

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): May 7, 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, 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	Slide presentation entitled, “AcelRx Pharmaceuticals, Inc. May 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: May 8, 2015

ACELRX PHARMACEUTICALS, INC.

By: /s/ Jane Wright-Mitchell

Jane Wright-Mitchell

Chief Legal Officer

---

## INDEX TO EXHIBITS

<b>Exhibit Number</b>	<b>Description</b>
99.1	Slide presentation entitled, "AcelRx Pharmaceuticals, Inc. February 2015"



May 2015

---



## Forward Looking Statements

This presentation contains forward-looking statements, including, but not limited to, statements related to the process and timing of anticipated future development of AcelRx's product candidates, including Zalviso and ARX-04; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the U.S., including potential additional clinical studies, additional Human Factors studies, or one of the dispute resolution processes provided for by the U.S. Food and Drug Administration, or FDA; resubmission of the Zalviso New Drug Application, or NDA, to the FDA; our ability to receive regulatory approval for our product candidates, including Zalviso, in the United States and Europe; the success, cost and timing of all product development activities and clinical trials, including the clinical trial requested by the FDA for Zalviso and the Phase 3 ARX-04 clinical development program; ability to finalize the contract with the Department of Defense, or DoD, to provide funding for the development of ARX-04; our future operating expenses; our future losses; the sufficiency of our cash resources; the market potential for our product candidates; our estimates regarding expenses, capital requirements and needs for financing; and potential milestones and royalty payments under the Grünenthal agreement.

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 finalize the pathway towards timely resubmission of the Zalviso NDA to the FDA, including its ability to use dispute resolution processes provided for by the FDA; potential additional clinical trials, human factors studies, and/or additional data analyses necessary in order to resubmit the Zalviso NDA; AcelRx's 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; its ability to receive any milestones or royalty payments under the Grünenthal agreement; its ability to obtain sufficient financing; the success, cost and timing of all development activities and clinical trials, including the 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 May 5, 2015. AcelRx Pharmaceuticals undertakes no duty or obligation to update any forward-looking statement 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

### ARX-04 Development timeline

- Study 301 – Abdominal: First Patient In Late February 2015
- Study 302 – Emergency Room: Commence post DoD contract execution
- Top Line Phase 3 results, Study 301, expected Q4

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

- Terms: \$250M upfront and potential milestones, mid-teens to mid-twenties % royalty
- CE Mark: Received December 2014
- EMA Centralized Procedure, and Swiss Medic MAA review on-going
- Other Territories: Continue to seek additional partnerships in Asia, South America

### Upcoming regulatory catalysts in US and EU

- US: FDA clarity
- EU: CHMP MAA Opinion meeting



## AcelRx Update Q1 2015

### Zalviso resubmission

- Received correspondence from the FDA stating that an additional clinical study is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures.
- Previously obtained confirmation from the FDA that the protocol designs for the bench testing evaluating dispensing failures and the Human Factors studies evaluating inadvertent dispensing were acceptable to the FDA.
- Type B Meeting Request submitted to the FDA denied. FDA reiterates request for clinical trial.
- ACRX reviewing all options to define Zalviso regulatory path forward.

### Zalviso EU Day 120 Response

- Day 120 Responses were submitted to EMA in Q1'15
- Anticipate receiving Day 180 List of Outstanding issues in Q2'15

### Zalviso Swiss Medic Procedure

- Swiss Medic List of Marketing Authorization Application Questions received, response in process
- Anticipate submission in Q2'15

### ARX-04

- Pivotal Phase 3 study (301) initiated in Q1 without DoD funding
- Discussion with DoD continues, finalized funding anticipated in H1 2015





# Zalviso™

(sufentanil sublingual  
tablet system) ©

**Post-operative, sublingual delivery,  
patient controlled analgesia**



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

**AcelRx**  
Pharmaceuticals, Inc.  
ACCELUSAR | HANOVER | ALLENBORO

**Investigational drug and delivery system not FDA approved for commercial use**



## Zalviso: Leveraging Sufentanil

- **High Therapeutic Index Opioid**
  - In preclinical studies

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

- **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
  - ~60% bioavailability
  - Tablet dissolution in < 10 minutes
  - Helps with goal of consistent dose delivery
- **Supplied in cartridge of 40 Tablets**
  - In Phase 3 studies, median (SD) number of tablets taken was 35



