**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): September 27, 2016**

# ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

| **DELAWARE** | **001-35068** | **41-2193603** |
|---|---|---|
| (State of incorporation) | (Commission File No.) | (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.**

Howie Rosen, chief executive officer of AcelRx Pharmaceuticals, Inc. (the "Company" or "AcelRx"), will be presenting at the Ladenburg Thalmann 2016 Healthcare Conference and will utilize a slide presentation. The slide presentation, together with a slide setting forth certain cautionary language intended to qualify the forward-looking statements included in the slide presentation, are furnished as Exhibit 99.1 to this Current Report and are incorporated herein by reference. The slide presentation 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 8.01. Other Events.**

On September 27, 2016, the Company issued a press release entitled "AcelRx Initiates Phase 3 Study of Zalviso® (sufentanil sublingual tablet system) in Patients with Moderate-to-Severe Acute Post-Operative Pain" a copy of which is attached as Exhibit 99.2 to this Report.

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

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Slide presentation entitled, "AcelRx Pharmaceuticals Corporate Presentation September 2016" |
| 99.2 | Press release dated September 27, 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: September 27, 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 September 2016" |
| 99.2 | Press release dated September 27, 2016 |

Exhibit 99.1


AcelRx Pharmaceuticals
Corporate Presentation
September 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, ARX-04 (sufentanil sublingual tablet, 30 mcg) and Zalviso® (sufentanil sublingual tablet system), including the ARX-04 clinical trial results; anticipated submission of the New Drug Application (NDA) for ARX-04 to the U.S. Food and Drug Administration (FDA); AcelRx's pathway forward towards gaining approval of Zalviso in the U.S.; the anticipated timing, design and results of the IAP312 clinical trial for Zalviso; anticipated resubmission of the Zalviso NDA to the FDA; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities for ARX-04 and Zalviso. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements, and as a result of these risks and uncertainties, which include, without limitation, risks related to AcelRx Pharmaceuticals' ARX-04 development program, including anticipated submission of the ARX-04 NDA and the fact that the FDA may dispute or interpret differently clinical results obtained from the Phase 3 studies of ARX-04; AcelRx's ability to successfully execute the pathway towards a resubmission of the Zalviso NDA to the FDA, including the initiation and completion of the IAP312 clinical study for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including ARX-04 in the United States and Europe, and Zalviso in the United States; the uncertain clinical development process, including adverse events; the risk that planned clinical trials, including IAP312 for Zalviso may not begin on time, have an effective clinical design, enroll a sufficient number of patients, or be initiated or completed on schedule, if at all; the success, cost and timing of all development activities and clinical trials; the accuracy of AcelRx's estimates regarding expenses, capital requirements and the need for financing; 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 July 29, 2016. AcelRx undertakes no duty or obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or changes in its expectations.*

# Sublingual Sufentanil:
## *New approach in development to treat moderate-to-severe acute pain*

**AcelRx Highlights:** **Over $98 million in cash**
**Two US Phase 3 products**

### ARX-04

- Emergency Medicine
- Short-stay Surgeries and Procedures

### Zalviso®


- Inpatient Surgeries
- Marketed in EU

AcelRx Pharmaceuticals, Inc.

# Opioids Remain Important Analgesics

- The Ebers Papyrus (ca. 1500 B.C.) documents many opioid remedies for pain and suffering[1]
- Over 3000 years later, opioids remain an important treatment for moderate-to-severe acute pain[2]
- 2016 American Pain Society Guidelines for managing postoperative pain include the use of opioids[3]
- Following major surgery, non-opioid adjuvants only reduce postoperative opioid use by 0 – 50%[4]
- Opioid medications remain the mainstay for treatment of severe pain in the ER[5]
- AcelRx products are intended for short-term use and only to be used in hospitals or administered by trained medical professionals

AcelRx Pharmaceuticals, Inc.

1. Brownstein, MJ: PNAS 90:5391, 1993.
2. Garimella V, Cellini C: Clin Colon Rectal Surg 26:191, 2013
3. Chou, The Journal of Pain (2016;17:131-157)
4. Buvanendran A, Kroin JS: Curr Opin Anaesthesiol 22:588, 2009
5. http://www.acep.org/opioids/

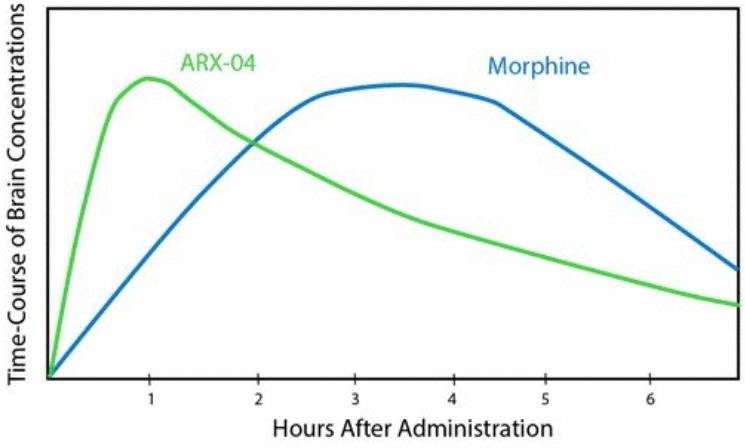
# Unmet Needs in Treatment of Moderate-to-Severe Acute Pain

