

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): July 6, 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))
-

Item 7.01. Regulation FD Disclosure.

AcelRx Pharmaceuticals, Inc. (the “Company” or “AcelRx”) will participate in various meetings with securities analysts and investors during the Cantor Fitzgerald 2nd Annual Healthcare Conference on July 12, 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.

On July 6, 2016, the start date for the IAP312 study was revised to September 2016 on clintrials.gov. The Company has finalized certain modifications to the Zalviso device and pending receipt of the devices from the manufacturer, the Company intends to initiate the IAP312 study in September 2016. The start date for the study may be delayed if the devices received from the manufacturer do not pass final quality checks and certain release specifications.

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 July 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: July 7, 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 July 2016"

AcelRx Pharmaceuticals

Corporate Presentation
July 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 Phase 3 SAP302 and SAP303 studies for ARX-04; 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 New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA; and the therapeutic and commercial potential of AcelRx's product candidates, including 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 limitations, risks related to AcelRx Pharmaceuticals' ability to complete Phase 3 clinical development 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; AcelRx's ability to receive regulatory approval 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 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, including the additional clinical trial for Zalviso, IAP312, and the Phase 3 ARX-04 SAP302 and SAP303 trials; the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 SAP301 study of ARX-04; 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 May 2, 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 \$100 million in cash
Two US Phase 3 products**

ARX-04



- Emergencies
- Short-stay Surgeries and Procedures

Zalviso®



- Inpatient Surgeries
- Approved in EU

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
- 2016 American Pain Society Guidelines for managing postoperative pain include the use of opioids³
- 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 ER⁵
- AcelRx products are for short-term use and only to be used in hospitals or administered by trained medical professionals

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

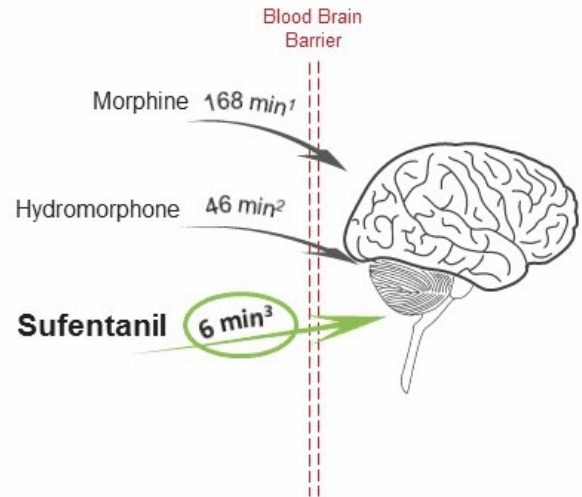
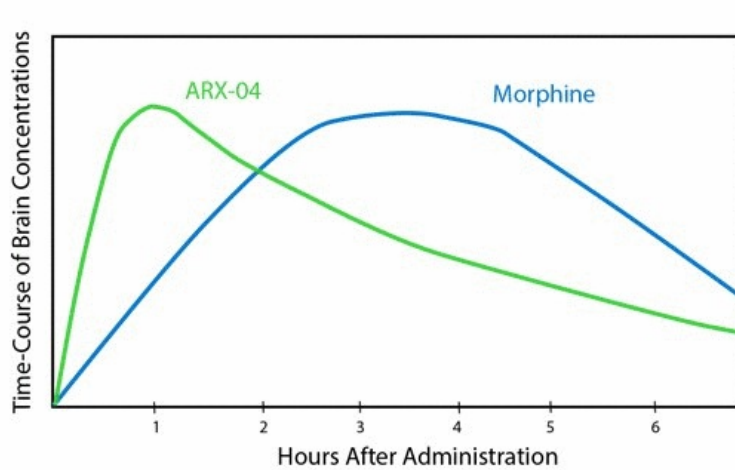
Unmet Needs in Treatment of Moderate-to-Severe Acute Pain

	Emergencies	Short-Stay Surgeries/Procedures	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 = delayed CNS uptake/slow off; active metabolites can cause prolonged opioid effects/side effects • IV fentanyl = rapidly absorbed/short-acting requiring frequent redosing 		

Sufentanil: Sublingual Route = Rapid Brain Penetration

*Sufentanil Penetrates CNS Due to Lipophilicity (vskeo)

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



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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