**AcelRx**  
Pharmaceuticals, Inc.  
ACCELERATE | INNOVATE | ALLEVIATE

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
- Fixed drug and dose (15 mcg sufentanil) eliminate end-user programming error risk associated with PCA pumps

### Design safety features

- Priming cap, RFID cartridge provides full inventory loop tracking of sufentanil tablets
- Single tablet delivery on patient demand
- RFID thumb tag co-located to device helps reduce unauthorized dosing
- HCP controlled access, device tether reduces risk of product loss
- Battery power ensures 72-hour function even in the event of power outage



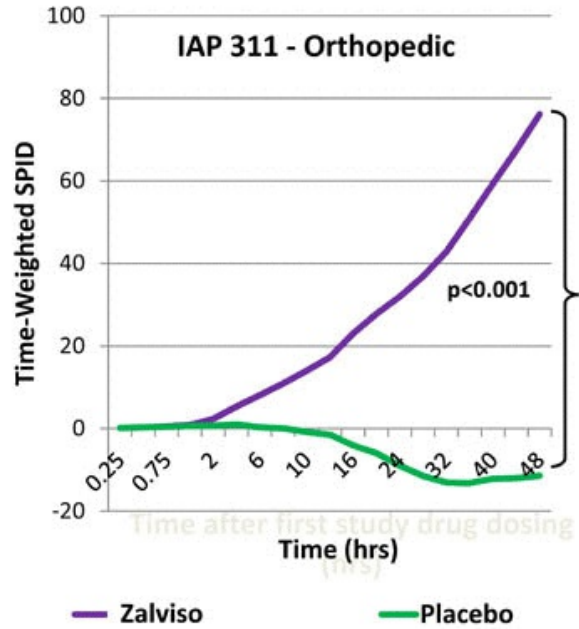
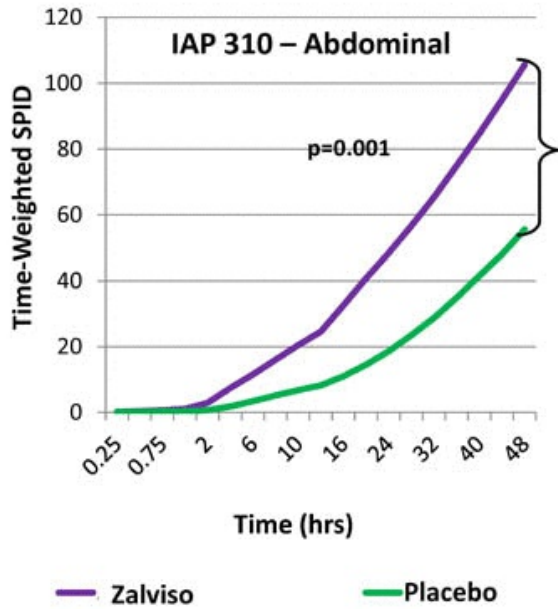
Investigational drug and delivery system not FDA approved for commercial use

**AcetRx**  
Pharmaceuticals, Inc.  
ACCESS POINT | INCREASE | ALL-PAIN

## Phase 3 Clinical Trials-Zalviso

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™

(sufentanil sublingual tablet system) (II)

## Commercial Opportunity



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



Investigational drug and delivery system not FDA approved for commercial use

---



## Target Market Potential

The potential market for Zalviso is defined as:

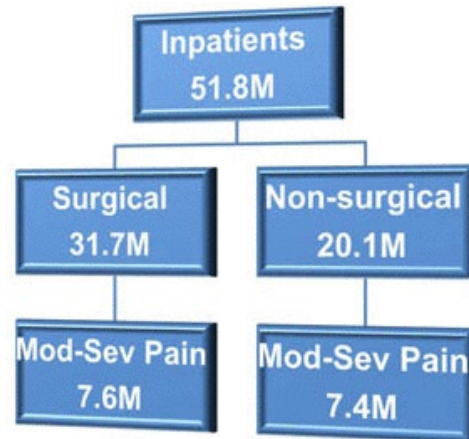
- Acute moderate-to-severe pain population in the hospital setting
- Includes post-operative as well as non-surgical pain

Market size for Zalviso is characterized by hospital in-patient sampling that demonstrates 15M annual patients annually <sup>1</sup>