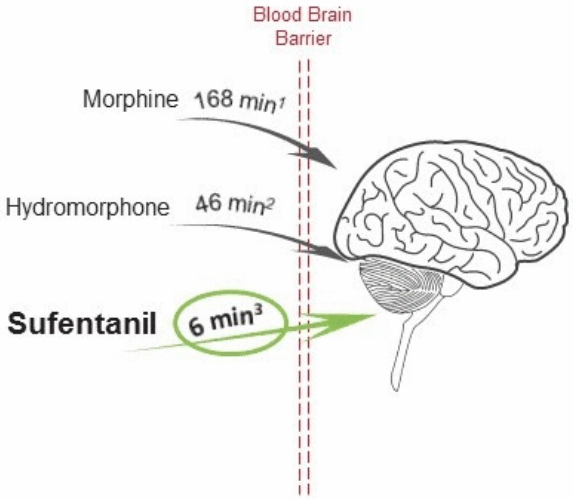
| | Emergencies | Short-Stay Surgeries/Procedures | Inpatient Surgeries |
|---|---|---|---|
| Route of Delivery | • IM/IV are invasive<br>• Oral = slow onset | • IV may prolong stay<br>• Oral = slow onset | • IV may limit mobility<br>• PCA pump = potential for programming errors |
| Common Opioids | • IV morphine and hydromorphone = delayed CNS uptake/slow off; active metabolites can cause prolonged opioid effects/side effects<br>• IV fentanyl = rapidly absorbed/short-acting requiring frequent redosing | | |

# Sufentanil:
## *Sublingual Route = Rapid Brain Penetration*

*Sufentanil Penetrates CNS Due to Lipophilicity ($t_{½ke0}$)

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



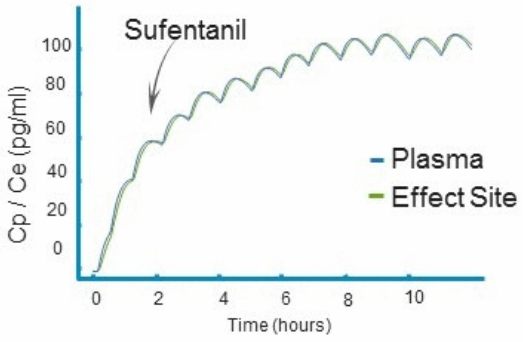

AcelRX Pharmaceuticals, Inc.


1. Lotsch et al., Anesthesiol 95:1329-38, 2001
2. Shafer et al., Geriatric Anesthesiology. 2nd ed. New York, NY: Springer; Chapter 15:209–28, 2007
3. Scott et al., Anesthesiol 74:34-42, 1991

# Sublingual Sufentanil
## *Potential for Real-Time Tracking Between Dosing & Effect*

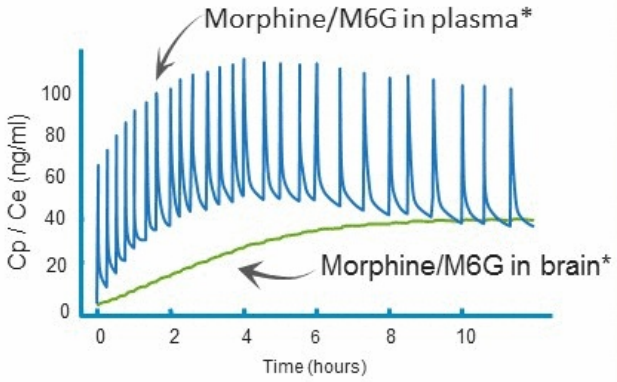
Sublingual sufentanil dosing closely matched with effect

**Sublingual Sufentanil Plasma vs. Brain Concentrations[2]**




Brain levels delayed with IV morphine dosing[1]

**IV Morphine Plasma vs. Brain Concentrations**




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

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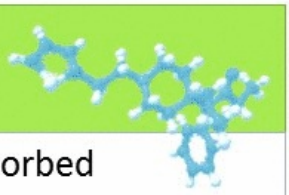
[1] *Sublingual sufentanil and IV PCA dosing frequency based on IAP309 study;*
[2] *Plasma and brain concentrations modelled from published plasma and CNS equilibration values by Dr. Dennis Fisher – consultant to AcelRx*

# Proprietary Sufentanil Sublingual Tablets Have Unique Properties

## Sufentanil



- **Lipophilic** so absorbed sublingually
- **Potent** so small tablet possible
- **Wide therapeutic index**[1] 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** may reduce dosing errors and diversion of clear liquids

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[1] as determined by animal models

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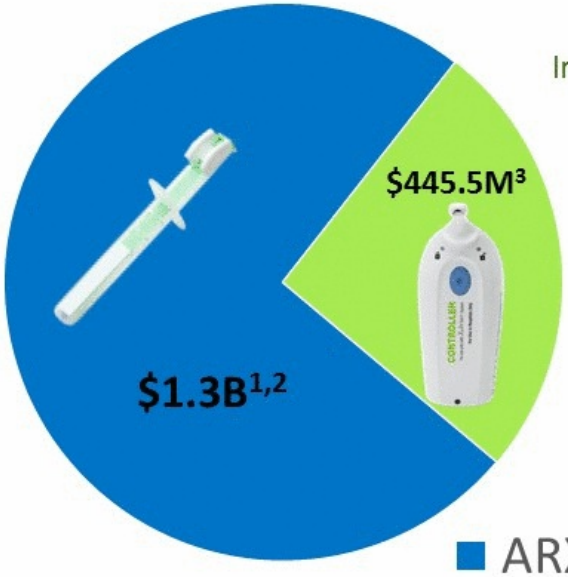
# In Medically Supervised Settings, ~90M Pts Treated Annually in the US for Moderate-to-Severe Acute Pain[1,2,3]

