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): December 1, 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.

AcelRx Pharmaceuticals, Inc. (the "Company" or "AcelRx") will host an Analyst & Investor Event on Thursday, December 1, 2016 in New York from 8:00am – 10:30am ET to discuss the Company's late-stage product candidate, ARX-04. The presentation, which includes a slide setting forth certain cautionary language intended to qualify the forward-looking statements included in the presentation, is furnished as Exhibit 99.1 to this Current Report and is incorporated herein by reference. The 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 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Slide presentation entitled, "ARX-04 AcelRx Pharmaceuticals, Inc. (ACRX:NASDAQ) New York City, NY December 1, 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: December 1, 2016

ACELRX PHARMACEUTICALS, INC.

By: /s/ Timothy E. Morris
Timothy E. Morris
Chief Financial Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Slide presentation entitled, "ARX-04 AcelRx Pharmaceuticals, Inc. (ACRX:NASDAQ) New York City, NY December 1, 2016"

Exhibit 99.1

ARX-04

AcelRx Pharmaceuticals, Inc. (ACRX:NASDAQ)
New York City, NY
December 1, 2016

AcelRx Pharmaceuticals, Inc.

Forward-Looking Statements

This presentation contains forward-looking statements, including, but not limited to, statements related to financial results and trends; the process and timing of anticipated future development of AcelRx's product candidates, ARX-04, sufentanil sublingual tablet, 30 mcg, and Zalviso, the sufentanil sublingual tablet system, including the ARX-04 clinical trial results; anticipated submission of the new drug application, or NDA, for ARX-04 to the US Food and Drug Administration, or FDA; AcelRx's pathway forward towards gaining approval of Zalviso in the US, including the successful completion of the IAP 312 clinical study for Zalviso; anticipated resubmission of the Zalviso NDA to the FDA, including the scope and timing of the resubmission and the FDA review time; the status of the collaboration and license agreement with Grünenthal, a company organized under the laws of Germany, or any other future potential collaborations, including potential milestones and royalty payments under the Grünenthal agreement; 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 possibility that the FDA may dispute or interpret differently clinical results obtained from the Phase 3 ARX-04 studies; the Zalviso development program, including completion of IAP312 and the resubmission of the Zalviso NDA to the FDA; 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; AcelRx's ability to receive any milestones or royalty payments under the Grünenthal agreement and the timing thereof; ability to manufacture and supply sufficient quantities of Zalviso to Grünenthal on a timely basis; the commercial success of Grünenthal's launch of Zalviso in the European Union, or the EU; the uncertain clinical development process, including adverse events; the success, cost and timing of all development activities and clinical trials; the market potential for AcelRx's product candidates; 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 US Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on November 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.

Agenda

Welcome	Howie Rosen, CEO
History and Background	Pamela Palmer, MD, PhD, Cofounder, CMO
Regulatory Perspective	Nat Katz, MD
Clinical Overview	David Leiman, MD
Commercial Opportunity	Gina Ford, RPh, MBA, VP Commercial Strategy
Emergency Medicine Expert Panel	James Miner, MD, FACEP COL (ret.) John B. Holcomb, MD, FACS Michael Ritter, MD, FAAEM, FACEP **Moderator:** Gina Ford, RPh, MBA
General Discussion / Q&A	Pamela P. Palmer, MD, PhD Gina Ford, RPh, MBA Tim Morris, CFO & Head of Business Development Howie Rosen, CEO
Close	

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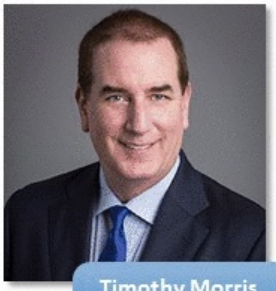
Welcome

Howie Rosen

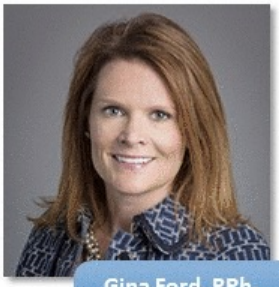
AcelRX Pharmaceuticals, Inc.