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

2013 U.S. Acute Pain Market \$6.7B <sup>2</sup>

- 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

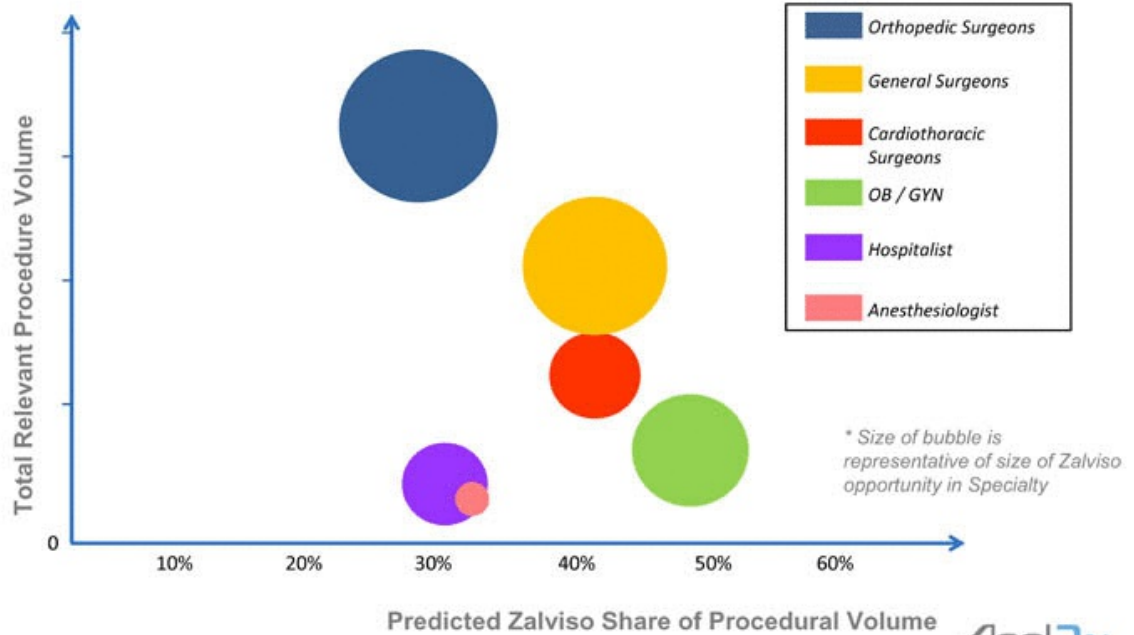
Earliest – 2 Months; Typical – 8-10 Months





## Strong Positive Reaction to Zalviso Clinical Profile

Market Research Among Hospital Specialists (n=244)<sup>1</sup>



## Hospital Targeting – For Rapid Formulary Access

A total of 563<sup>1</sup> of 1232<sup>2</sup> targeted institutions are identified as Super or Fast Adopters, indicating potential for faster Zalviso adoption when launched

Projected Size of Zalviso Opportunity Per Physician					
	Tier 1 Hospitals	Tier 2 Hospitals	Tier 3 Hospitals	Tier 4A Hospitals	Tier 4B Hospitals
Superfast (Early)	Primary target	Primary target	Secondary target	Secondary target	Final target
Fast (Early Majority)	Primary target	Primary target	Secondary target	Tertiary target	Final target
Slow (Late Majority)	Tertiary target	Tertiary target	Tertiary target	Final target	Final target
Never (Laggards)	Final target	Final target	Final target	Final target	Final target

350 institutions out of total of 1232 institutions fully profiled

- 4 of 7 Regions, ~25% profiling complete

■ Primary target    ■ Tertiary target  
■ Secondary target    ■ Final target

**AcelRx**  
 Pharmaceuticals, Inc.  
ACCELERATE | INNOVATE | ALLEVIATE

<sup>14</sup>  
 1. Derived from Symphony Health Solutions, Non-Retail, 2009-2014 Ad Hoc Analgesic Products  
 2. ZS Associates, Go to Market Quantification, Spring 2014, Sponsored by AcelRx Pharmaceuticals



## Current Publications

### 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 Press

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



**ARX-04**  
HCP Administered, Single  
30mcg Sufentanil Sublingual  
Tablet



Investigating moderate-to-severe acute pain treatment in medically supervised settings