## $1.7 Billion Combined Market Potential

Emergency Departments
Ambulatory Surgery Centers
Short-stay Surgeries
Interventional Procedures

Inpatient Postoperative

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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

# ARX-04 Overview

- EMS (pre-hospital)
- Emergency Departments
- Ambulatory Surgery Centers
- Short-Stay Surgeries
- Interventional Procedures

## Proposed Indication

AcelRx Pharmaceuticals is developing ARX-04, sublingual sufentanil 30 mcg tablet pre-filled in a single-dose applicator for the management of moderate-to-severe acute pain in a medically supervised setting.

## Dosing

Maximum dose utilized in the studies was 30 mcg.

## Development Status

- Clinical studies complete
- NDA submission anticipated in Q4 2016

# Department of Defense Provides Support for Treating Pain Associated with Trauma

## Battlefield

- IM morphine standard of care[1]
- IM dosing often ineffective due to shock and lack of circulation to muscles; death can occur due to oxygen desaturation upon reperfusion[2]
- IV lines time-consuming and challenging to start
- DoD Needs: Rapid onset with predictable offset and minimal cognitive effects

## Civilian Equivalent = EMS/ED

- Guidelines support opioids for moderate-to-severe acute pain[3]
- IV lines challenging to start in ambulances[4]
- Can take 30 minutes or more to have an IV line inserted in ED[5]

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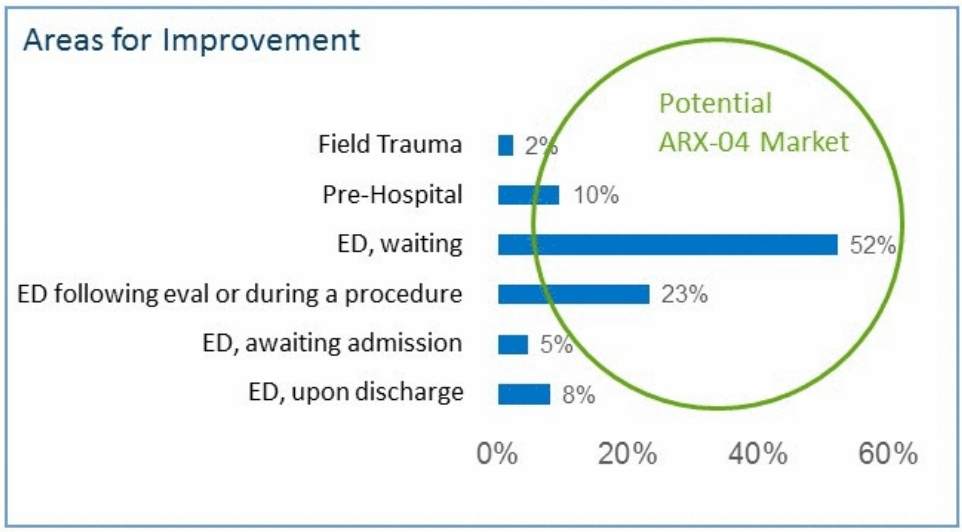
1. US Defense Health Board. *Pre Hospital Use of Ketamine in Battlefield Analgesia in Tactical Combat Casualty Care Pain Guidelines*. 2012 Mar http://goo.gl/w2rfR0
2. de Moya, M. A. *Shock*. In Merck manual online, professional version. Retrieved from http://goo.gl/lBXpa2
3. Byers, PA; Counselman, FL. *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