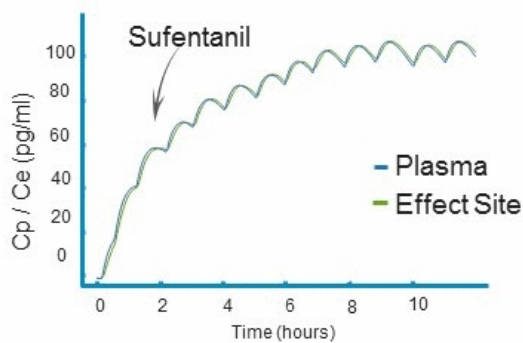
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Sublingual Sufentanil

Potential for Real-Time Tracking Between Dosing & Effect

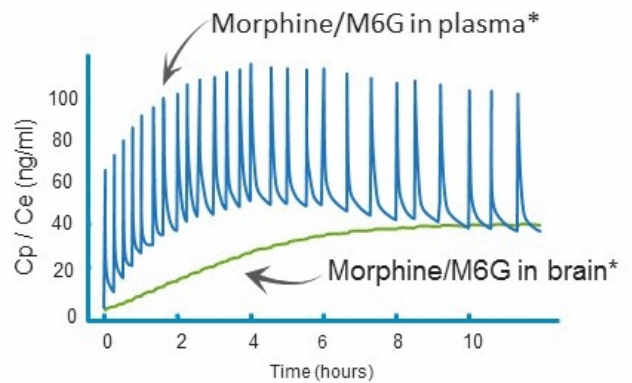
Sublingual sufentanil dosing closely matched with effect

Sublingual Sufentanil Plasma vs. Brain Concentrations²



Brain levels delayed with IV morphine dosing¹

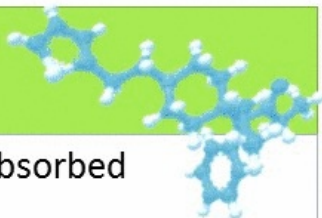
IV Morphine Plasma vs. Brain Concentrations



* 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 index¹** to maximize analgesia while minimizing side effects
- **Low GI bioavailability** minimizes delayed effect of swallowed drug

Tablet

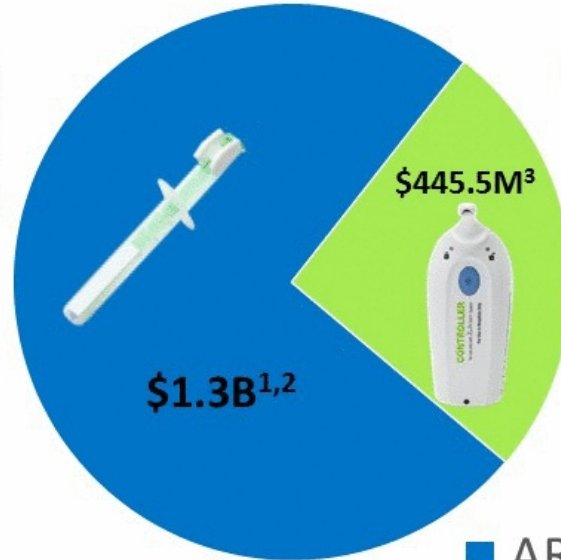


- **Small size** dissolves in minutes
- **Minimizes saliva production** to limit swallowed drug and avoid delayed drug uptake from GI
- **Bioadhesive** to keep in place under tongue
- **Discrete dosing unit** reduces errors of continuous dosing

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

Emergency Departments
Ambulatory Surgery Centers
Short-stay Surgeries
Interventional Procedures



Inpatient Postoperative

■ ARX-04 ■ Zalviso



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 Development

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.

Development Status

- SAP302 in the emergency room – LPO June 2016
 - SAP303 in postoperative patients – LPO June 2016
 - NDA submission anticipated in Q4 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 = EMS/ED