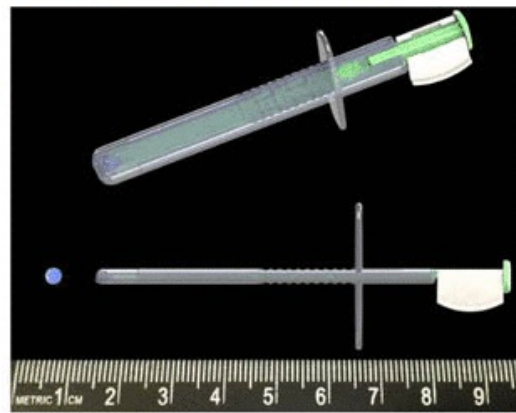
Investigational drug and delivery system not FDA approved for commercial use

**AcelRx**  
Pharmaceuticals, Inc.  
ACCELERATE | INNOVATE | ALLEVIATE



## ARX-04 – Sublingual Sufentanil

- Developed for the treatment of moderate-to-severe acute pain in a medically supervised setting
- Product to be administered to patient by healthcare professional (HCP)
- Can be administered, per patient's request, every 60 minutes
- Tablet pre-loaded in a single-dose applicator (SDA) within a pouch so suitable for field/trauma use
- Single tablet dosage strength – 30 mcg



**AcelRx**  
Pharmaceuticals, Inc.  
ACCESS POINT | INVERSE | ALL POINT



## Phase 2: Dose Finding Study

### Pivotal Trial

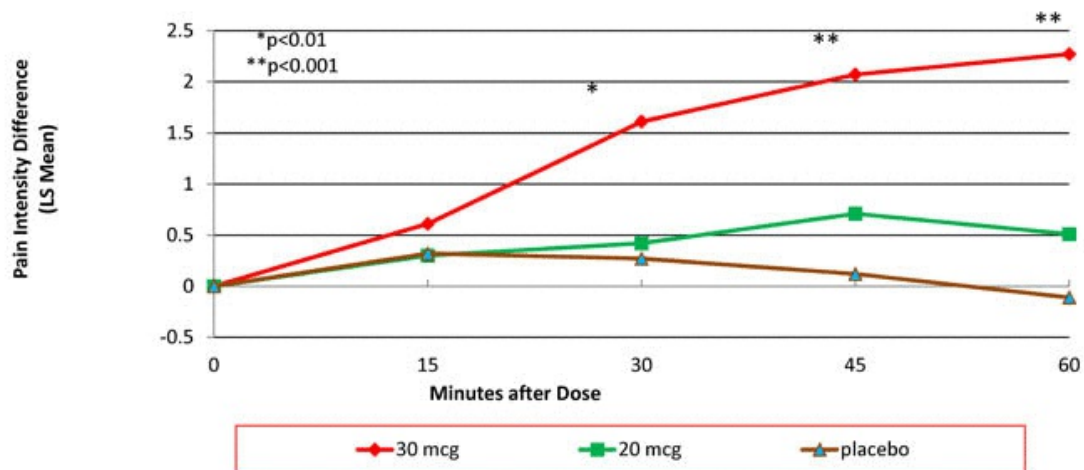
- Randomized, double-blind, placebo-controlled safety and efficacy study in bunionectomy pain model at two experienced sites
- Sufentanil Tablet 20 mcg, 30 mcg and placebo
- 100 patients evaluated (randomized 2:2:1)
- 12 hour study duration with minimum re-dose interval 1 hour
- Primary endpoint: Summed Pain Intensity Difference over 12 hours (SPID12)
- 30 mcg results
  - Efficacious (difference (active – placebo) in LS Mean SPID12: 13.7, p=0.003)
  - Average inter-dosing interval was 2.4 hours
  - Median number of doses was 4.5
  - Rescue (Vicodin): 30% none, 40% 1 dose, 25% 2 doses, 5% 3 doses
  - Most common AEs (considered related) were nausea, vomiting, dizziness, somnolence and pruritus



## ARX-04 Phase 2 Trial Shows Efficacy Over Placebo

### Successful Phase 2 Bunionectomy Study

- Will count as pivotal trial





## SAP301 Phase 3 Study Design

### Abdominal

- Randomized, Double-blind, Placebo-controlled in post-operative patients following abdominal surgery normally performed as out-patient procedure
- Surgical procedures permitted
  - Abdominoplasty
  - Open inguinal hernioplasty
  - Laparoscopic abdominal surgery
- The primary outcome measure is time-weighted summed pain-intensity difference over the first 12 hours of the study period (SPID12)
- First Patient In (FPI): Feb 2015
- Last Patient In (LPI): Q3
- Top Line Data: Q4





