

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): January 11, 2016

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))
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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, 2015 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 11, 2016 through January 14, 2016. The aforementioned financial information is included on slides #3 and #31 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 11, 2016 through January 14, 2016 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.

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 Corporate Presentation January 2016”

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 11, 2016

ACELRX PHARMACEUTICALS, INC.

By: /s/ Jane Wright-Mitchell _____

Jane Wright-Mitchell
Chief Legal Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Slide presentation entitled, "AcelRx Pharmaceuticals Corporate Presentation January 2016"

AcelRx Pharmaceuticals

Corporate Presentation
January 2016

AcelRx
Pharmaceuticals, Inc.



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; anticipated results and timing of the completion of the SAP302 and SAP303 studies for ARX-04; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the United States, including the anticipated timing, design and results of the additional clinical trial for Zalviso (IAP312); the timing of anticipated resubmission of the Zalviso NDA to the FDA; statements related to the timing and success of commercial launch of Zalviso in Europe; ability to fund ARX-04 development from the contract with the Department of Defense; the status of the Collaboration and License Agreement with Grunenthal, including potential milestones and royalty payments under the Grunenthal Collaboration and License Agreement; anticipated cash balance at year-end 2015 and cash forecasts. These forward-looking statements are based on AcelRx's current expectations and inherently involve significant risks and uncertainties. AcelRx's 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: any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso and ARX-04; its ability to successfully design and complete the additional clinical study (IAP312) requested by the FDA to support resubmission of the Zalviso NDA; its ability to timely resubmit the Zalviso NDA to the FDA and to receive regulatory approval for Zalviso; the fact that the FDA may dispute or interpret differently positive clinical results obtained to date from the pivotal Phase 3 SAP301 ambulatory surgery study of ARX-04; its ability to complete Phase 3 clinical development of ARX-04; inability to successfully manufacture Zalviso to meet the requirements of Grunenthal and potential delays in the timing of the European launch; the success, cost and timing of all product development activities and clinical trials, including the SAP302 and SAP303 ARX-04 trials and the IAP312 Zalviso trial; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on November 3, 2015. AcelRx 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.

Sublingual Sufentanil:

