

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 25, 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 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.ace1rx.com.

The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 to this Current Report shall be deemed to be “furnished” and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act. The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission under the Securities Act or the Exchange Act made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Slide presentation entitled, “AcelRx Pharmaceuticals, Inc. ARX-04, Sublingual Sufentanil 30 mcg Update”

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 25, 2016

ACELRX PHARMACEUTICALS, INC.

By: /s/ Jane Wright-Mitchell

Jane Wright-Mitchell

Chief Financial Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Slide presentation entitled, "AcelRx Pharmaceuticals, Inc. ARX-04, Sublingual Sufentanil 30 mcg Update"

AceRx Pharmaceuticals Inc.

*ARX-04, Sublingual Sufentanil 30 mcg
Update*

AceRx
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; timing and completion of SAP302, timing for initiation of IAP312 for Zalviso and SAP303 studies for ARX-04; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the United States; and anticipated resubmission of the Zalviso NDA to the FDA and potential market and market size for AcelRx' product candidates, including Zalviso and ARX-04.

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 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 ambulatory surgery study of ARX-04 (SAP301); its ability to complete Phase 3 clinical development of ARX-04; 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; the market potential for its product candidates; the accuracy of AcelRx's estimates regarding market size and expectations 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.

Agenda

Introductions

Tim Morris, CFO

Clinical Update

- SAP302 (Emergency Room Study) interim results
- SAP302 (Emergency Room Study) extension
- SAP303 (Postoperative Study) clinical study design
- ARX-04 Regulatory Timeline

Jon Cole, MD

Jon Cole, MD

Brenda Yvette Lemus, MD

Brenda Yvette Lemus, MD

Commercial Update

- Emergency Room Personnel survey results
- U.S. Payer research to date
- Questions & Answers

Gina Ford, VP Commercial

Gina Ford, VP Commercial

All

Presenters

- **Jon B. Cole, MD**
 - Medical Director of Minnesota Poison Control System
 - Faculty Emergency Physician and Medical Toxicologist, Chair of Pharmacy and Therapeutics Committee, Hennepin County Medical Center
 - Associate Professor of Emergency Medicine, University of Minnesota Medical School
- **Brenda Yvette Lemus, MD**
 - Sr. Director, Medical Affairs (Field) at AcelRx Pharmaceuticals Inc.
- **Gina Ford, RPh**
 - VP of Commercial Strategy at AcelRx Pharmaceuticals Inc.

ARX-04 Summary



Potential Settings for Use

- Battlefield/EMS/Pre-hospital
- ER Departments
- Ambulatory Surgery Centers
- Short-Stay Surgeries
- Interventional Procedures

Proposed Development

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

Development Status

- Study SAP302 ongoing in the ER
- Study SAP303 to be initiated in postoperative patients Q1 2016
- NDA submission anticipated in 2H 2016

ARX-04, Sublingual Sufentanil 30 mcg

Clinical Update

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Department of Defense Provides Support for Treating Acute 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 the management of 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/w2rfR0>

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

MRC0045 12FEB2016

Current Therapies for the Management of Acute Pain in the Emergency Settings

IV morphine

- Delayed CNS penetration resulting in poor analgesic onset and slow offset which can delay discharge
- Active metabolite morphine-6-glucuronide can cause delayed side effects¹

IV hydromorphone

- Slightly more rapid onset than morphine but known for delayed and prolonged side effects (e.g., sedation, respiratory depression)¹

IV fentanyl

- Known brain penetration results in rapid onset of analgesia but alpha distribution of this lipophilic drug (1.7 minutes) results in quick offset and requires frequent re-dosing to maintain analgesia^{2,3}

IV/IM Ketamine

- Dissociative agent used in the ED over the last 2 decades for procedural sedation and analgesia.
- Contraindicated for infants and schizophrenia; not recommended for adults with cardiac disease, hypertension, central nervous system concerns, thyroid disorder or those at risk for laryngospasm. High correlation of vomiting with IM route⁴

MDI Methoxyflurane

- Handheld inhaler used for self-administration of the non-opioid pain reliever methoxyflurane. Contraindicated for anesthesia but approved in Australia and U.K for analgesia. Maximum recommended daily dose is 6 milliliters, due to risk of nephrotoxicity. Contraindicated in patients with respiratory depression, renal impairment, head injury or cardiac instability.⁵