# Survey of Emergency Departments Underscores Need for Improvements in Pain Management[1]

- 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

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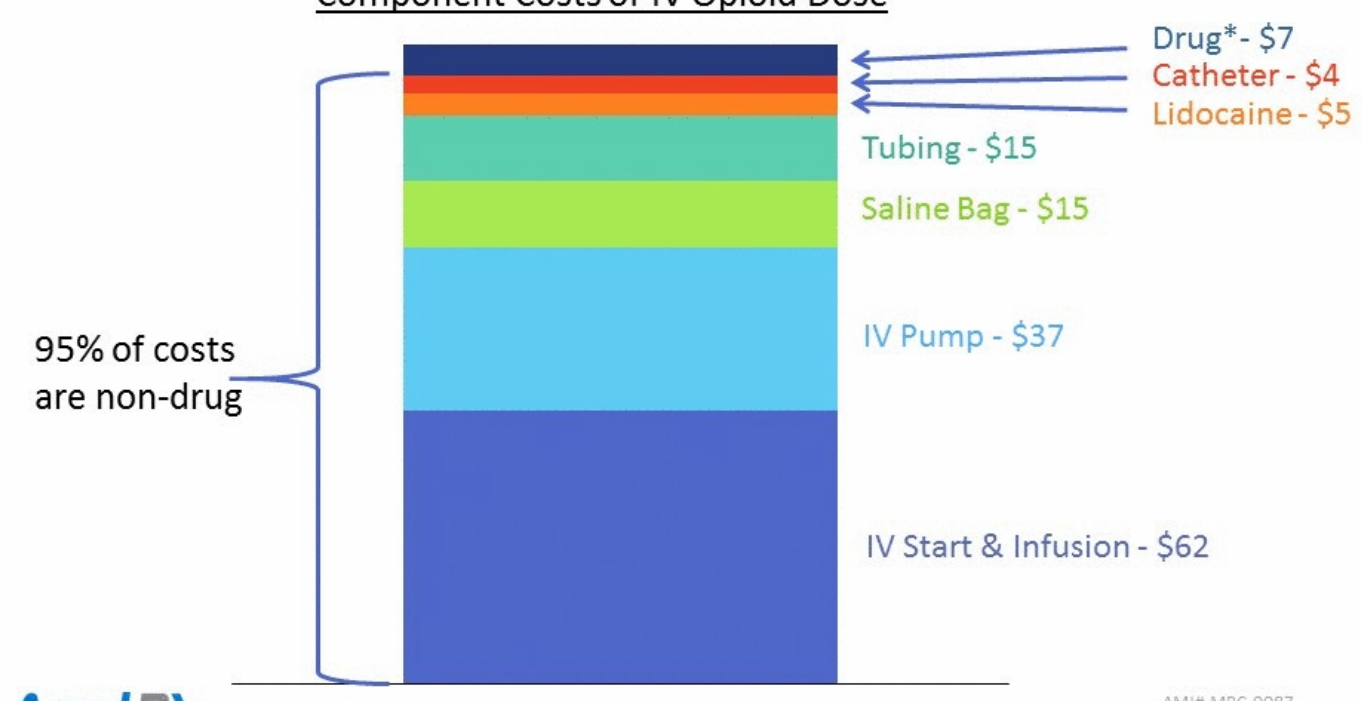
1. *Data on file. In-house market research. Conducted at American College of Emergency Physicians (ACEP) November 2015*

# Cost of Initial IV Opioid Dose in the ED for the Treatment of Acute Pain Exceeds $140 - ISPOR[1]

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[1]Oral presentation at the International Society for Pharmacoeconomic and Outcomes Research Meeting, May 21-25, 2016 in Washington, DC.
*Fentanyl $7, Morphine $6, Hydromorphone $7

# ARX-04 Clinical Studies Completed

*Data From Open-Label Safety Studies Reported in Q3*

## Pivotal Studies – Completed

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

## Safety Studies – Completed

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

# ARX-04 Abdominal Surgery Study: SAP301

*Postoperative Ambulatory Surgery Patients*

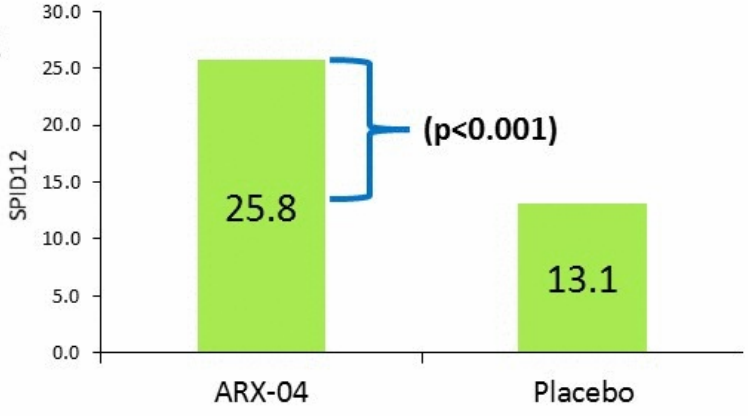
| Surgery Types | Study Details |
| --- | --- |
| ▪ Open Hernioplasty<br>▪ Abdominoplasty<br>▪ Laparoscopic Abdominal Surgery | ▪ Randomized 163 patients<br>▪ Randomized 2:1 active to placebo<br>▪ Completers = 24 hours in the study, extension to 48 hours if needed<br>▪ Primary endpoint: Sum of the pain 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*

- 163 patients randomized 2:1 active to placebo
- Significantly greater SPID12 compared to placebo
- Positive on secondary endpoints
- AE's not different between ARX-04 and placebo
- Typical opioid AEs (nausea, headache, vomiting)

**SPID Over 12 hours**

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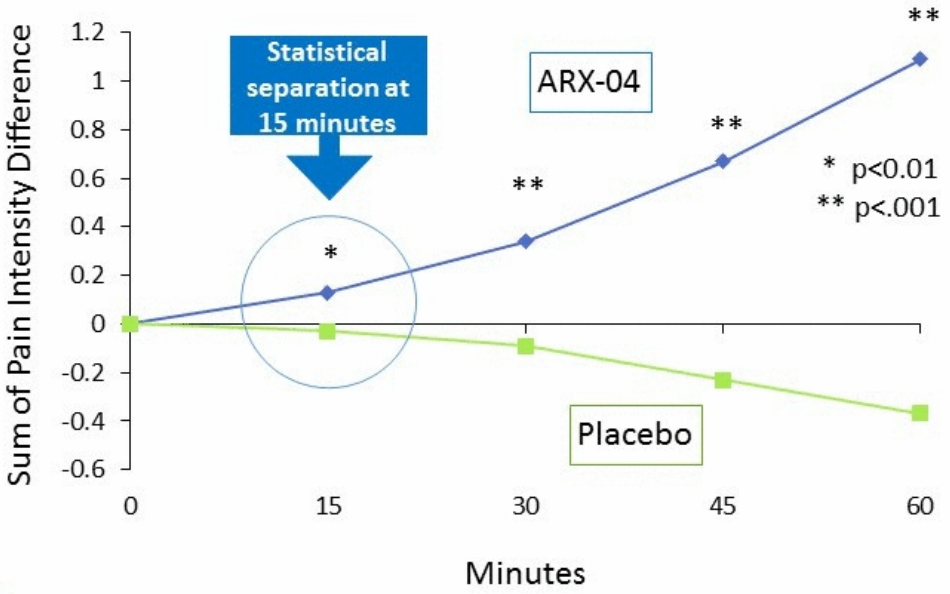
# ARX-04 Abdominal Surgery Study: SAP301