Company Leadership

Pamela Palmer, MD, PhD, Cofounder, CMO



Timothy Morris, CFO & Head of Business Development



Gina Ford, RPh, MBA, VP Commercial Strategy

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Analyst Day Objectives

- Review the summary of efficacy from four ARX-04 clinical studies and the integrated summary of safety to be submitted with the New Drug Application (NDA) for ARX-04
- Summarize the results of the study (SAP302) of ARX-04 in the emergency department (ED)
- Provide a current perspective of the Regulatory environment for potential approval of opioids for the treatment of acute pain
- Discuss market research relating to the treatment of acute pain in the ED
- Provide insights on the potential market for ARX-04

ARX-04 History and Background

Pamela Palmer, MD, PhD

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ARX-04 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 maintain sublingual bioavailability
- **Bioadhesive** to keep in place under tongue
- **Discrete dosing unit** may reduce dosing errors and circumvent risk of diversion with clear liquids

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1. Mather LE. Opioids: a pharmacologist's delight! *Clin Exp Pharmacol Physiol* 1995; 22:833-6.

ARX-04 Overview

Potential Use Settings

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

Proposed Indication

Management of moderate-to-severe acute pain in a medically supervised setting.

Dosing

Sublingual sufentanil 30 mcg tablet pre-filled in a disposable single-dose applicator.

Development Status

- All clinical studies complete
- NDA submission by end of 2016
- 505(b)(2) based on Sufenta®

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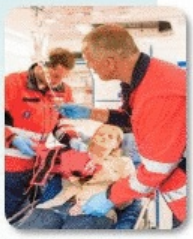
Department of Defense Provides up to $22M in Support for the Development of ARX-04

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 can be challenging to start in field or in moving ambulances[4]
- Can take 30 minutes or more to have an IV line inserted in ED[5]



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/l8Xpa2
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

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Opioid Regulatory Perspective

Nathaniel Katz, MD

AcelRx Pharmaceuticals, Inc.

Nathaniel P. Katz, MD

CEO, Analgesic Solutions
Adjunct Assistant Professor of Anesthesia, Tufts

- Dr. Katz is currently the CEO of Analgesic Solutions which was founded in 2007 with the mission of modernizing the design and conduct of pain clinical trials to advance the scientific quality of clinical research, and empower effective treatments for patients. He is the principal consultant in charge of scientific oversight at Analgesic Solutions.
- From 2000-2004 he served as chair of the Advisory Committee at the US Food and Drug Administration in the Anesthesia, Life Support, and Addiction Drug Products Division. He joined Tufts University School of Medicine in 2005 as an assistant professor of anesthesia and holds the position of adjunct professor.
- He is considered one of the leading experts on the treatment of pain and design of pain clinical trials.
- Dr. Katz graduated from the Medical College of PA and earned a Masters of Science in biostatistics from Columbia. He completed a residency in neurology and a fellowship in pain management, after which he served as an associate physician and a staff neurologist at Brigham and Women's Hospital.

ARX-04 Clinical Overview

David Leiman, MD

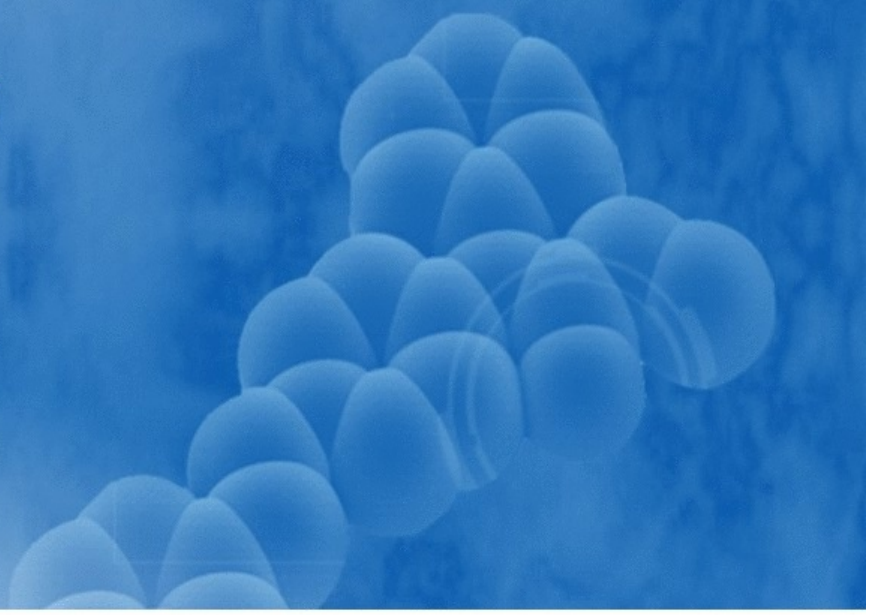
AcelRX Pharmaceuticals, Inc.