New Approach to Treat Moderate-to-Severe Acute Pain

AcelRx Highlights: Over \$100 million in cash
Two US Phase 3 products

ARX-04



- Emergencies
- Procedures and Short-stay Surgeries

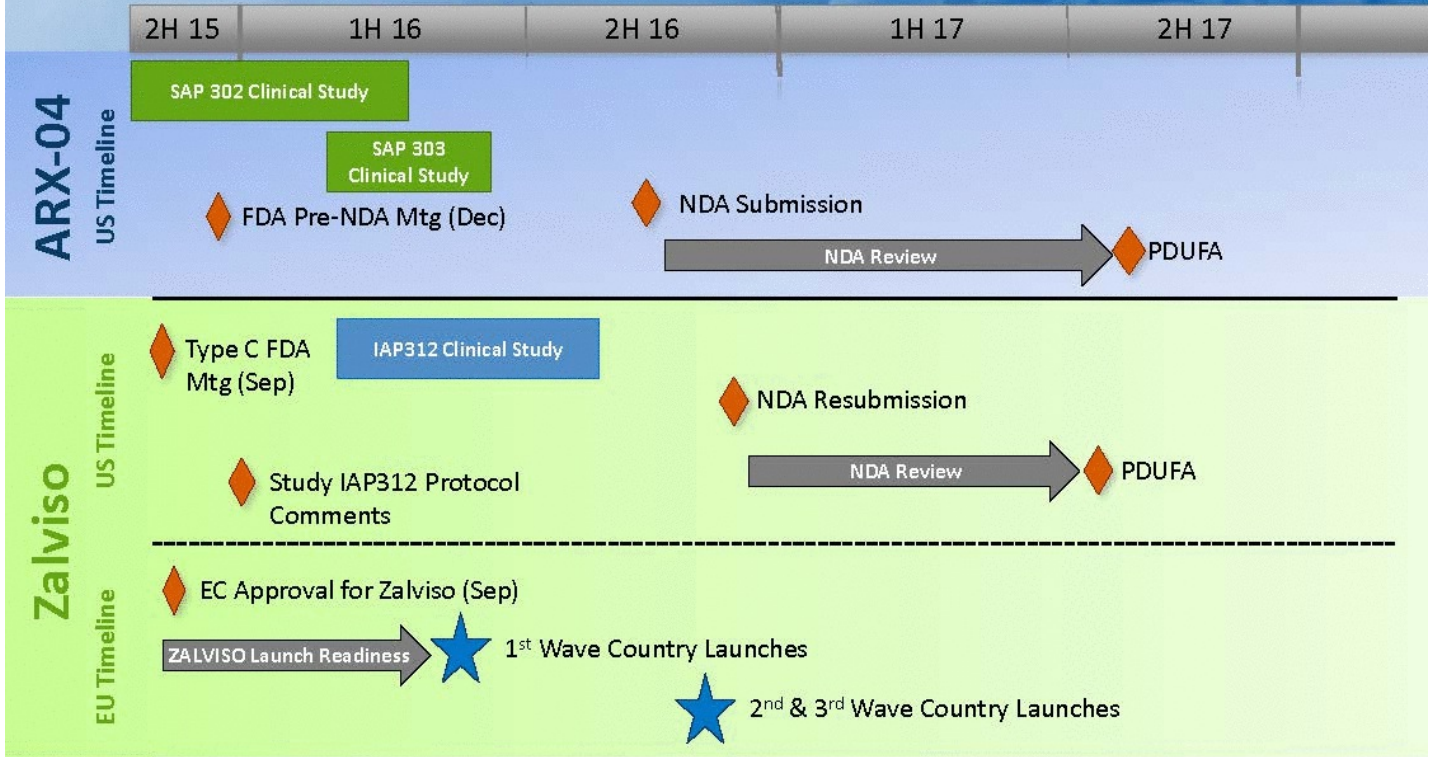
Zalviso



- Inpatient Surgeries
- Approved in EU

Zalviso and ARX-04 Anticipated Timelines

Two US Submissions Planned in 2016



Opioids Remain Important Analgesics

- The Ebers Papyrus (ca. 1500 B.C.) documents many opioid remedies for pain and suffering¹
- Over 3000 years later, opioids remain an important treatment for moderate-to-severe acute pain²
- Following major surgery, non-opioid adjuvants only reduce postoperative opioid use by 0 – 50%³
- Opioid medications remain the mainstay for treatment of severe pain in the ER⁴
- AcelRx products are for short-term use and only to be used in hospitals or administered by trained medical professionals

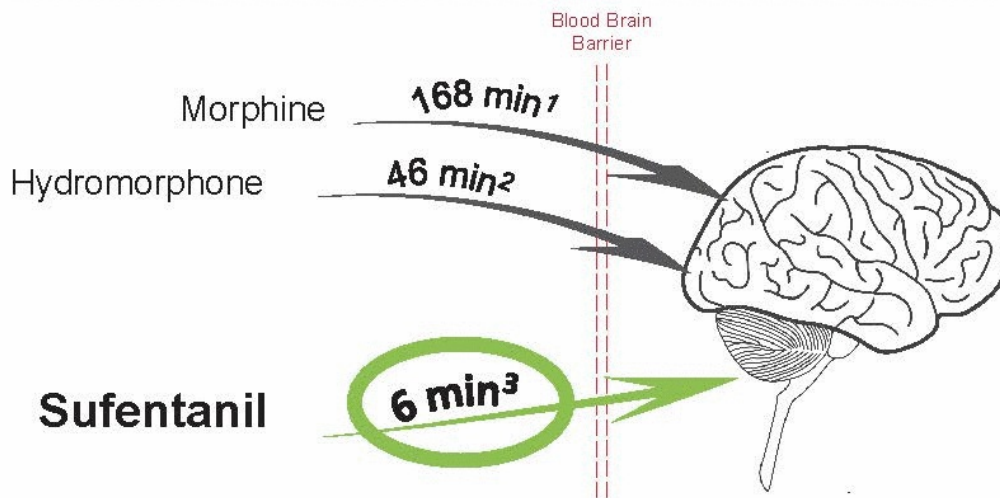
Unmet Needs in Treatment of Moderate-to-Severe Acute Pain

