject to FDA review.

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.ancelrx.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.

**Exhibit
Number**

Description

99.1 Slide presentation entitled, “AcelRx Pharmaceuticals, Inc. February 24, 2015”

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: February 24, 2015

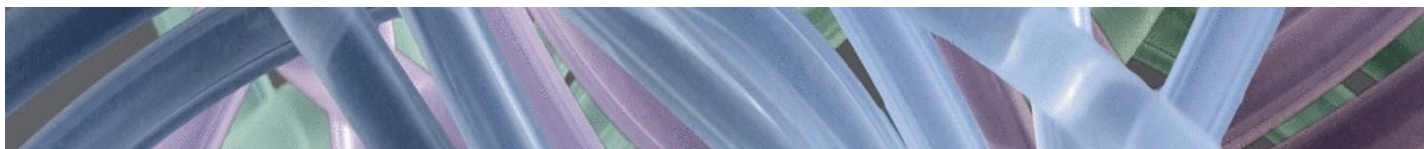
ACELRX PHARMACEUTICALS, INC.

By: /s/ Timothy E. Morris

Timothy E. Morris
Chief Financial Officer

INDEX TO EXHIBITS

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AcelRx

Pharmaceuticals, Inc.

February 24, 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 Type A 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, O₂ 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)**

AcelRx Update Q1 2015

Zalviso resubmission

- Received FDA comments on bench testing protocol
- Bench testing completed
 - 700 systems tested
 - Met endpoint but results subject to FDA review
- Human Factors protocols deemed acceptable to FDA as submitted
- HF studies completed in two populations:
 - Healthy volunteers-met endpoints, demonstrating patients could follow revised instructions
 - Post-op patients-awaiting study report
 - Both results subject to FDA review

Zalviso EU Day 120 Response

- Received 120 day questions from EMA, and in process of preparing a response
- CE mark approved and to be included as part of response
- Anticipate submission in Q1'15

ARX-04

- Single pivotal Phase 3 study to be initiated in Q1 without DoD funding
- Discussion with DoD continues, finalized funding anticipated in H1 2015

Zalviso NDA Status-CRL received July 25, 2014

Major items in CRL:

- **Demonstration of a reduction in the incidence of system errors**
 - 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
 - Formal bench testing in process 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 underway to confirm IFU/GUI changes are adequate
- **Support for shelf life (not approvability issue)**
 - Data to be provided to support 24 month dating



Zalviso™

(sufentanil tablets) (II)

Clinical Data

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 / mortality¹
 - 1/9 harmful hospital errors due to IV PCA²

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1. FDA / AAMI Summit Meeting held October 2010; http://www.gami.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 ¹
Hydromorphone	232 ²
Fentanyl	277 ¹
Sufentanil	26,716¹

- **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 PurduePharma 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

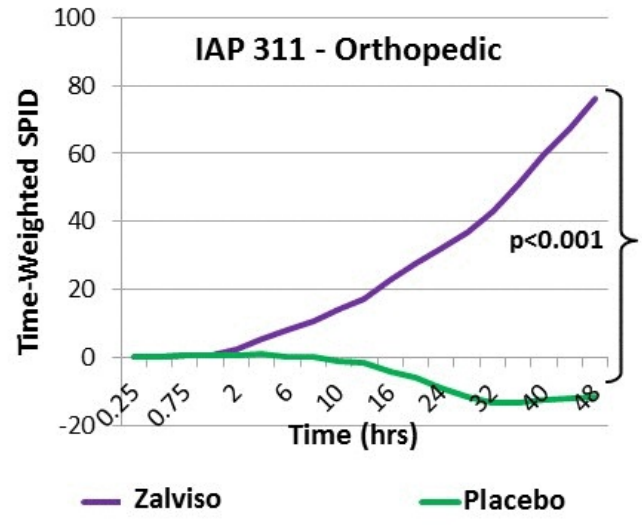
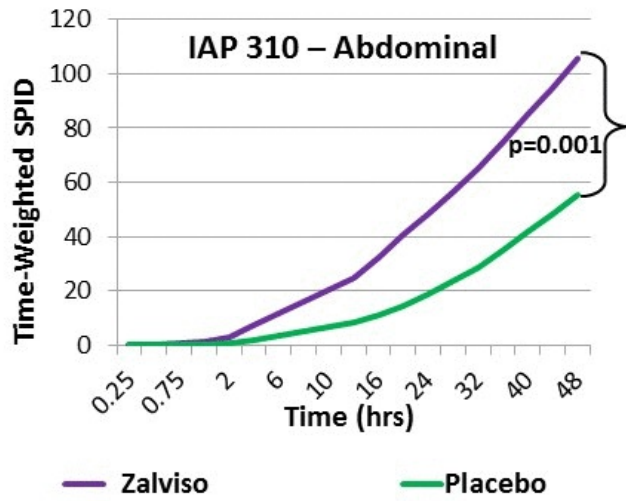