1. Löttsch J. *J Pain Symptom Manage* 2005; 29(5 Suppl):S90-S103.

2. Scott JC, Cooke JE, Stanski DR. *Anesthesiol* 1991; 74:34-42.

3. Shafer, S and Varvel, J. *Anesthesiol* 1991; 74:53-63

4. Green, S, et al. Clinical Practice Guideline for Emergency Department Ketamine Dissociative Sedation: 2011 Update. *Annals of Emergency Medicine*. 2001; 57:449-461

5. Penthrax (Methoxyflurane) inhalation. Product information

ARX-04 Emergency Room Study: SAP302

Single-Arm, Open-Label

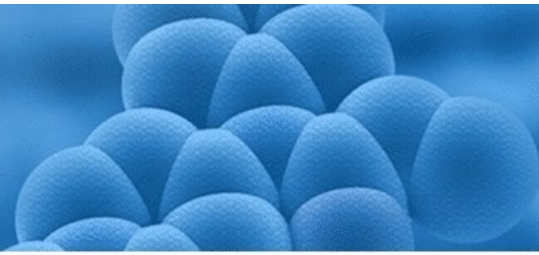
Study Design and Interim Results

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ARX-04 ER Study: SAP302

Single-Arm, Open-Label



Patient Types

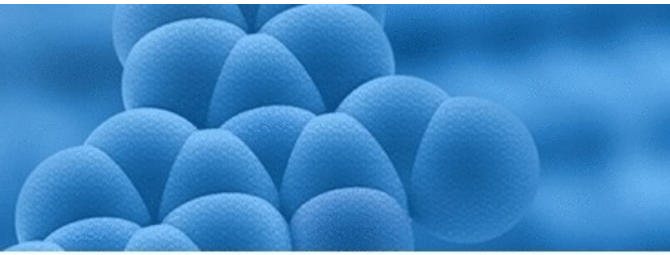
- Patients 18 years and older, who present to the ER with moderate-to-severe acute pain due to obvious trauma or injury evident on physical examination.
- Injuries included contusions, lacerations, muscular tenderness and limited ROM, extremity swelling, abrasions, mandible fracture.

Study Details

- 40 patients
- Multicenter, Single-Arm, Open-Label
- Completers = if they complete the study through 1 hour in this 2 hour study
- **Primary endpoint:** Sum of the pain intensity difference to baseline over the first 1 hour (SPID1) after receiving ARX-04

ARX-04 ER Study: SAP302

Single-Arm, Open-Label



Study Exclusions	Secondary Efficacy Endpoints	Key Safety Endpoints
<ul style="list-style-type: none">▪ Pregnant▪ Opioid-tolerant<ul style="list-style-type: none">– (>15 mg oral morphine equivalent daily)▪ Dependent on supplemental oxygen	<ul style="list-style-type: none">▪ TOTPAR1▪ SPID2▪ TOTPAR2▪ Proportion of patients requiring rescue medication▪ HPGA/PGA▪ Pain intensity (PI)▪ Pain intensity difference (PID)▪ Pain relief (PR)	<ul style="list-style-type: none">▪ Six-item Screener<ul style="list-style-type: none">– (cognitive impairment test: pre- and post-dosing)▪ Adverse Events▪ Vital Signs

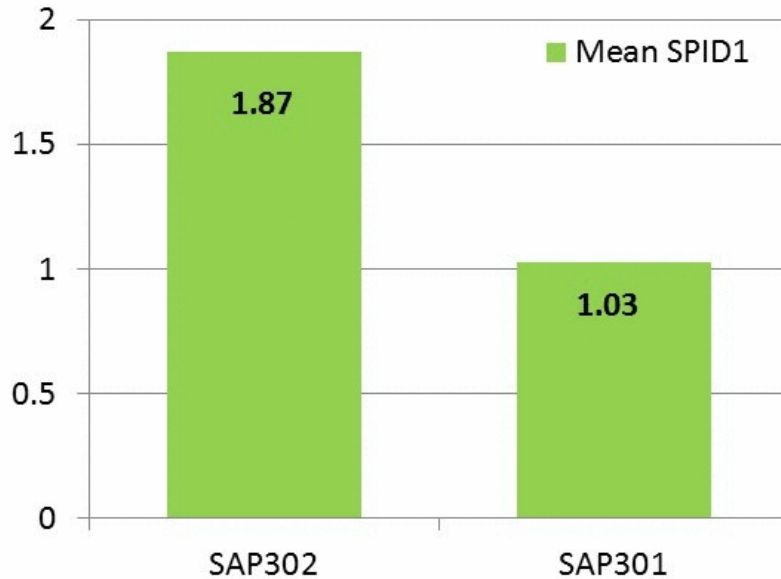
ARX-04 ER Study: SAP302 – Interim Results