	Emergencies	Procedures/ Short-Stay Surgeries	Inpatient Surgeries
Route of Delivery	<ul style="list-style-type: none"> • IM/IV are invasive • Oral = slow onset 	<ul style="list-style-type: none"> • IV may prolong stay • Oral = slow onset 	<ul style="list-style-type: none"> • IV may limit mobility • PCA pump = potential for programming errors
Common Opioids	<ul style="list-style-type: none"> • IV morphine and hydromorphone = slow on/slow off; active metabolites can cause prolonged opioid effects/side effects • IV fentanyl = rapid on/too short-acting requiring frequent redosing 		



Sufentanil: Sublingual Route = Rapid Brain Penetration

Commonly used IV opioids have a delayed equilibration time between plasma and brain

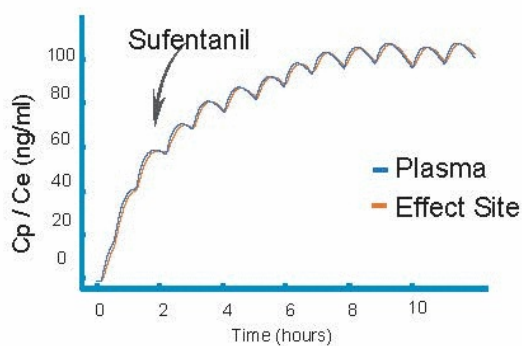


Sublingual Sufentanil

Potential for Real-Time Tracking Between Dosing & Effect

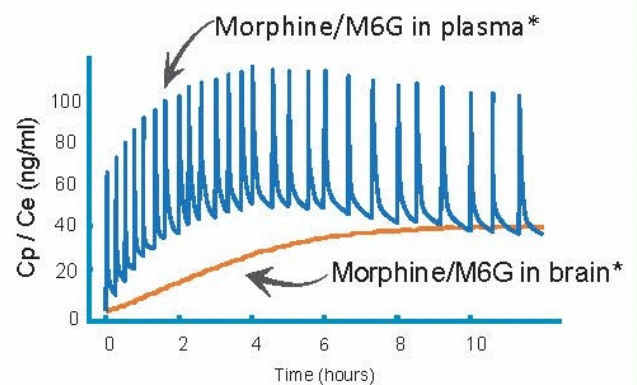
Sublingual sufentanil dosing closely matched with effect

Sublingual Sufentanil Plasma vs. Brain Concentrations



Brain levels delayed with IV morphine dosing¹

IV Morphine Plasma vs. Brain Concentrations



* Assumes equipotency of morphine and M6G;
other potency ratios achieved similar results

Proprietary Sublingual Sufentanil Tablets Have Unique Properties

Sufentanil

- **Lipophilic** so absorbed sublingually
- **Potent** so small tablet possible
- **Wide therapeutic index** to maximize analgesia while minimizing side effects
- **Low GI bioavailability** minimizes delayed effect of swallowed drug



Tablet

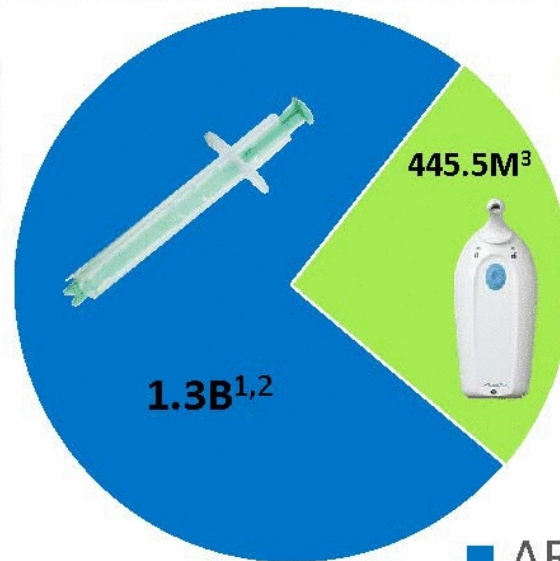
- **Small size** dissolves in minutes
- **Minimizes saliva production** to limit swallowed drug and avoid delayed drug uptake from GI
- **Bioadhesive** to keep in place under tongue
- **Discrete dosing unit** reduces errors of continuous dosing