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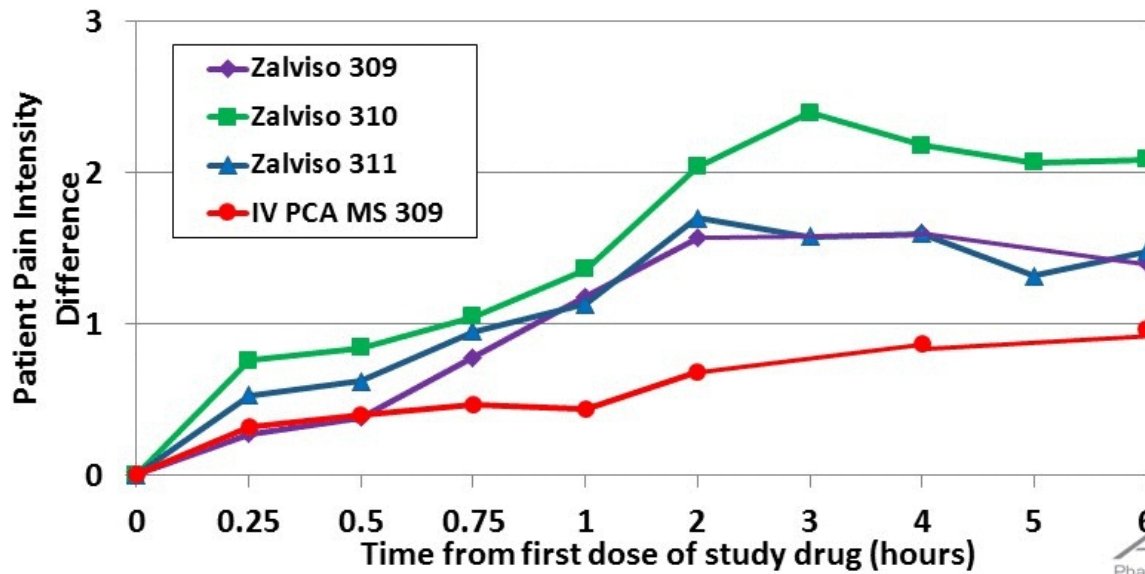
Zalviso Phase 3 Program

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 Rapid 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) (II)

Commercial Opportunity

**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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Target Market Potential

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The potential market for Zalviso is defined as:

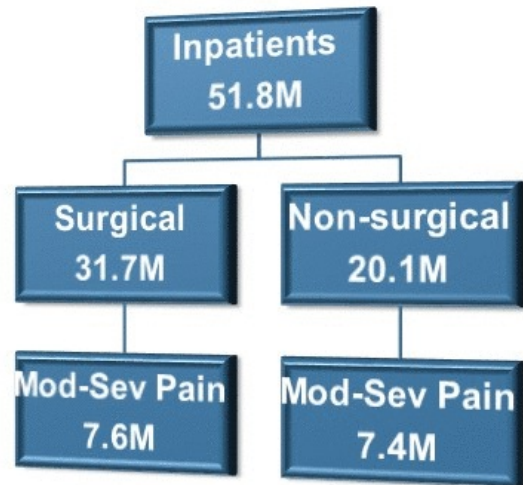
- Acute moderate-to-severe pain population in the hospital setting
- Includes post-operative as well as non-surgical pain

The market size for Zalviso is characterized by hospital in-patient sampling that demonstrates 15M annual patients annually¹