Single-Arm, Open-Label: Demographics

Demographics	Results
Sex, female, %	52.5
Age, years, mean (range)	42.4 (20-77)
BMI, mean (range)	32.2 (19.7-59.4)
Race/ethnicity, %	
Caucasian	57.5
Am. Indian	7.5
African American	35.0
Asians & other	0.0
Pain Intensity Baseline, mean (0-10 scale)	8.5

ARX-04 ER Study: SAP302 – Interim Results

A Comparison to SAP301



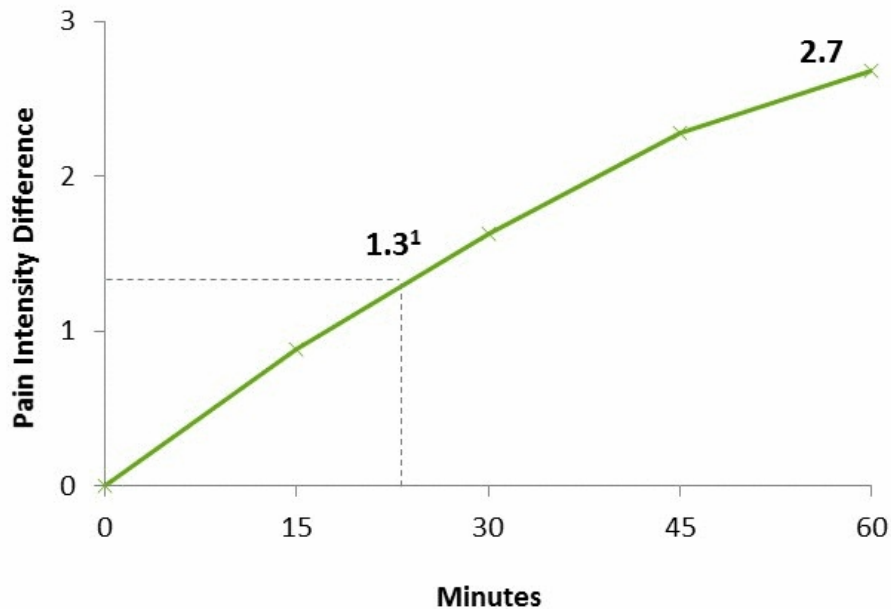
Comparison of Results:

- SAP301 (abdominal surgery study)
- SAP302 (emergency room study)

- Both studies demonstrate improvement in Summed Pain Intensity Difference over 1 hour (SPID1)

ARX-04 ER Study: SAP302 – Interim Results

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: Six-Item-Screener Cognitive Test

- DoD requested cognitive test before and after dosing of ARX-04
- Impaired cognitive skills a concern with other field-based analgesics used in the military (e.g., ketamine).
- Ketamine has been found to induce acute and severe impairments of working, episodic and semantic memory as well as psychotogenic and dissociative effects.¹

ARX-04 ER Study: SAP302 – Interim Results

Single-Arm, Open-Label: Six-Item-Screener Cognitive Test

- The SIS is a test used to detect cognitive dysfunction. It evaluates recall and orientation.
- Each correct response is awarded one-point. Two or more errors are considered high-risk for cognitive impairment.
- SIS results SAP302 for ARX-04:
 - pre-dose score: 5.73 out of 6 correct answers
 - 1-hr post-dose score: 5.90 out of 6 correct answers

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 ER Study: SAP302 – Interim Results