In Medically Supervised Settings, ~90M Pts Treated Annually in the US for Moderate-to-Severe Acute Pain^{1,2,3}

\$1.7 Billion Combined Market Potential

ER Departments
Ambulatory Surgery Centers
Short-stay Surgeries
Interventional Procedures



Inpatient Postoperative

■ ARX-04 ■ Zalviso

AcelRx
Pharmaceuticals, Inc.

1. Data on file. In-house commissioned market research. ZS Associates "Opportunity Assessment, US & EU" Study dated August 2014
2. Data on file. In-house commissioned market research. Millennium Research Group "US Market Opportunity Study for Sublingual Sufentanil" March 24, 2010
3. Data on file. In-house commissioned market research. ZS Associates "Go-to-Market Strategy Segmentation and Opportunity Quantification" March 2014

Patient Satisfaction with Pain Management a Focus for Medical Facilities and Healthcare Professionals

Patients now shopping for hospitals and comparing based on HCAHPS scores

Medicare.gov | Hospital Compare

The Official U.S. Government Site for Medicare

Hospital Compare
Home

About Hospital
Compare

About the data

Resources

The HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey is the first national, standardized, publicly reported survey of patients' perspectives of hospital care.

4) How often was patients' pain well controlled?

During this hospital stay...

- ♦ How often was your pain well controlled?
- ♦ How often did the hospital staff do everything they could to help you with your pain?

Medicare & Medicaid reimbursement tied directly to HCAHPS scores

December 2015: Centers for Medicare & Medicaid Services (CMS) refreshed the HCAHPS results on the Hospital Compare Web site, www.medicare.gov/hospitalcompare

ARX-04



- ER Departments
- Ambulatory Surgery Centers
- Short-Stay Surgeries
- Interventional Procedures

Development Status

- SAP302 ongoing in the emergency room
 - SAP303 to be initiated in postoperative patients with moderate-to-severe acute pain
 - NDA submission anticipated in 2H 2016
-

Department of Defense Provides Support for Treating Pain Associated with Trauma

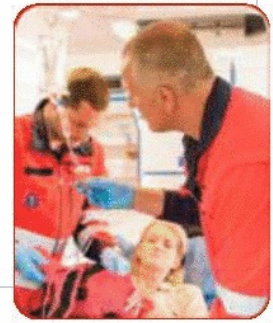
Battlefield

- IM morphine standard of care¹
- IM dosing often ineffective due to shock and lack of circulation to muscles; death can occur due to oxygen desaturation upon reperfusion²
- IV lines time-consuming and challenging to start
- DoD Needs: Rapid onset with predictable offset and minimal cognitive effects



Civilian Equivalent = ER

- Guidelines support opioids for moderate-to-severe acute pain³
- IV lines challenging to start in ambulances⁴
- Can take 30 minutes or more to have an IV line inserted in ER⁵



AcelRx
Pharmaceuticals, Inc.

1. US Defense Health Board. *Pre Hospital Use of Ketamine in Battlefield Analgesia in Tactical Combat Casualty Care Pain Guidelines*. 2012 Mar <http://goo.gl/v2rR0>

2. de Moya, M. A. *Shock*. In Merck manual online, professional version. Retrieved from <http://goo.gl/8Xpa2>

3. Byers, PA; Counselman, FL. *Appropriate Analgesic Use in the Emergency Department*. *Emerg Med* 2014;46(6): 249-255.

4. Sweeney, T. and Marques, A. *Prehospital Vascular Access for the Trauma Patient*. In Soreid E. and Grande, C. (Eds) *Prehospital Trauma Care* (Page 291). CRC Press Feb 02, 2015

5. *Ann Emerg Med*. 2005 Nov;46(5):456-61.