# ARX-04

## Commercial Opportunity



Investigating moderate-to-severe acute pain treatment in medically supervised settings

**Investigational drug and delivery system not FDA approved for commercial use**

**AcelRx**  
Pharmaceuticals, Inc.  
ACCELERATE | INNOVATE | ALLEVIATE

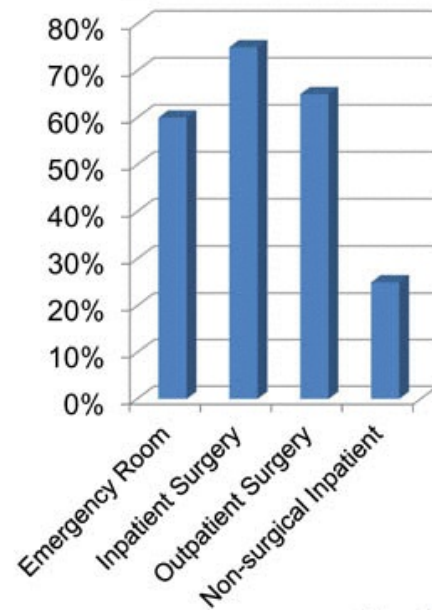


## Target Market Opportunity

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

- **Emergency Room (ER)**
  - 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



**AcelRx**  
Pharmaceuticals, Inc.  
ACCESS POINT | INCREASE | ALIGNMENT

## ARX-04 Opportunity

### ER represents the largest opportunity for ARX-04 in the US

- Based on qualitative feedback the largest opportunity in the US for ARX-04 is in the emergency room **as an alternative to IV opioids** and as a bridge from IV to oral opioids
- In the US, we estimate that the ER represents approximately **12M–15M ARX-04 doses annually**
- Overall in the US, ARX-04 product adoption could be driven through the ER once broader market access hurdles (formulary acceptance, pricing, etc) are overcome
- In general, in terms of the level of physician price sensitivity, **ER physicians appear to have the highest “willingness to pay” for ARX-04**

Patients	ER Setting
Total Patients	109,980K
Patients with M/S-aP	51,381K
Patients on ARX-04 (Stated)	16,772K
Patients on ARX-04 (Adjusted)	5,451K – 6,709K
ARX-04 Doses	11,953K –14,711K
Ability to Secure Utilization	High

- *A major driver of use for ARX-04 will likely be its mode of administration combined with ease of use*
- *A significant barrier for ARX-04 will likely be hospital formulary placement*





## Scientific Conference Schedule - 2015

American Society of Peri-Anesthesia Nurses (ASPAN)

April 26-30; San Antonio, TX – Booth & Symposium

American Society of Regional Anesthesia and Pain Medicine (ASRA)

May 14-16 – Poster

European Pain Federation (EFIC)

September 2-5 – Poster

American Society of Anesthesiologists (ASA)

October 24-28; San Diego, CA – Poster

American Society of Regional Anesthesia and Pain Management (ASRA)

November 19-21; Miami, FL – 1 Poster

American Society of Health System Pharmacists (ASHP)

December 6-10; New Orleans, LA – Poster



## Financial Summary

- Cash position at March 31, 2015: \$64 million
- Q1 2015 cash usage of ~\$11 million
- Cost reduction plan implemented in March 2015 designed to conserve cash resources until Zalviso regulatory clarity obtained
- Headcount at March 31, 2015: 36
- 44 million shares outstanding at March 31, 2015



## Future Catalysts

Event	Timing
180 day question response to Zalviso MAA review	Q2 2015
ARX-04 DoD contract finalized	Q2 2015
CHMP meeting	Mid-year 2015
Zalviso MAA decision	Q3 2015
ARX-04 Phase 3 data	Q4 2015



## **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

### **ARX-04 Development timeline**

- Study 301 – Abdominal: First Patient In Late February 2015
- Study 302 – Emergency Room: Commence post DoD contract execution
- Top Line Phase 3 results, Study 301, expected Q4

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

- Terms: \$250M upfront and potential milestones, mid-teens to mid-twenties % royalty
- CE Mark: Received December 2014
- EMA Centralized Procedure, and Swiss Medic MAA review on-going
- Other Territories: Continue to seek additional partnerships in Asia, South America

### **Upcoming regulatory catalysts in US and EU**

- US: FDA clarity
- EU: CHMP MAA Opinion meeting