Single-Arm, Open-Label

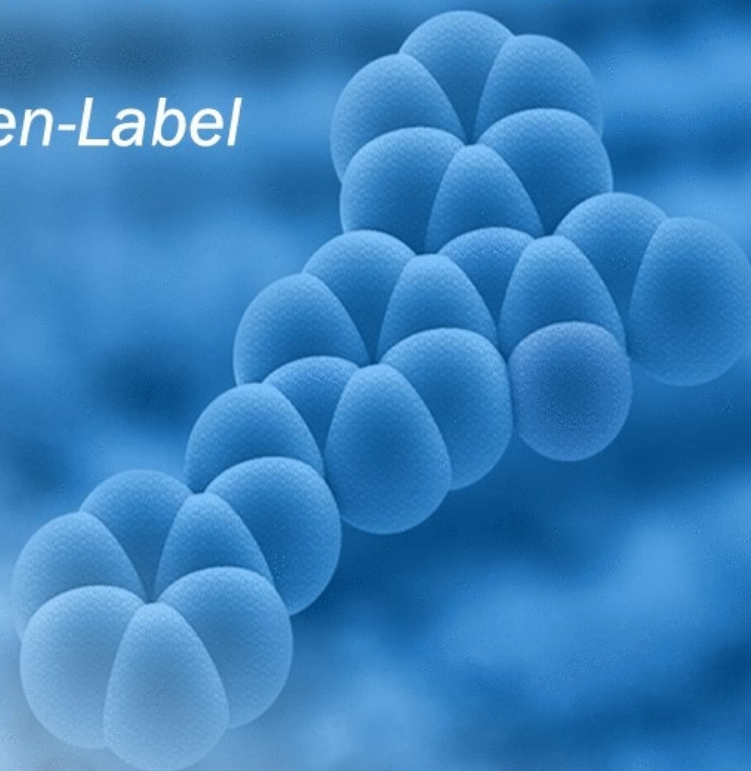
- Reduction in Pain Intensity (mean drop of 2.7 on a 0-10 scale) occurs within first hour
- Only 1 patient had an early termination within the 1st hour of study due to inadequate analgesia
- Cognitive test (Six-Item Screener) shows no cognitive impairment caused by ARX-04
- No serious adverse events (SAE) or AE causing early termination
- Low frequency of AE's overall - however, only 1 dose administered. Most common AE's were nausea and somnolence.

ARX-04 Emergency Room Study: SAP302

Single-Arm, Open-Label

Expanded Design

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ARX-04 ER Study: SAP302

Single-Arm, Open-Label: Expanded Design

Patient Types

- Patients 18 years and older, who present to the ER with moderate-to-severe acute pain due to obvious trauma or injury evident on physical examination.

Study Details

- 120 patients
- Multicenter, Single-Arm, Open-Label
- 5 hour Study
- **Primary endpoint:** Sum of the pain intensity difference to baseline over the first 1 hour (SPID1) after receiving ARX-04
- **May receive up to 3 additional doses, no more frequently than once every 60 min, as needed for pain. Patients should remain in the ER for observation for 1 hour after the last dose has been administered, or for up to 5 hours.**

ARX-04 Post-operative Study:
SAP303

*Single-Arm, Open-Label in Short-Stay
Postoperative Patients*

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ARX-04 Post-operative Study: SAP303

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

Patient Types

- Up to 170 post-operative patients (40 years or older) will be enrolled after surgery in order to ensure that at least 150 patients will receive sufentanil sublingual tablets 30 mcg to provide safety and efficacy data for analysis.

Study Details

- At least 150 patients
- Multicenter (8-10), Single-Arm, Open-Label
- 12 hour Study
- **Primary endpoint:** Sum of the pain intensity difference to baseline over the 12 hour study period (SPID12)
- Patients may receive additional doses of sublingual tablet 30 mcg PRN pain, but no more frequently than every 60 minutes.

ARX-04 Post-operative Study: SAP303

Single-Arm, Open-Label in Short-Stay Postoperative Patients

Secondary Efficacy Endpoints

- Time-weighted summed pain intensity difference (SPID) over the first hour of the study period (SPID1)
- Total pain relief (TOTPAR) over the first hour study period (TOTPAR1)
- Total pain relief (TOTPAR) over the 12-hour study period (TOTPAR12)
- SPID up to each evaluation time point
- TOTPAR up to each evaluation time point
- Pain intensity (PI) at each evaluation time point
- Pain intensity difference (PID) at each evaluation time point
- Pain relief (PR) at each evaluation time point
- Pain relief intensity difference (PRID) at each evaluation time point. The PRID is sum of PR and PID.