David Leiman, MD

President, AIPM of Houston

- Dr. Leiman received his medical degree from St. George's University in Grenada and completed an internship and residency in anesthesiology at the University of Texas at Houston. He was named chief resident in anesthesiology at the University of Texas in 2010.
- He holds numerous positions in the field of pain management, including the director of research and staff anesthesiologist at Memorial Hermann Southeast Hospital, where he created an anesthesia technician education program. He also serves as staff anesthesiologist at Texas Orthopedic Hospital, and director research at Gulf Coast Cancer and Diagnostics Center.
- He is involved in a number of research programs, including the ARX-04 clinical program, and has authored several peer-reviewed publications and medical meeting posters on the topic of post-surgical anesthesia.
- He is a member of the American Society of Anesthesiologists and the Texas Society of Anesthesiologists, and is certified by the American Board of Anesthesiology.

Clinical Overview



ARX-04 Clinical Program Included More Than 900 Patients

Study	Number of Patients	Study Design	Patient Population	Efficacy Endpoint	Efficacy
SAP202	100	Multi-center, randomized, placebo-controlled	Postoperative; bunionectomy	SPID12: ARX-04 vs placebo	ARX-04 demonstrated pain relief over placebo
SAP301	161	Multicenter, randomized, placebo-controlled	Postoperative; outpatient abdominal surgery	SPID12: ARX-04 vs placebo	ARX-04 demonstrated pain relief over placebo
SAP302	76	Multicenter, Open-Label	Trauma/injury in the Emergency Department	Drop in pain intensity from baseline	ARX-04 patients had >35% drop in pain at one hour after a single dose
SAP303	140	Multicenter, Open-Label	Postoperative; elderly and organ impaired	Drop in pain intensity from baseline	ARX-04 patients had 57% drop in pain
Select Zalviso® Patients	427	Varied	Postoperative; inpatient orthopedic and abdominal surgery	SPID48: SS vs. placebo or IV PCA morphine	Sublingual sufentanil patients demonstrated pain relief over placebo and morphine

SPID12 = summed pain intensity difference to baseline over 12 hours

Outcome Measures

SPID Used As Primary Efficacy Endpoint As Requested By FDA, Multiple As Reported and Predetermined Safety Measures Collected

Primary Efficacy

- **Primary Efficacy Variable:** Summed pain intensity difference to baseline over the entire study period
  - Post-operative studies through 12 hours (SPID12)
  - Emergency Department study first hour only (SPID1)

**Pain intensity was measured at designated intervals and on an 11-pt numeric rating scale, where "0" = "no pain" and 10 = "worst pain imaginable"*

Safety

- Assessment of adverse events
- Vital sign monitoring, including oxygen saturation
- Use of concomitant medications
- Cognitive function test (SAP302 study only)

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Baseline Demographics: Late-Phase Studies of ARX-04 30 mcg Includes Excellent Diversity of Age, Gender, Weight and Surgery Type

Category, n(%)	N = 437
Sex, male	193 (44)
Age (years)	
< 55 years	320 (73)
≥ 55 years	117 (27)
Race	
White	316 (72)
African American	93 (21)
Other	28 (7)
Ethnicity	
Hispanic/Latino	104 (24)

Category, n(%)	N = 437
Body Mass Index (BMI)	
< 30kg/m^2	275 (64)
≥ 30kg/m^2	158 (36)
Surgery Type	
Orthopedic	88 (20)
Abdominal	244 (56)
Other Surgery	29 (7)
Non-surgery	76 (17)