*SPID1 Statistically Better than Placebo after 15 Minutes*

**SPID Over First Hour of Treatment**

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# ARX-04 Emergency Room Study: SAP302

## *Outcome Measures*

### Study sites

- Hennepin County Medical Center, Minneapolis, MN (James Miner, MD)
- Memorial Hermann-Memorial City Medical Center, Houston, TX (Harold Minkowitz, MD)
- Baylor College of Medicine, Ben Taub General Hospital, Houston, TX (Zubaid Rafique, MD)

| Primary Endpoint | Key Secondary Efficacy Endpoints | Safety Endpoints |
|---|---|---|
| ▪ Sum of the pain intensity difference to baseline over the first hour of treatment (SPID1) | ▪ PID assessments<br>▪ Patient and Healthcare Global Assessment<br>▪ Rescue medication<br>▪ Drop-outs - inadequate analgesia | ▪ Adverse Events<br>▪ Vital Signs<br>▪ Six-item Cognitive Screener<br>▪ Concomitant Medications |

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# ARX-04 Emergency Room Study: SAP302

## *Demographics with high baseline pain scores*

| Category | | Category | |
|---|---|---|---|
| Sex, male, % | 61 | BMI, % | |
| Age, years, mean | 42 | < 30kg/$m^2$ | 61 |
| Race, % | | ≥ 30kg/$m^2$ | 39 |
| Caucasian | 59 | ASA Classification, % | |
| African American | 34 | 1 | 61 |
| Native American | 7 | 2 | 33 |
| Ethnicity, % | | 3 | 7 |
| Hispanic/Latino | 16 | Baseline Pain | 8.1/10 |

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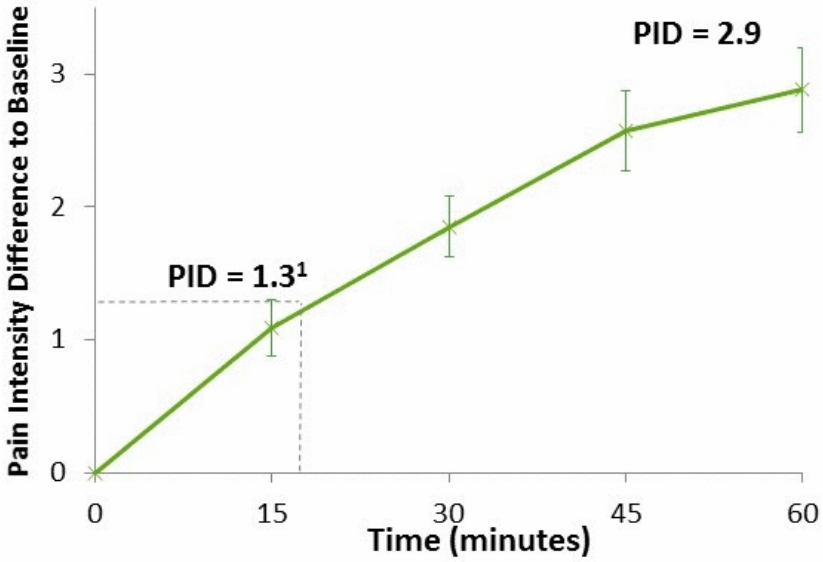
# ARX-04 Emergency Room Study: SAP302

## *Clinically significant pain relief*

- **Over 35% reduction in pain intensity by 60 min**
- **A clinically significant drop in pain intensity when administering 0-10 point numerical rating scale (NRS) to measure pain is 1.3[1]**

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AMI# MRC 0087

1.Bijur, Polly E., et al.. Validation of a Verbally Administered Numerical Rating Scale of Acute Pain four Use in the Emergency Department. Academy Emergency Medicine. 2003;10: 390-392.

# ARX-04 Emergency Room Study: SAP302

*Adverse events (> 2% of patients)*

- **Majority of patients experienced no side effects**
- **Six-Item Screener demonstrated no effect on cognition by ARX-04**

| Adverse Event, n (%) | ARX-04 (30 mcg) n=76 |
|---|---|
| No Adverse Event | 79% |
| Nausea | 9% |
| Somnolence | 5%[1] |
| Vomiting | 4% |
| Oxygen Desaturation | 3%[2] |

1. All 4 patients with somnolence were rated as mild
2. Two patients experienced transient room air oxygen desaturations below 95% (88% and 94% which immediately improved with nasal cannula oxygen)

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# ARX-04 Postoperative Study: SAP303