ARX-04 Post-operative Study: SAP303

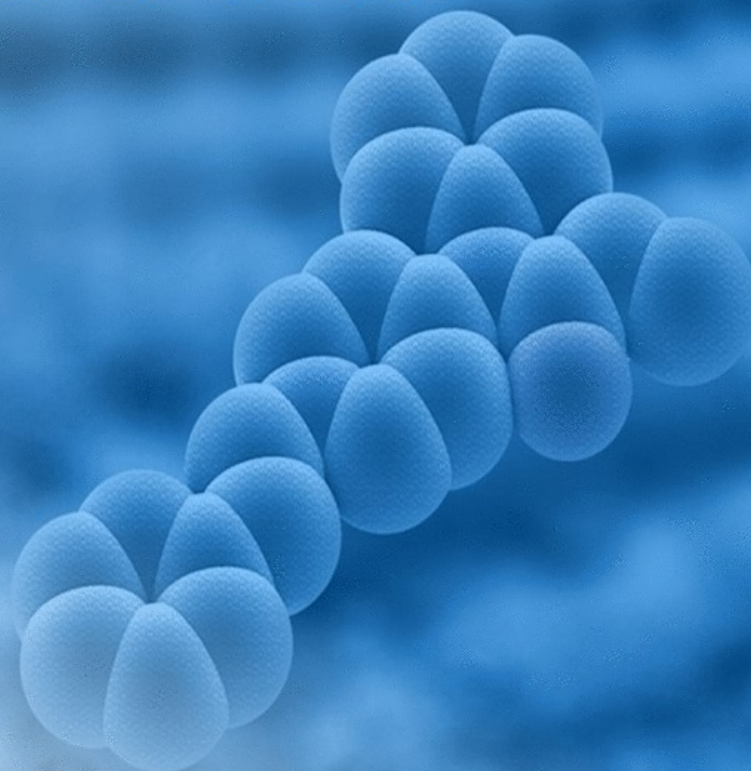
Single-Arm, Open-Label in Short-Stay Postoperative Patients

Secondary Efficacy Endpoints

- Proportion of patients who terminate from the study due to inadequate analgesia
- Proportion of patients requiring rescue medication due to inadequate analgesia
- Proportion of patients and healthcare professionals who responded to the global assessments as “excellent” or “good”
- Proportion of patients and healthcare professionals who responded in each category of the global assessments
- Total number of doses of study medication used
- Mean duration of inter-dosing interval
- Time to first use of rescue medication
- Total number of doses of rescue medication used
- Plasma sufentanil levels of subgroups defined by age, gender, body-mass index, renal and liver function