- 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 ED⁵



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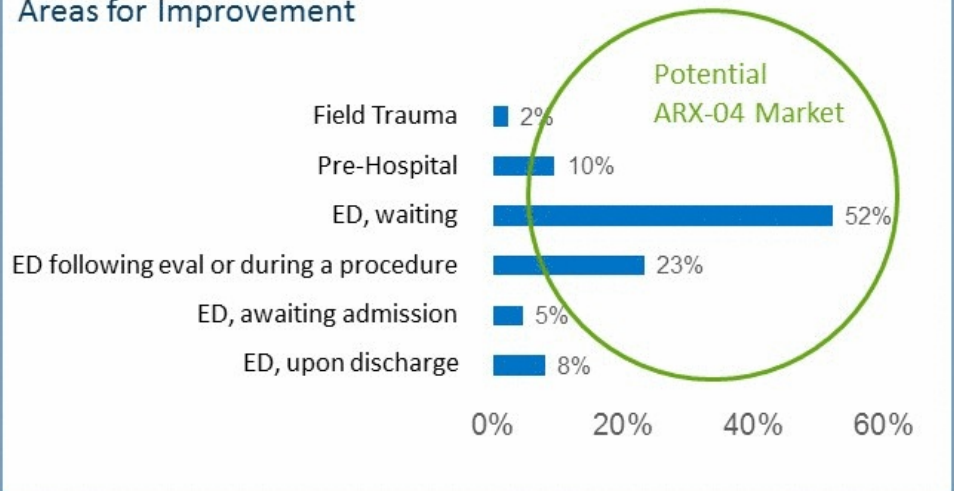
1. US Defense Health Board. *Pre Hospital Use of Ketamine in Battlefield Analgesia in Tactical Combat Casualty Care Pain Guidelines*. 2012 Mar <http://goo.gl/w2rFRO>
2. de Moya, M. A. *Shock*. In Merck manual online, professional version. Retrieved from <http://goo.gl/lBXpa2>
3. Byers, PA; Counselman, FL. *Appropriate Analgesic Use in the Emergency Department*. *Emerg Med* 2014;46(5): 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

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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



Cost of Initial IV Opioid Dose in the ED for the Treatment of Acute Pain Exceeds \$140 - ISPOR¹

Title

- *Cost of Delivering Intravenous Opioid Analgesia in Emergency Departments (EDs) in the U.S.*

Study Design

- Descriptive analyses, sponsored by AcelRx and using Premier database (2013-2014) of > 600 US hospital EDs for cost of starting an IV and delivering an initial dose of IV opioid
- Average costs of each component were aggregated for total costs; direct acquisition and indirect cost (labor, pharmacy, etc.) were also included

Results

- Based on an analysis of over 7 million patients, the cost ranges from \$143 for morphine to \$145 for fentanyl

Conclusion

- The cost of materials and labor to establish an IV line to administer an opioid is almost 95% of the total cost, which is a substantial considering the number of ED visits annually

ARX-04 Clinical Studies Completed

Data From Open-Label Safety Studies Expected Q3

Pivotal Studies - Completed

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

Safety Studies – Enrollment and LPO Completed

- SAP302: Emergency Room Study
- 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