*Short-stay Postoperative Patients - Single-Arm, Open-Label*

| Patient Types | Study Details |
| --- | --- |
| ▪ Post surgical patients moderate-to-severe pain<br>▪ Age 40 or older<br>▪ Encourage enrollment of patients with comorbidities (renal impairment, liver impairment, etc.) | ▪ ARX-04 dosed no more than every 60 minutes as needed for up to 12 hours<br>▪ Multi-center – Enrolled 140 patients<br>▪ Primary endpoint: Sum of the pain intensity difference to baseline over 12 hours (SPID12) |

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# ARX-04 Postoperative Study: SAP303

## *Demographics with older patients and co-morbidities*

| Category | | Category | |
|---|---|---|---|
| Sex, female, % | 54 | BMI, % | |
| Age, years, mean | 55 | < 30kg/$m^2$ | 56 |
| < 65,% | 73 | ≥ 30kg/$m^2$ | 44 |
| ≥ 65, % | 17 | ASA Classification, % | |
| Race, % | | 1 | 32 |
| Caucasian | 84 | 2 | 52 |
| Hispanic/Latino (ethnicity) | 16 | 3 | 16 |
| African American | 14 | Baseline Hepatic and/or Renal Impairment, % | 29 |
| Asian | 1 | Baseline Pain | 6/10 |
| Native American | 1 | | |

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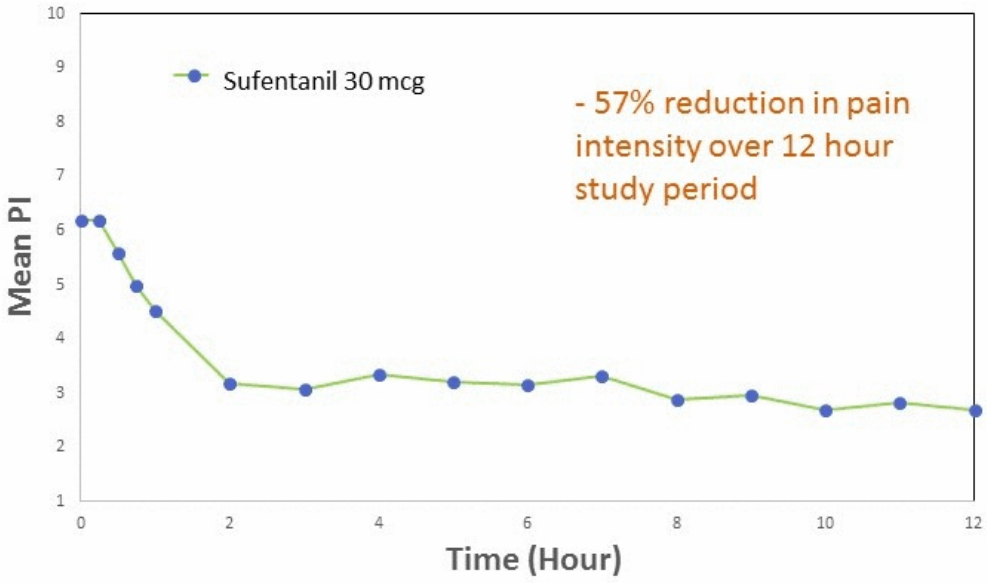
# ARX-04 Postoperative Study: SAP303

## *Mean Pain Intensity*

**Mean Pain Intensity (PI) by Evaluation Time Point: All Enrolled Patients**

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# ARX-04 Postoperative Study: SAP303

*Adverse events (> 2% of patients)*

- **Majority of patients experienced no AEs: 63% overall; 63% aged ≥65 years; 62% with hepatic impairment; 70% with renal impairment**

| All Patients Adverse Event, n (%) | ARX-04 (30 mcg) n=140 |
|---|---|
| No Adverse Event | 63% |
| Nausea | 27% |
| Headache | 6% |
| Dizziness | 4% |
| Pruritus | 3% |
| Hypotension | 2% |
| Oxygen Desaturation | 2%[1] |

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1. Three patients experienced transient room air oxygen desaturations all events were mild, possibly/probably related, and no opioid reversal agent required

# ARX-04 is on track for anticipated NDA submission by year end now that clinical trials are complete

# Zalviso® Overview

- Inpatient Surgeries requiring overnight stays

## Proposed Indication

AcelRx Pharmaceuticals is developing Zalviso sufentanil sublingual tablet system for the management of moderate-to-severe acute pain in adult patients in a hospital setting.

## Dosing

Maximum dose utilized in the studies was 15 mcg.

## Development Status

- Marketed in Europe
- Additional US study anticipated to start 3Q
- NDA resubmission planning in process

# 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 syringe can facilitate drug diversion

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1. Meissner, Hospital Pharmacy 44:312, 2009
2. ISMP: http://www.ismp.org/Newsletters/acutecare/articles/20070222.asp
3. K. New and K. Loya. Health Facility Drug Diversion: Essential Compliance & Auditing Measures. 2013

# Zalviso:

## *Non-invasive 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 IV-Related Infection Risk:** Noninvasive sublingual delivery
- **Less Hampering of Ambulation:** Patient not tethered to IV pole with Zalviso
- **20 minute Dose Lockout**


- **Multiple Anti-Diversion Features**
  - RFID on cartridge provides full inventory tracking of tablets
  - HCP-controlled access, device tethered to bed, anti-diversion alarms

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*http://globalrph.com/pca.htm