ARX-04 Sublingual Sufentanil (30 mcg)

Intended for Treating Moderate-to-Severe Acute Pain in Medically Supervised Settings

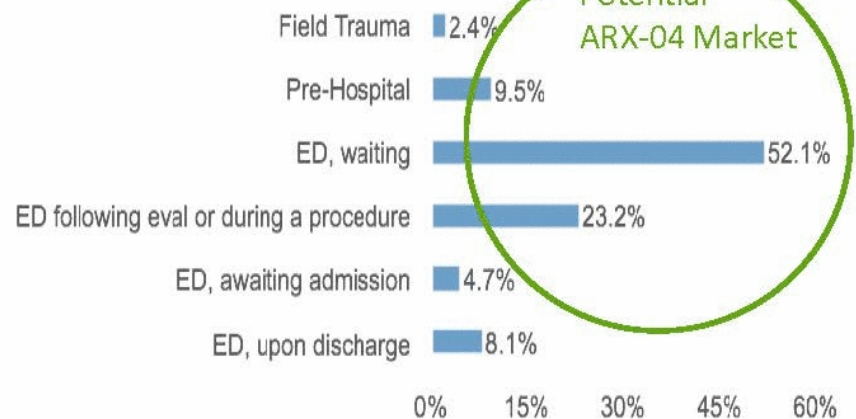
- Single dosage strength - 30 mcg
- Tablet pre-loaded in a single-dose applicator
- Administered, per patient's request, by healthcare professional every 60 minutes
- Packaged in a foil pouch making it suitable for field/trauma use



Survey of Emergency Departments Underscores Need for Improvements in Pain Management¹

- Surveyed physicians expect fewer than 20% of their ER patients to wait 15 min or less for their first dose of IV opioids
- 65% of physicians stated that they would use a product like ARX-04 in their institution

Areas for Improvement



ARX-04 Pivotal Efficacy Studies Completed

Remaining Trials are Open-Label Safety Studies

Pivotal Studies

- Positive Phase 2: SAP202 Bunionectomy Study
- Positive Phase 3: SAP301 Abdominal Surgery Study

Safety Studies

- SAP302: Emergency Room Study underway
- SAP303: Postoperative Elderly Patients and Patients with Comorbidities

ARX-04 Abdominal Surgery Study: SAP301

Postoperative Ambulatory Surgery Patients

Surgery Types

- Open Hernioplasty
- Abdominoplasty
- Laparoscopic Abdominal Surgery

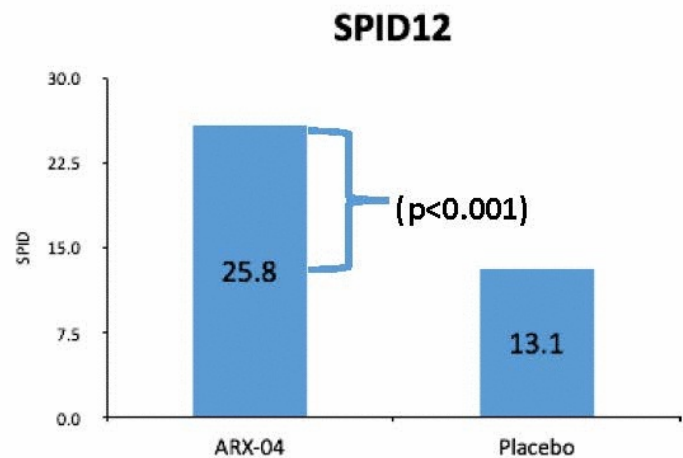
Study Details

- Randomized 163 patients
- Randomized 2:1 active to placebo
- Completers = 24 hours in the study, extension to 48 hours if needed
- Primary endpoint: Sum of the pain intensity difference to baseline over the first 12 hours (SPID12)