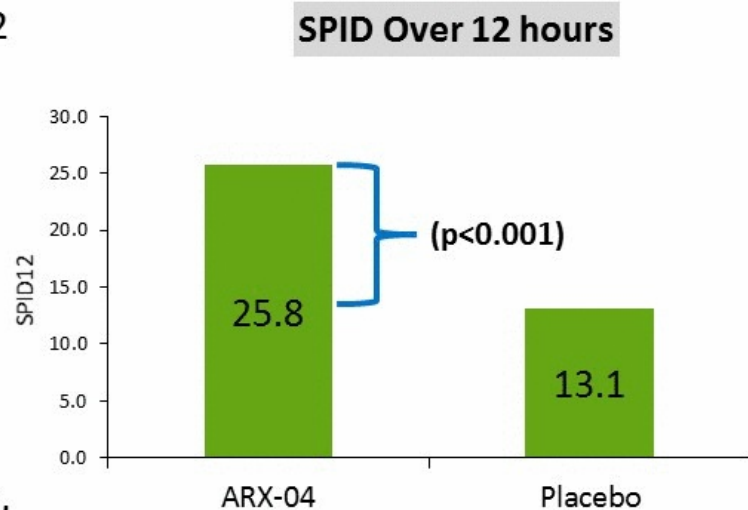
Study Details

- 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

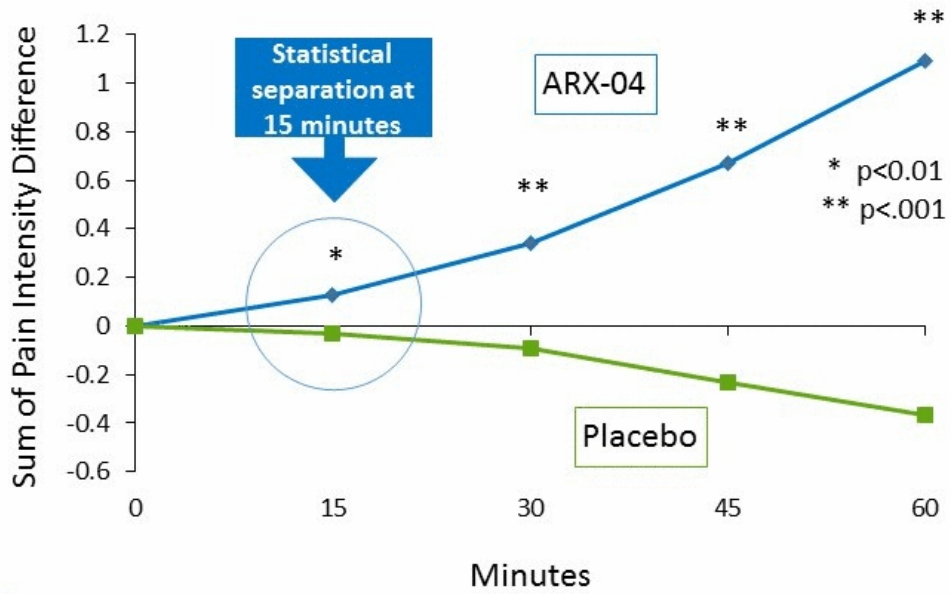
- Significantly greater SPID12 compared to placebo
- ARX-04 also positive on secondary endpoints
- No difference in AE's between ARX-04 and placebo
- AE's typical of opioid therapy (nausea, headache, vomiting)



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

Emergency Room Patients

ER Patient Types

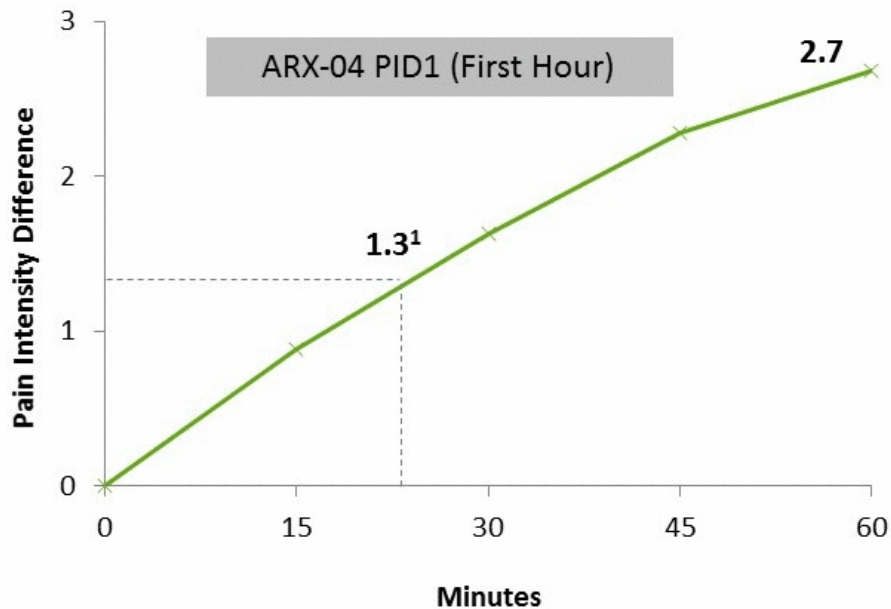
- Patients presenting to the Emergency Room with trauma or injury associated with moderate-to-severe pain
- Exclusions: Pregnant, opioid tolerant, oxygen dependent

Study Details

- Single arm open label
- 40 patients single and up to 60 patients multiple dose
- Primary endpoint: Sum of the pain intensity difference to baseline over the first hour (SPID1)
- Six-item cognition screener

ARX-04 ER Study: SAP302 – Interim Results

40 patients - Single-Arm, Open-Label: PID1



- 1.3 has been identified as the minimum clinically significant difference in pain when administering 0-10 point numerical rating scale (NRS) to measure pain¹

ARX-04 ER Study: SAP302 – Interim Results

Single-Arm, Open-Label: Adverse Events

Adverse Event	Total n=40 n (%)
No Adverse Event	34 (85%)
Nausea	2 (5%)
Somnolence	2 (5%)
Feeling Hot	1 (2.5%)
Dizziness	1 (2.5%)
Disorientation	1 (2.5%)
Facial Hypoesthesia	1 (2.5%)
Pruritus	1 (2.5%)
Vomiting	0 (0%)

ARX-04 Postoperative Study: SAP303

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

Patient Types

- Post surgical patients moderate-to-severe pain
- Age 40 or older
- Encourage enrollment of patients with comorbidities (renal impairment, liver impairment, etc.)