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

## Placebo-Controlled Studies

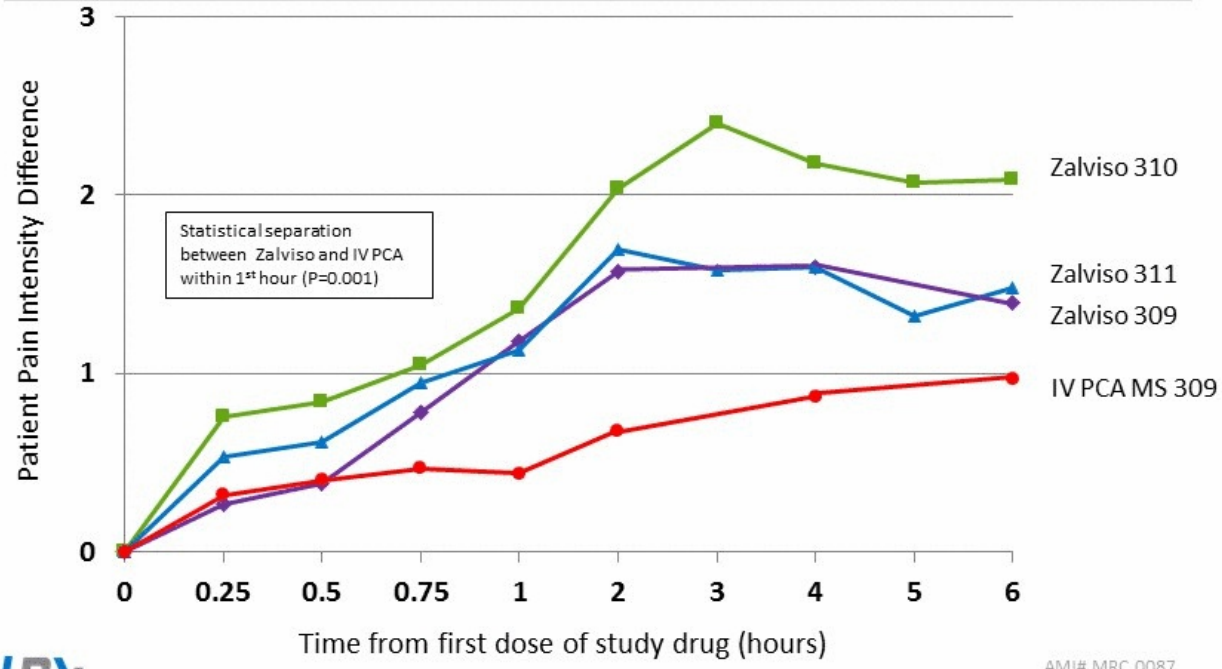
- Study IAP310: postoperative pain after abdominal surgery
- Study IAP311: postoperative pain after total hip or knee replacement surgery

## 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: Studied for Ability to Treat Moderate-to Severe-Acute Pain

**Pain Intensity Difference to Baseline for Phase 3 Studies[1]**

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[1]Presentation at the 2014 American Pain Society Annual Meeting, April 30 – May 3, Tampa, FL.

# Zalviso 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 and revised based on FDA comments
- Plan to enroll ~315 patients
- 24- to 72-hour duration
- Single-arm, open-label, various postsurgical settings
- Multimodal analgesia allowed
- Study will collect device failure rate
- Nurses will actively look for dropped tablets
- clintrials.gov revised to reflect start date of September 2016
- Clinical supplies are being shipped to sites
- Study initiation site visits have started

# ZALVISO

Approved in Europe: First commercial sale by Grunenthal in April 2016

## Collaboration Details

- $50M received to date
- R&D and sales milestones remain
- Royalties from mid teens to mid twenties
- EU royalties and milestones partly sold
- Peak Revenues in EU expected to be $150M*
- Launched in Germany, France, UK, Belgium, Netherlands, Italy


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* Per market forecast study commissioned by ACRX performed by LEK

# 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
  8 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
- 28 issued patents in other territories
- 11 US applications plus 30+ foreign applications in late stage prosecution

AcelRX Pharmaceuticals, Inc.

# Cash on hand at June 30, 2016 > $98M

| | |
|---|---|
| ▪ Cash on hand at June 30, 2016 | $98.8 million |
| ▪ Projected cash balance Dec 31, 2016 | $70-75 million |
| ▪ Outstanding Loan Amount | $21 million |
| ▪ Shares Outstanding | 45 million |
| ▪ Headcount at June 30, 2016 | 39 |

AcelRX Pharmaceuticals, Inc.

# Significant number of key milestones anticipated over the next 18 months

| | Milestone | 2016 | | 2017 | | | |
|---|---|---|---|---|---|---|---|
| ARX-04 | SAP-302 ER study results | August 2016 | | | | | |
| | SAP303 Post-op results | Sept 2016 | | | | | |
| | NDA | | 4Q16 submission | FDA Review | | | 4Q17 PDUFA |
| | MAA | | | 1Q17 submission | | EMA Review | |
| Zalviso | EU launch continues | 3Q16 | 4Q16 | EU expansion | | | |
| | IAP312 Initiation | Sept 2016 | Enrollment and treatment in post-operative patients | | | Prepare NDA | File NDA |

AcelRX Pharmaceuticals, Inc.

AMI# MRC 0087

# Thank you for listening

For more information, visit:
www.acelrx.com

AcelRx
Pharmaceuticals, Inc.