ARX-04 Abdominal Surgery Study: SAP301

ARX-04 Superior to Placebo on Primary and Secondary Endpoints

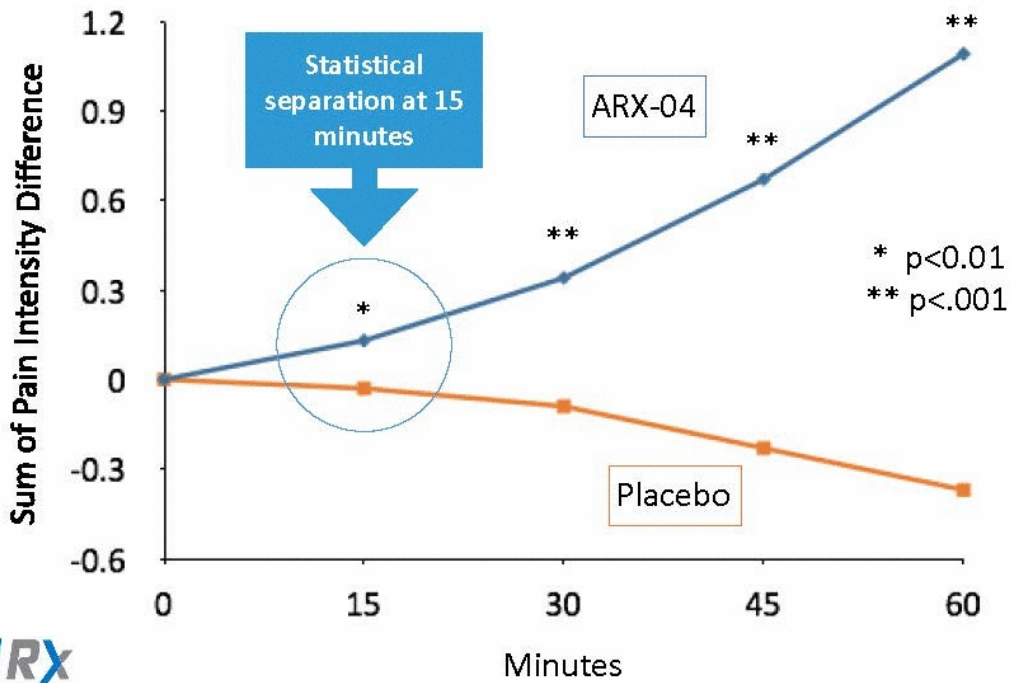
- Significantly greater SPID12 compared to placebo
- ARX-04 also positive on secondary endpoints
- No difference in AE's between ARX-04 and placebo
- AE's typical of opioid therapy (nausea, headache, vomiting)



ARX-04 Abdominal Surgery Study: SAP301

SPID1 Statistically Better than Placebo after 15 Minutes

SPID Over First Hour of Treatment



ARX-04 Emergency Room Study: SAP302

Single-Arm, Open-Label

Single and multiple-dose treatment in patients presenting to the ER with trauma or injury associated with moderate-to-severe acute pain

Study Exclusions

- Pregnant
- Opioid-tolerant
 - (>15 mg oral morphine equivalent daily)
- Dependent on supplemental oxygen

Primary Efficacy Endpoint: SPID1

- Summed pain intensity difference to baseline
 - (over first hour after receiving ARX-04)

Key Safety Endpoints

- Six-item Screener
 - (cognitive impairment test: pre- and post-dosing)
- Adverse Events
- Vital Signs

ARX-04 Postoperative Study: SAP303

Single-arm, Open-label in Short-stay Postoperative Patients

- Post-surgical patients with moderate-to-severe acute pain
- Age 40 years or older, encourage enrollment of patients with comorbidities (renal impairment, liver impairment, etc.)
- ARX-04 30 mcg may be dosed once every 60 minutes, as needed, for up to 12 hours
- Expected to enroll up to 100 patients
- Multiple clinical sites experienced with sublingual sufentanil
- Represents another potential market segment for ARX-04

Zalviso™



- Inpatient Surgeries requiring overnight stays

Development Status

- Approved in Europe
 - Additional US study planned
 - NDA resubmission planned H2 2016
-