ARX-04 Publications Plan

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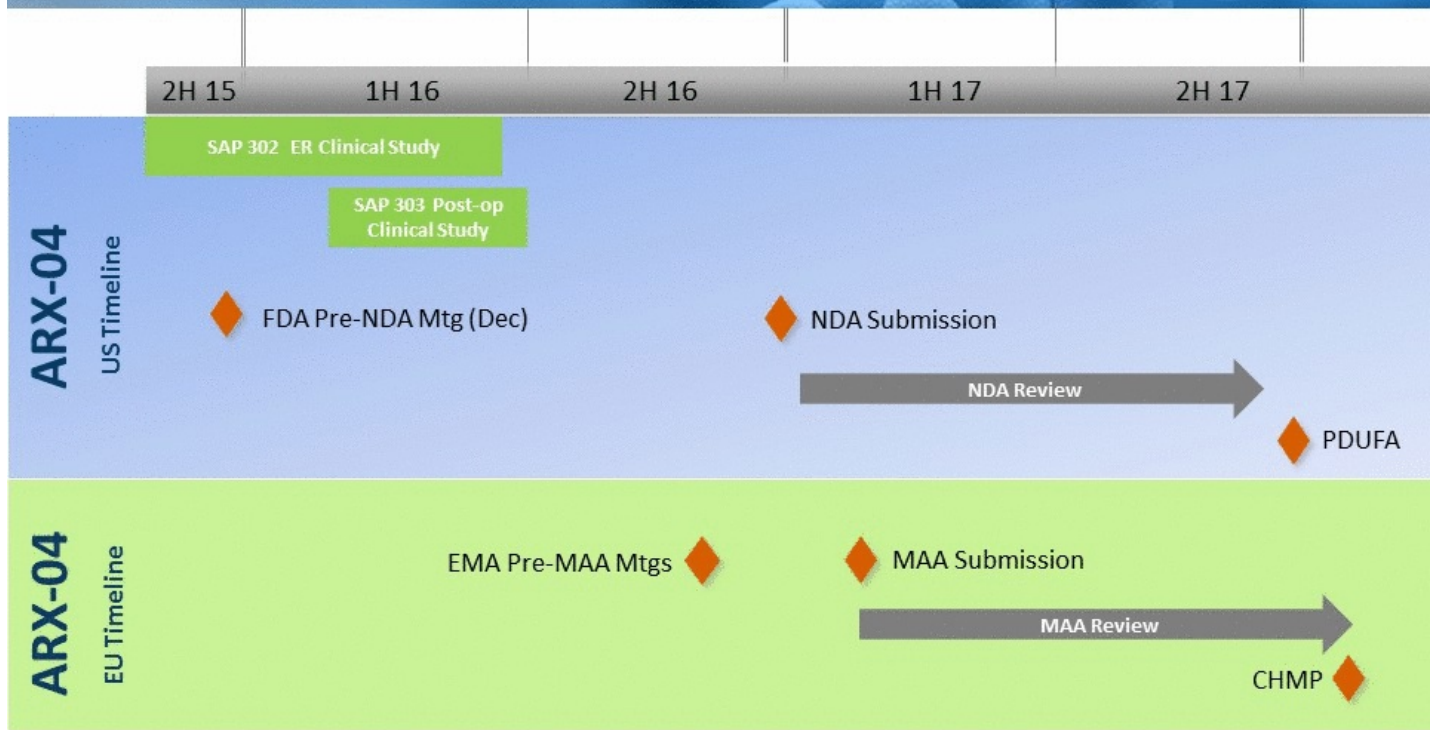


ARX-04 Presentations and Peer-reviewed Publications

Presentations -Meeting	Location	Date	
European Society of Emergency Medicine (EUSEM)	Torino, Italy	October 10-14, 2015	✓
American Society of Anesthesiology (ASA)	San Diego, CA	October 24-28, 2015	✓
Regional Anesthesia & Pain Management (ASRA)	Miami, FL	November 19-21, 2015	✓
International Association of Ambulatory Surgery (IAAS)	Paris, France	January 28-29, 2016	✓
John A. Boswick Burn Symposium	Wailea, HI	February 16-19, 2016	✓
ASRA (SPRING)	New Orleans, LA	March 31-April 2, 2016	
Society for Ambulatory Anesthesia (SAMBA)	Orlando, FL	May 5-7, 2016	
International Society for Pharmacoeconomics and Outcomes Research (ISPOR)	Washington, DC	May 21-25, 2016	
Emergency Nursing Association (ENA)	Los Angeles, CA	September 12-17, 2016	
American College of Emergency Physicians (ACEP)	Las Vegas, NV	October 15-18, 2016	
ASA	Chicago, IL	October 22-26, 2016	
ASRA (FALL)	San Diego, CA	November 17-19, 2016	
Title	Authors	Journal	Status
A dose-finding study of sufentanil sublingual microtablets for the management of post-operative bunionectomy pain	N. Singla, MD, D. Muse, MD, M. Evashenk, P. Palmer, MD, PhD	<i>J. Trauma and Acute Care Surgery</i>	Published 2014
Sublingual sufentanil for the management of post-operative pain following outpatient abdominal surgery	H. Minkowitz, MD, N. Singla, MD, T. Melson, MD, D. Leiman, P. Palmer, MD, PhD	<i>Anesthesia and Analgesia (target)</i>	In process

ARX-04 Anticipated Timelines

US Submission Planned in 2H 2016



ARX-04, Sublingual Sufentanil 30 mcg

Commercial Update

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2016 Commercial Planning Activities