**Exhibit 99.2**

## AcelRx Initiates Phase 3 Study of Zalviso® in Patients with Moderate-to-Severe Acute Post-Operative Pain

**REDWOOD CITY, California, September 27, 2016** – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain, announced today the initiation of the Phase 3 IAP312 study of Zalviso® (sufentanil sublingual tablet system), an investigational product candidate being developed for the management of moderate-to-severe acute pain in adult patients in a hospital setting. IAP312 is a multicenter, open-label study designed at the request of the Division of Anesthesia, Analgesia and Addiction Products of the U.S. Food and Drug Administration (FDA). The IAP312 study will enroll approximately 315 hospitalized, post-operative patients who will use Zalviso to self-administer sublingually tablets containing 15 micrograms of sufentanil as often as once every 20 minutes for 24-to-72 hours to manage their moderate-to-severe acute pain. In addition to safety and efficacy measures, IAP312 will collect information on device usability, including any incidence of Zalviso's failure to dispense medication as well as the incidence of misplaced or dropped tablets.

Zalviso is a preprogrammed, patient-controlled analgesia (PCA) system designed to dispense a non-invasive sublingual formulation of sufentanil. Zalviso is currently approved by the European Commission and is marketed by Grunenthal GmbH, AcelRx's European commercial partner. Based on the Company's experience in previous clinical trials and in Europe, AcelRx has incorporated certain software and hardware revisions to improve device usability and optimize system functionalities. AcelRx has worked with its commercial supply chain partners to produce the clinical materials for use in the IAP312 study.

"Anecdotal experience from Grunenthal's Zalviso launch that began in April has been favorable, with patients and healthcare workers providing positive feedback on the pain control offered by sublingual sufentanil," commented Howie Rosen, AcelRx's chief executive officer. "We look forward to conducting the IAP312 study and submitting the findings to the FDA so that they may consider the product for approval here in the U.S. We will provide an update on study duration once we are further along with enrollment."

Three Phase 3 studies for Zalviso in a total of 768 patients have been completed to date: IAP309, IAP310 and IAP311, detailed information for which may be found on www.clinicaltrials.gov. In brief, IAP309 was a Phase 3 open-label, active comparator study, in which Zalviso was shown to be non-inferior ($p<0.001$), as well as superior ($p=0.007$), to intravenous (IV) PCA morphine based on the primary endpoint of Patient Global Assessment method of pain control comparison over the 48-hour trial period (PGA48). IAP310 and IAP311 were Phase 3 double-blind, placebo-controlled studies in which patients treated with Zalviso to manage their post-operative pain reported a greater summed pain intensity difference to baseline over 48 hours (SPID48, the primary endpoint) compared to placebo-treated patients ($p=0.001$ and $p<0.001$, respectively). The most common adverse events experienced by patients using Zalviso in these clinical studies were nausea, pyrexia (fever) and vomiting.

“We designed Zalviso to have characteristics that would offer patients and healthcare providers benefits over IV morphine, the current standard of care for the treatment of moderate-to-severe acute pain in hospitalized patients,” concluded Dr. Pamela Palmer, AcelRx’s co-founder and chief medical officer. “The initiation of IAP312 is an important milestone, as it represents what we expect to be the last step in the Zalviso clinical development program, bringing a product that we believe can offer patients a new option for treating their moderate-to-severe acute pain, closer to market.”

**About AcelRx Pharmaceuticals, Inc.**
AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain. The Company's late-stage pipeline includes ARX-04 (sufentanil sublingual tablet, 30 mcg), designed for the treatment of moderate-to-severe acute pain in medically supervised settings; and Zalviso® (sufentanil sublingual tablet system), designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting. Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. Zalviso is approved in the EU as well as Norway, Iceland, and Liechtenstein and is investigational and in late-stage development in the U.S. Grunenthal Group holds the rights for Zalviso in Europe and Australia, while AcelRx retains all other world-wide rights.

For additional information about AcelRx's clinical programs, please visit www.acelrx.com.

***Forward Looking Statements***
*This press release 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, ARX-04 (sufentanil sublingual tablet, 30 mcg) and Zalviso® (sufentanil sublingual tablet system), including the ARX-04 clinical trial results; anticipated submission of the New Drug Application (NDA) for ARX-04 to the U.S. Food and Drug Administration (FDA); AcelRx's pathway forward towards gaining approval of Zalviso in the U.S.; the anticipated timing, design and results of IAP312 clinical trial for Zalviso; anticipated resubmission of the Zalviso NDA to the FDA; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities for ARX-04 and Zalviso. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements, and as a result of these risks and uncertainties, which include, without limitation, risks related to AcelRx Pharmaceuticals' ARX-04 development program, including anticipated submission of the ARX-04 NDA and the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 studies of ARX-04; AcelRx's ability to successfully execute the pathway towards a resubmission of the Zalviso NDA, including the successful completion of the IAP312 clinical study for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates including ARX-04 in the United States and Europe, and Zalviso in the United States; the uncertain clinical development process, including adverse events; the risk that planned clinical trials, including IAP312 for Zalviso, may not have an effective clinical design, enroll a sufficient number of patients, or be completed on schedule, if at all; the success, cost and timing of all development activities and clinical trials, including the IAP312 clinical study for Zalviso; 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 July 29, 2016. 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.*

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