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Source ISS PTT 14.1.20

Postoperative Studies:
ARX-04 Studied in Postoperative Pain in a Variety of Surgery Types in Multiple Surgery Settings

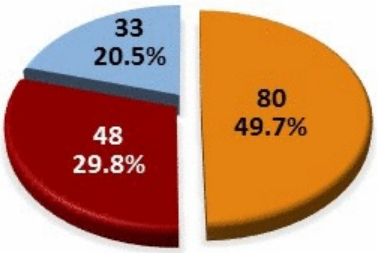
SAP202: ASC

Surgery Type

- Bunionectomy

100 Total patients

SAP301: ASC

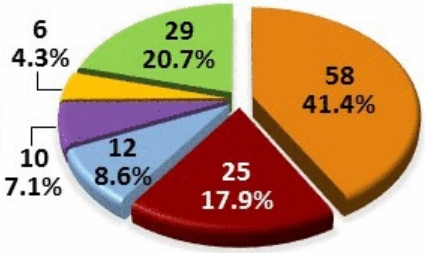


Surgery Type

- Abdominoplasty
- Laparoscopic Abdominal
- Hernioplasty

161 Total patients

SAP303: Hospital



Surgery Type

- Laparoscopic Abdominal
- Open Abdominal
- Knee Replacement
- Orthopedic, Other
- Hip Replacement
- Other

140 Total patients

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Postoperative Studies: Analysis of SPID-12 Reveals Positive Efficacy in all 3 Trials

Time-weighted SPID12	ARX-04	Placebo	SPID12 Delta	P-value
SAP 301	n=107	n=54		
LS Mean	25.8	13.1	12.7	<0.001
SAP202	n=40	n=20		
LS Mean	6.53	-7.12	13.7	0.003
SAP303	n=137	NA		
LS Mean	36.0	NA	NA	NA

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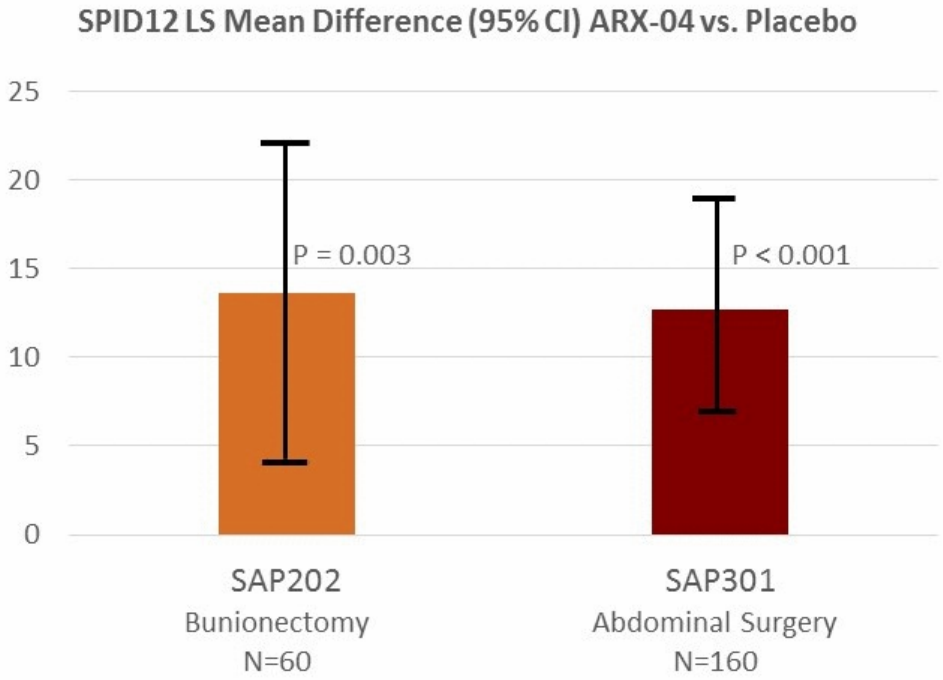
LS = least squares mean; SPID12 = summed pain intensity difference to baseline over 12 hours