- 7.6M patients post-op
- 7.4M patients non post-op

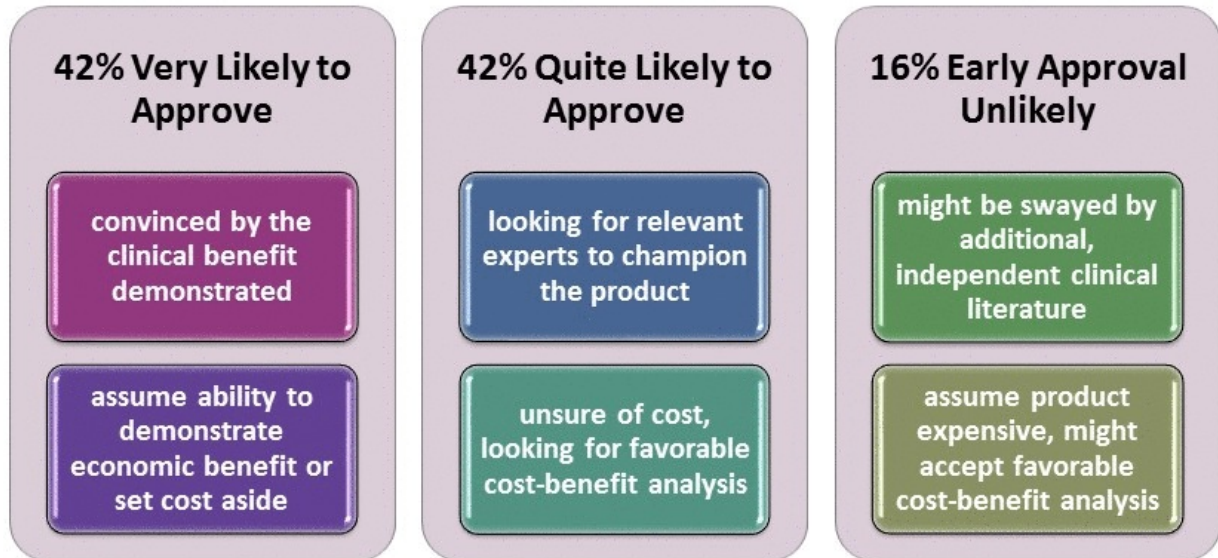
2013 U.S. Acute Pain Market \$6.7B²

- 43% of which is post-op pain
- 20% of which is other acute pain (non post-op)



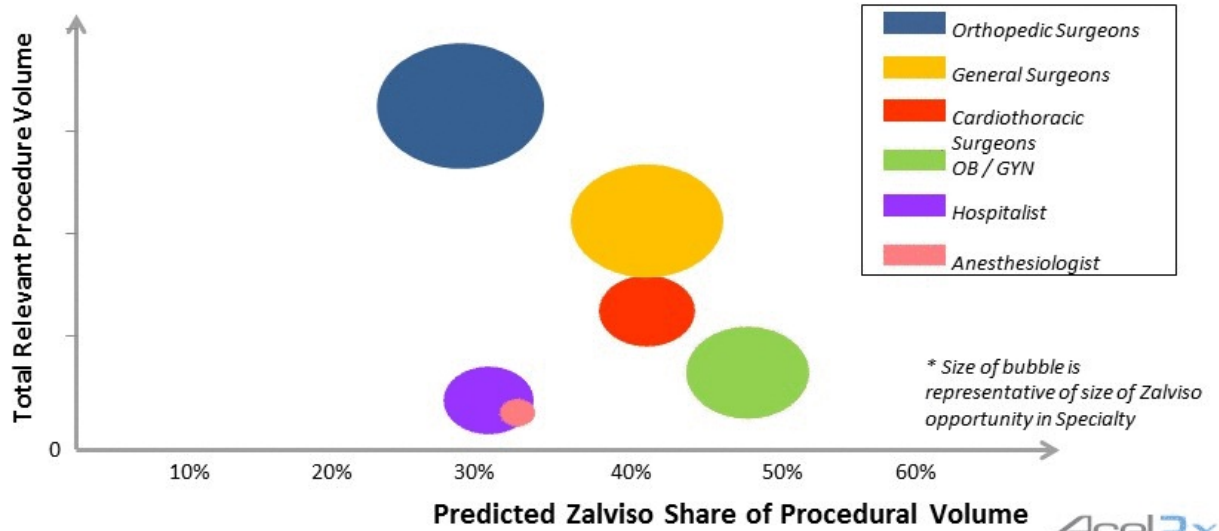
1. Rosetta, 2009 Inpatient sample
2. Decision Resources, Pain Management Study, Acute Pain, October 2014