- Preliminary results shown in October 2015 equate to large market opportunity
 - 33 million doses at peak * \$20 (2017 baseline) ~ \$1.3B
- Further define and study specific segments to determine launch strategy
 - Emergency Medicine
 - Ambulatory Surgery
 - Short-stay procedures
 - Plastics
 - Burns
- Interview payers to determine market access process and price sensitivity
- Determine cost of current therapies
- Future work includes
 - Brand Positioning
 - High-level Messaging
 - Coding Strategy
 - ER Prioritization

Market Research Project

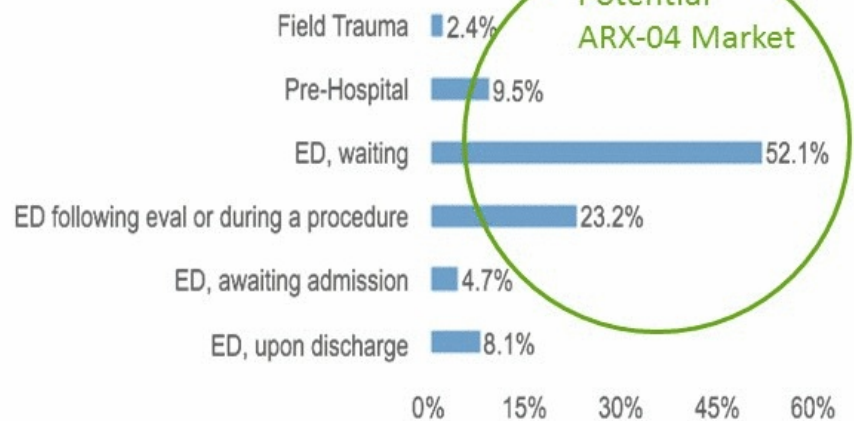
Current Practice of treating Moderate-to-Severe Pain

- Conducted at 2015 American College of Emergency Physicians
- 15 question survey
- 272 Participants
 - MDs and DOs
 - Nurses, Pharmacists, Paramedics, PAs, Administrators
- Intent
 - Inform our commercial strategy about the products that were favored for treating acute pain in various situations in the emergency setting
 - Provided insight into the time patients in the emergency department wait to receive pain medication after initial evaluation

Survey of Emergency Departments Underscores Need for Improvements in Pain Management¹

- Surveyed 272 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



ER setting has the largest moderate to severe acute pain patient population- some overlap with the EMS setting

Care Setting		Pre-Hospital		Hospital			Hospital / ASC	
		Non-Surgery			Surgery			
Pain Type		EMS	ER	IP-F	IP-F Pre-Op	IP-F Post-Op	OP-S	
Acute Pain ¹	Mild Acute Pain / Unknown	EMTs on BLS ambulances cannot provide opiates						
	Moderate / Severe	BLS Non-Available Market 1,330K	ALS Available Market 11,965K	Re-Dose Available Market 10,170K ²	First Dose Available Market 41,211K ³	Available Market 3,894K	Available Market 8,126K ⁴	Available Market 12,901K
Chronic	Breakthrough Pain	Paramedics provide analgesia to 80-85% of M-S aP patients – 90% IV opiates, 10% other		Depending on length of stay, EMS patients given pain meds may receive additional analgesia in the ER			Surgery type often dictates post-operation analgesia needs – regional blocks require less / none while general anesthesia requires more	
	Chronic Pain							
No Pain								
Total M-S aP Pop.		13,295K	51,381K	3,894K		8,126K	12,901K	
Total Adult Pop.		28,595K	109,980K	18,198K ²		16,069K	30,658K	

¹ "Available Market" defined as M-S aP patient population within each setting that is able to receive ARX-04 under medical supervision

1. ZS Opportunity Assessment Research Data

2. M-S aP patients who received pre-hospital pain medication

3. M-S aP patients who did not arrive to ED via EMS, who arrived via BLS, and who arrived via ALS but did not receive pre-hospital analgesia