Current Problems with IV PCA Devices and Delivery

Documented Problems with IV PCA^{1,2,3}

- User programming errors resulting in adverse events including death
- Proxy dosing can cause injury and death
- Infection risk
- Can limit ambulation
- Clear liquid drug can encourage drug diversion



Zalviso:

Noninvasive Patient-Controlled Analgesia (PCA) Designed to Mitigate Issues with IV PCA

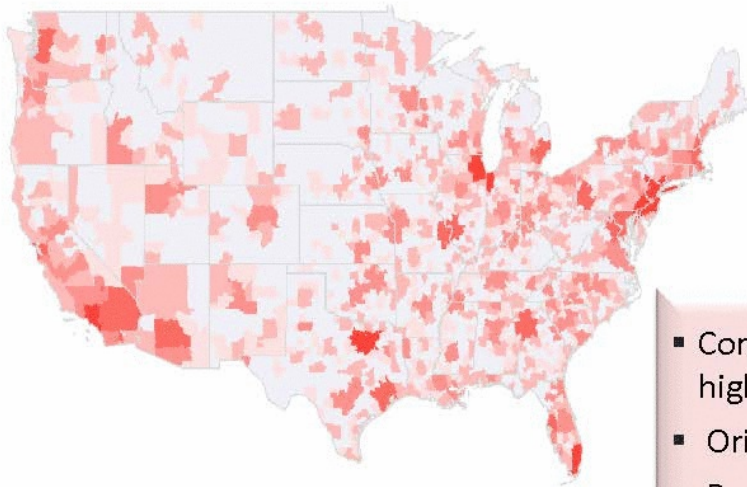
- **Decrease Medication Errors Associated with IV PCA:** Pre-programmed delivery/single-strength tablet
- **Reduce Proxy Dosing:** Patient RFID thumb tag required for dosing
- **Reduces Infection Risk:** Noninvasive sublingual delivery
- **Less Hampering of Ambulation:** Patient not tethered to Zalviso
- **Multiple Anti-Diversion Features:**
 - RFID on cartridge provides full inventory tracking of tablets
 - HCP-controlled access, device tethered to bed, anti-diversion alarms



Investigational drug and delivery system not FDA approved for commercial use

The Opportunity for Zalviso is Geographically Concentrated

Hospital Potential¹



CBSA ² Relevant Procedure Volume	# of CBSAs	# of accounts	% of relevant procedure volume
100K+	6	591	19%
50K – 100K	13	570	18%
10K – 50K	88	1,191	34%
1K – 10K	367	1,238	25%
0-1K	473	623	4%

- Commercialization efforts specific to high-volume surgical specialists
- Original sales force size: ~65
- Profiling showed early opportunity in ~60 accounts²

Zalviso Pivotal Studies: *Positive versus Placebo and Active Comparator*

Placebo-Controlled Studies

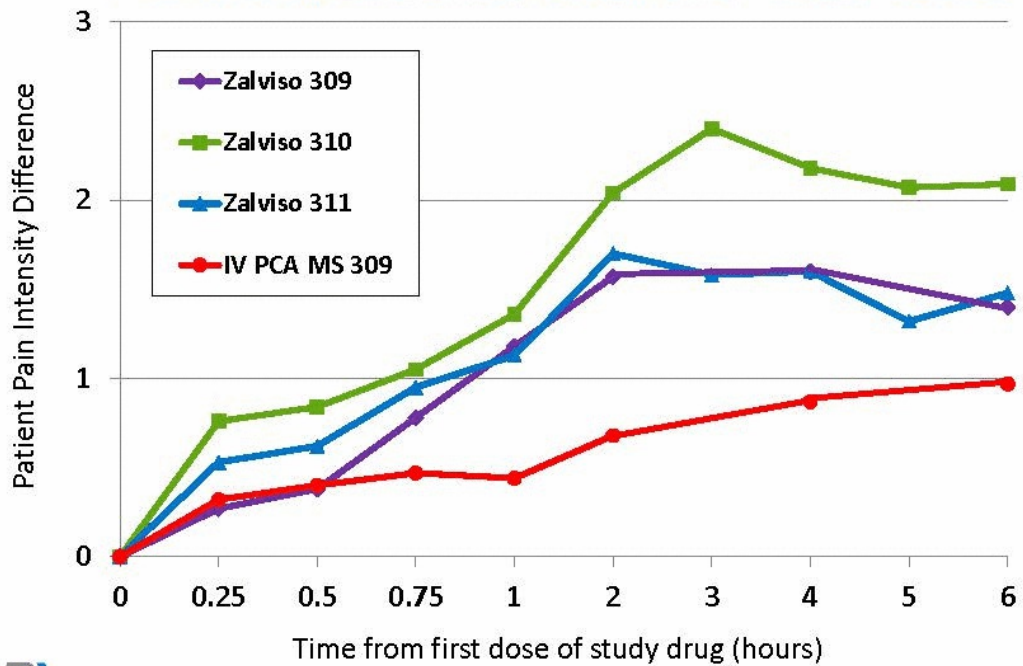
- Study IAP310: postoperative pain after abdominal surgery
- Study IAP311: postoperative pain after total hip or knee surgery