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



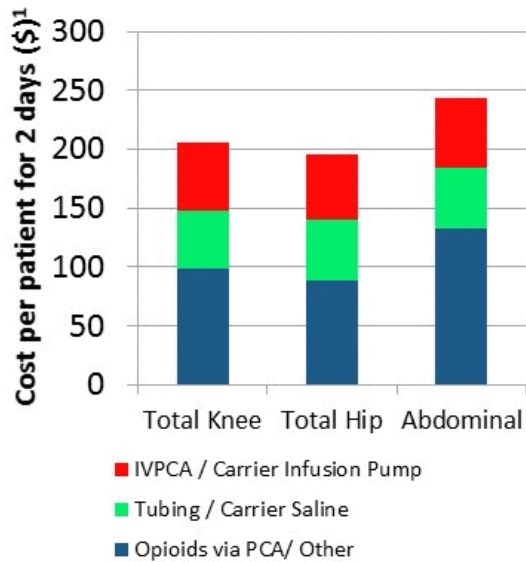
Strong Positive Reaction to Zalviso Clinical Profile

Market Research Among Hospital Specialists (n=244)¹



1. ZS Associates Quantitative Survey Among Hospital Specialists, Winter 2013, sponsored by AceRx Pharmaceuticals, Inc.

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:

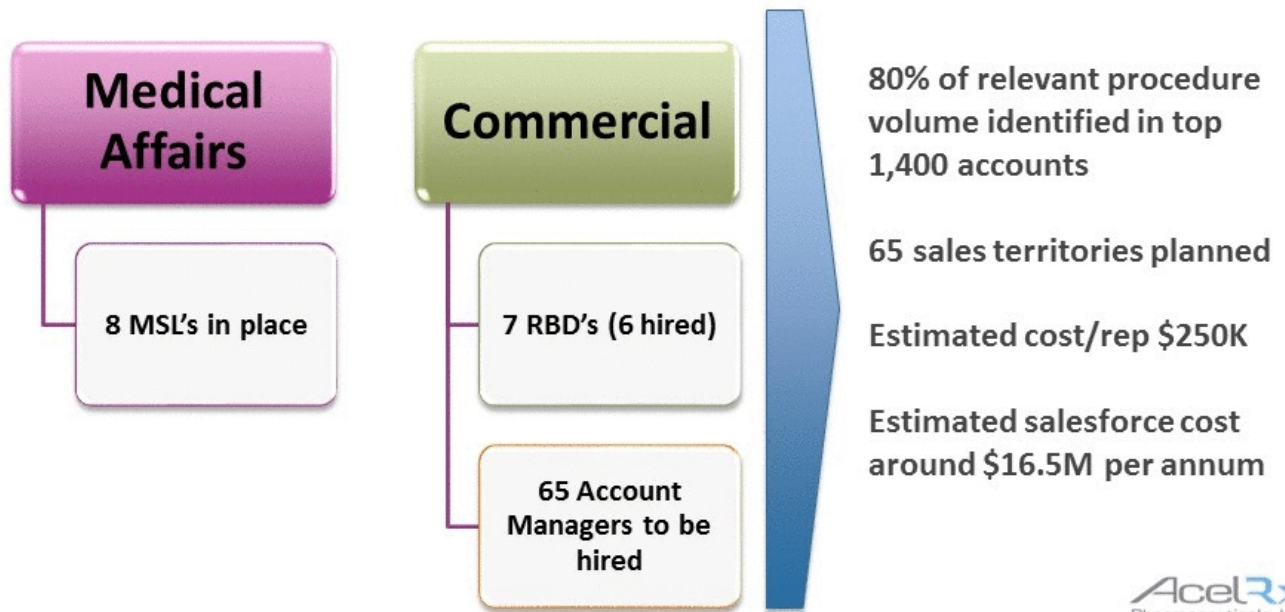
- Addresses programming errors
- Elimination of PCA IV site infection risk
- Supports early ambulation
- Enhanced patient satisfaction