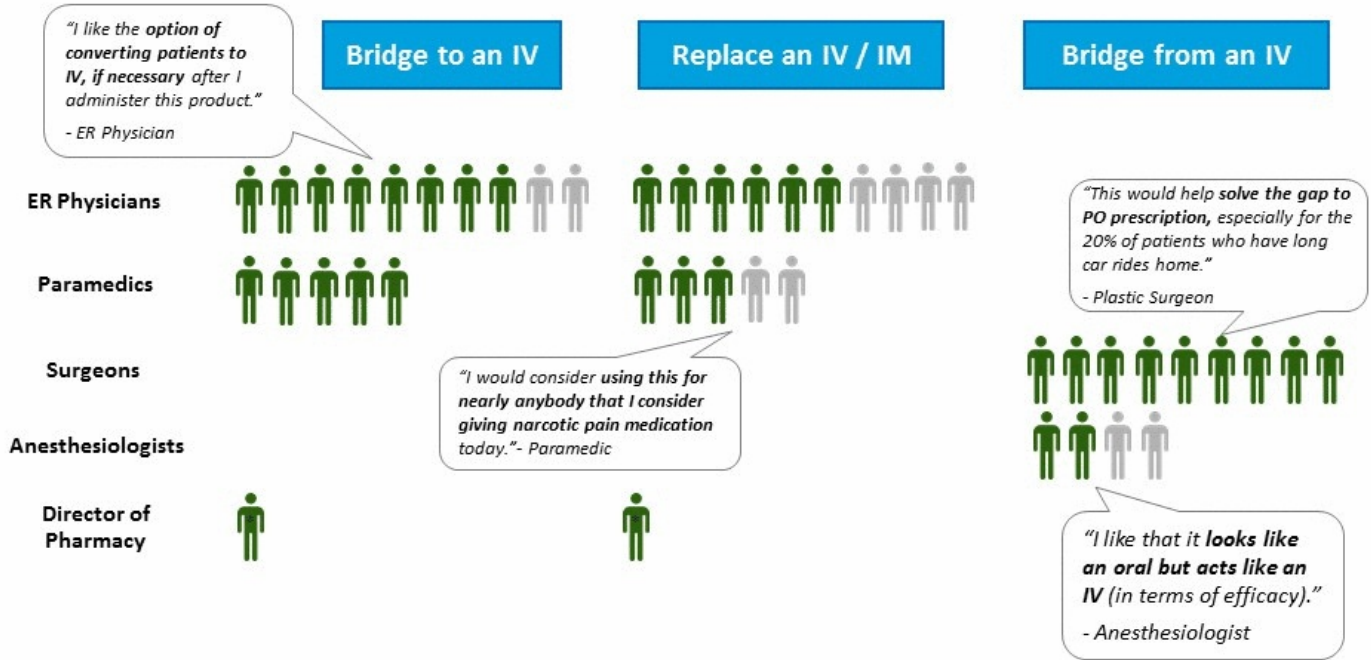
4. Inclusive of Pre-Surgery and Post-Surgery IP-F patients

□ Data breakdown unavailable at this level

■ Market opportunity (# of patients)

□ Total adult patient population by care setting

Internal research finds, ER physicians and paramedics were more interested in ARX-04 as a bridge - ARX-04 “bought time” to decide whether an IV is required



Market Access Research Defines Review Process for ARX-04 by Payers and Pharmacy Directors

- Payers and Hospital Pharmacy Directors had a positive reaction to sublingual sufentanil profile
- Pain medications used in a medically supervised setting reside under Medical Benefit - they are unlikely to be formally reviewed by health plans
- ARX-04 will be subject to Formulary review process in institutions and ambulatory surgery centers
- Centers for Medicare and Medicaid Services cover Emergency Medicine Services under the Outpatient Prospective Payment System (OPPS) via Ambulatory Payment Classification (APC)
- Commercial payers have similar bundled methodologies
 - Separate payment for ARX-04 is unlikely

Cost of Delivering Intravenous Opioid Analgesia in U.S. Emergency Departments

Descriptive analyses using the Premier database (2013-2014) of > 600 US hospital EDs were conducted on the cost of starting an IV and delivering an initial dose of an IV opioid in EDs.

- Over 24 months, 7.3M patients received IV opioids in 614 EDs in the US
- Morphine (56%), hydromorphone (45%) and fentanyl (25%) were the most frequently administered IV opioids
- Analyzed costs include:
 - initiating an IV, IV catheter, infusion pump tubing, infusion pump to maintain IV patency, saline bag, 2% lidocaine and cost of a single dose of morphine 5 mg, hydromorphone 1 mg or fentanyl 100 mcg
- Aggregated mean IV opioid total costs per patient for a single standard dose of opioid were calculated

Thank you

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Pharmaceuticals, Inc.