ARX-04 Demonstrated Significant and Consistent Differences From Placebo in All RCT



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Secondary Efficacy Endpoints Demonstrate Statistical Significance over Placebo

Endpoint	Study SAP202 Bunionectomy	Study SAP301 Abdominal Surgery
SPID1 – summed patient intensity difference over first hour	<0.001	<0.001
TOTPAR12 – total pain relief over first 12 hours	0.001	<0.001
Patient Global Assessment – responding "good" or "excellent"	0.002	<0.001
Healthcare Professional Global Assessment – responding "good" or "excellent"	NA	<0.001
Patients Using Rescue Analgesia	0.006	<0.001
Time to First Rescue Analgesia	<0.001	<0.001

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SAP302 Emergency Department

SAP302 Emergency Department: Study Design Intended to Demonstrate Efficacy in Moderate-to-Severe Acute Pain Due to Trauma or Injury

Study Details

Multicenter, Single-Arm, Open- label Study

Two Cohorts:

- Single-dose (after 1 hour, other opioids administered if needed)
- Multiple-dose up to 5 hours (rescue opioids allowed if study drug not effective)

Inclusion/Exclusion

Key Inclusion:

- 18 years and older
- Moderate-to-severe acute pain due to trauma or injury

Key Exclusion:

- Opioid-tolerant (>15mg oral MSO_4 equivalent daily)
- Dependent on supplemental oxygen
- Pregnant

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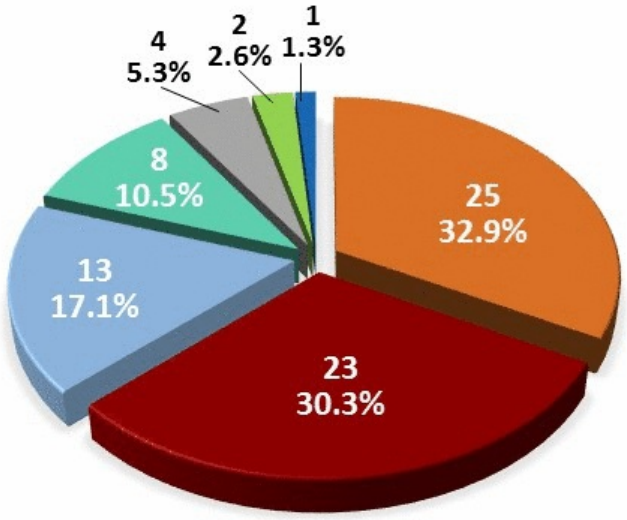
SAP302 Emergency Department: Demographics (n=76) Included Multiple Injury Types

Trauma classifications



Injury Type

- Fractures
- Sprains/strains
- Contusion/hematoma (soft tissue)
- Laceration
- Joint dislocation
- Burns
- Infections

76 Total patients

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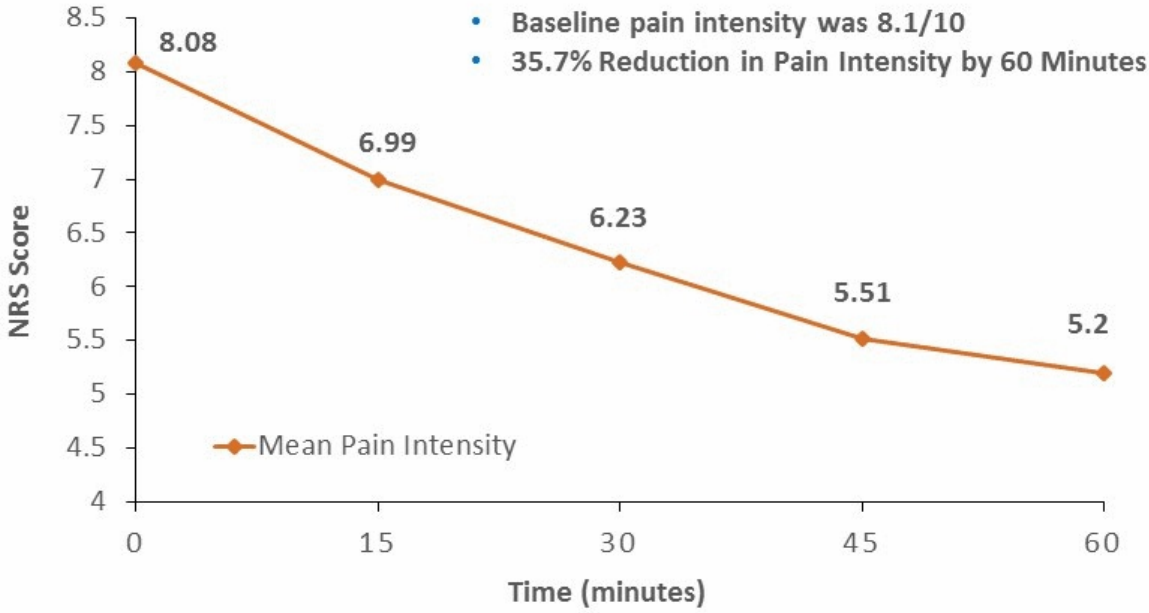
SAP302 Emergency Department: Mean Pain Intensity by Evaluation Time Point Shows Improvement in Pain Early and Often