Study Details

- ARX-04 dosed once every 60 minutes as needed for up to 12 hours
- Multi-center – Enroll at least 100 patients
- Primary endpoint: Sum of the pain intensity difference to baseline over the first 12 hours (SPID12)

Zalviso[®] Overview



- Inpatient Surgeries requiring overnight stays

Proposed Development

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.

Development Status

- Approved in Europe
 - Additional US study planned
 - 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

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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 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



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

Placebo-Controlled Studies

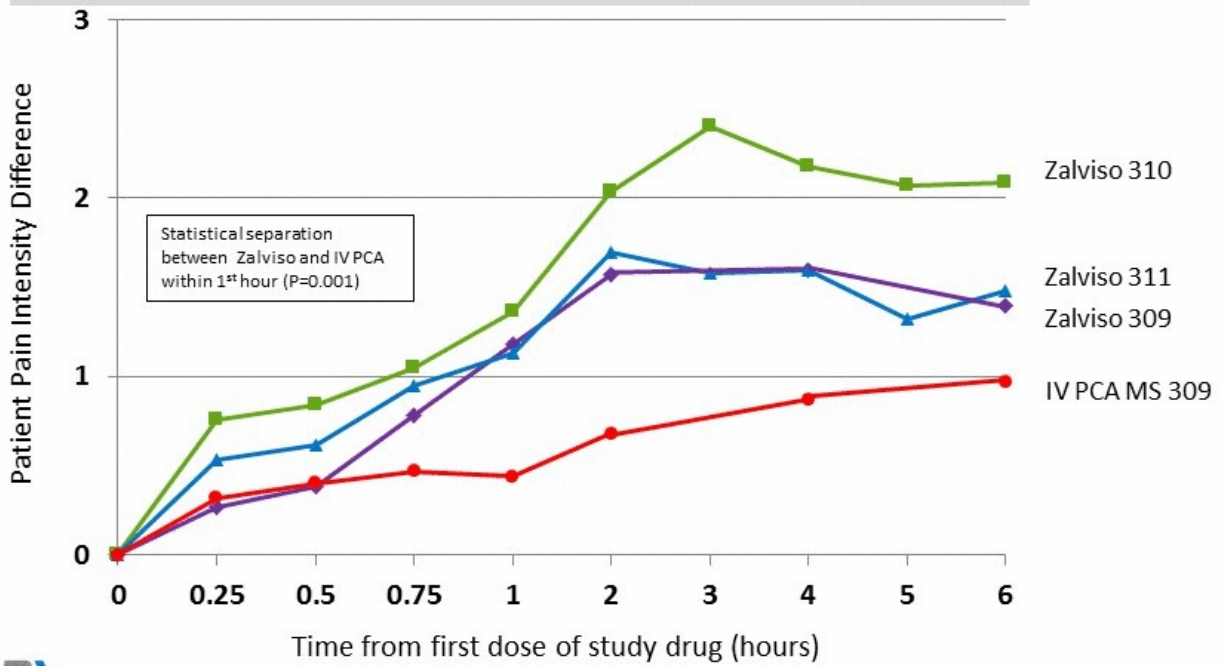
- Study IAP310: postoperative pain after abdominal surgery
- Study IAP311: postoperative pain after total hip or knee replacement surgery

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 Studies¹



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
- Study will collect device failure rate
- Nurses will actively look for dropped tablets
- Multimodal analgesia allowed
- Clinical supplies being prepared and tested
- clinicaltrials.gov revised to reflect start date of September 2016
- Study initiation subject to receipt and approval of final clinical supplies

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
- Next launch countries: Belgium, Netherlands, Ireland, Italy, Portugal



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* Per market forecast study commissioned by ACRX performed by LEK

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

Cash on hand at March 31, 2016 > \$100M

▪ Cash on hand at March 31, 2016	\$107 million
▪ Projected cash balance Dec 31, 2016	\$70-75 million
▪ Outstanding Loan Amount	\$21 million
▪ Shares Outstanding	45 million
▪ Headcount at March 31, 2016	41

Significant number of data readouts and regulatory milestones anticipated over the next 18 months

	Milestone	2016		2017			
ARX-04	SAP-302 ER study results	3Q16					
	SAP303 Post-op results	3Q16					
	NDA		4Q16 submission	FDA Review			4Q17 PDUFA
	MAA			1Q17 submission	EMA Review		
Zalviso	EU launch continues	3Q16	4Q16	EU expansion			
	IAP312 Initiation (TBD)						

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Thank you for listening

For more information, visit:
www.aceirx.com

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