Zalviso vs. IV PCA morphine (IAP309)

- Zalviso superior as measured by Patient Global Assessment (PGA) and onset of analgesia
- Easier to use as rated by patients and healthcare professionals

Zalviso: Studies Demonstrate Ability to Treat Moderate to Severe Acute Pain

Pain Intensity Difference to Baseline for Phase 3 Studies



Final Phase 3 Study IAP312: *Open-Label, Single-Arm Designed to Evaluate Device Performance*

IAP312 Multicenter Study

- Study designed specifically to address remaining FDA questions
- Protocol reviewed by FDA
- Revised protocol includes FDA comments
- Planned to enroll ~310 patients
- 24- to 72-hour duration
- Single-arm, open-label, various postsurgical settings
- Study will collect device failure rate
- Nurses will actively look for dropped tablets
- Multimodal analgesia allowed

ZALVISO

Approved in Europe: Grunenthal Preparing for a 1H 2016 launch

Commercial rights to European Union

Collaboration Details

- \$30M upfront received
- \$5M on MAA filing received
- \$15M on MAA approval received
- \$28.5 in R&D milestones remain
- \$166 commercial milestones remain (20% of first four worth \$44.5M in total retained as part of PDL deal)
- Royalties from mid teens to mid twenties expected over life of agreement (25% retained as part of PDL deal)
- Peak Revenues in EU expected to be \$150M



Issued Patents on Both Device and Drug Formulations

IP Strategy

- Drug-device combination allows for broad patent coverage
- Integrated IP and regulatory strategy designed to minimize ANDA exposure

IP Portfolio

- 12 US patents issued on NanoTab
7 US patents issued on Devices
Coverage through 2027 - 2031
- 3 EU patents issued on NanoTab
2 EU patents issued on Device
Coverage through 2027 - 2029
- 19 issued patents in other territories
- 11 US applications plus 30+ foreign applications in late stage prosecution

Projected to End 2015 with \$100+ million in cash

▪ Cash on hand at September 2015	\$104 million
▪ EU approval milestone (received Q4 2015)	\$15 million
▪ Projected cash balance Dec 31, 2015	\$100+ million
▪ Outstanding Loan Amount	\$21 million
▪ Shares Outstanding	45 million

Achievement of Significant Milestones Anticipated in 2016

Completed in 2015

- ARX-04 DoD Contract Executed May
- ARX-04 SAP301 Topline Data Sept
- Completed \$65M Royalty Deal Sept
- Zalviso MAA Approval Sept
- ARX-04 Pre NDA Meeting Dec
- FDA comments on IAP312 Dec

Anticipated in 2016

- ARX-04 ER Study Results Q2
- ARX-04 Post-op Study Results Q2
- ARX-04 NDA Submission H2
- Zalviso EU Commercial launch H1
- Zalviso Single-arm Study Results H2
- Zalviso NDA Resubmission H2

Thank you for listening

For more information, visit:
www.acerx.com

AceIRx
Pharmaceuticals, Inc.