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1. COST OF INTRAVENEOUS PATIENT-CONTROLLED ANALGESIA (IV PCA) EQUIPMENT AND OPIOID MEDICATION FOR ORTHOPEDIC AND ABDOMINAL SURGERIES IN US HOSPITALS
Xiang (Jay) Ji, MS, Jennifer Stephens, PharmD, Pamela Palmer, MD, PhD. Poster presented at ISPOR meeting, June 2014

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
- **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

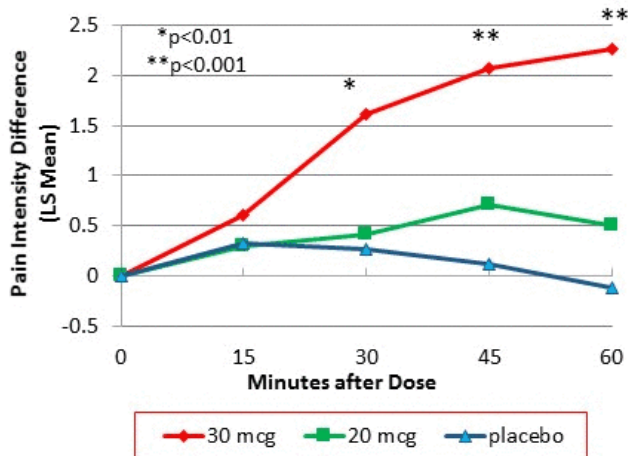
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ARX-04 – Short Term Acute Pain Management

Successful Phase 2 Bunionectomy Study

- Will count as pivotal trial



End of Phase 2 Meeting held Dec. '13

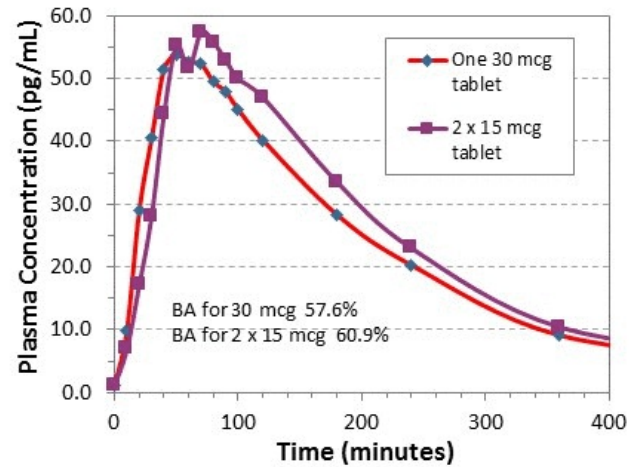
- 505(b)(2) submission
- 500 patient safety database, 100 multiple dose, 400 single dose
- Single & repeat dose PK study - completed
- Phase 3 placebo-controlled study
 - Abdominal surgery, SPID-12 primary, follow for 48 hours
 - Results expected H2 2015
- Small safety study in ER patients planned - results expected H2 2015

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ARX-04 – PK Study Results

Demonstration of Bioequivalence of 2 x 15 mcg and 1 x 30 mcg 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

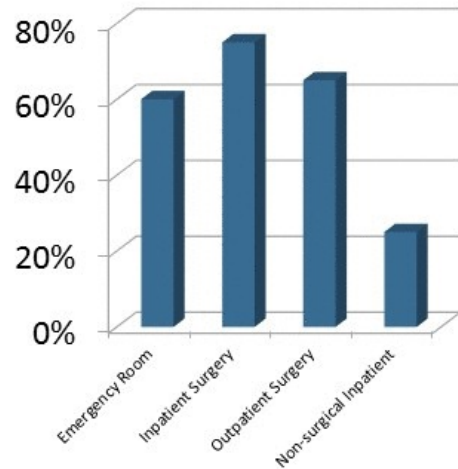


ARX-04 – Commercial Opportunity

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

- ER Department
 - 51MM pats/yr, 2 doses per patient
- Inpatient Surgery
 - 8MM pats/yr, 2-9 doses per patient
- Outpatient Surgery
 - 13MM pats/yr, 3 doses per patient
- Non-surgical Acute Pain
 - 4MM pats/yr, 8 doses per patient

Physician Stated Share



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	H1 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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