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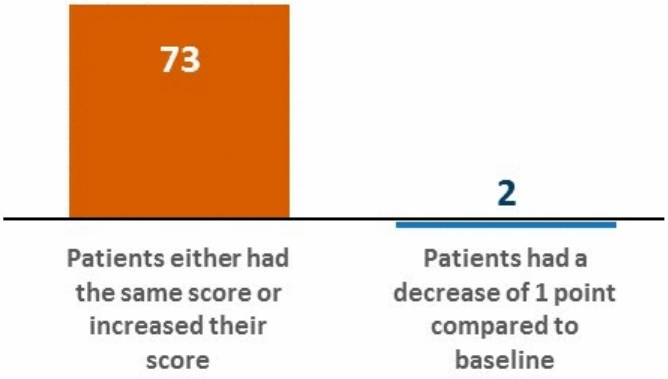
SAP302 Emergency Department: Six-Item Screener (SIS) Cognitive Test

SAP302 SIS results suggested that ARX-04 was not associated with cognitive impairment



- DoD requested cognitive test before and 1 hour after dosing of ARX-04
- DoD concerned about impaired cognitive skills with other field-based analgesics used in the military

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SAP302 Emergency Department:

79% of patients in SAP302 reported no side effects

Adverse Events (> 2% of patients)

ARX-04 (30 mcg)

n=76

No Adverse Event 79%

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)

Most Common Adverse Events:* All ARX-04 Phase 2 and 3 Studies Demonstrate No Meaningful Difference Compared to Placebo

Adverse Event, n(%)	Combined Sufentanil (N=363)	Combined Placebo (N=74)	Treatment p-value
Nausea	105 (28.9)	16 (21.6)	NS
Vomiting	23 (6.3)	1 (1.4)	NS
Headache	29 (8.0)	10 (13.5)	NS
Dizziness	21 (5.8)	3 (4.1)	NS
Somnolence	15 (4.1)	2 (2.7)	NS
Pruritus	11 (3.0)	2 (2.7)	NS
Hypotension	8 (2.2)	1 (1.4)	NS
Flatulence	4 (1.1)	4 (5.4)	0.031
Procedural nausea	3 (0.8)	3 (4.1)	NS

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*Includes AEs from sublingual sufentanil studies SAP202, SAP301, SAP302 and SAP303 (ISS PTT 14.2.14)

Additional Results from Clinical Program Provide Support for Safety, Efficacy and Ease of Use for ARX-04

- Statistically significant reductions in pain intensity vs placebo were evident within 15-30 minutes for SAP202 ($p<0.001$ at 30 min) and SAP301 ($p=0.002$ at 15 min).
- Clinically relevant reductions in pain intensity were evident within 15-20 minutes for open-label studies SAP302 and SAP303 compared to baseline.
- Average duration of action across all studies for each dose was approximately 3 hours.
- No opioid-reversal agents were required in any of the ARX-04 clinical trials.
- The Single-Dose Applicator used to deliver the SST 30 mcg under the tongue was rated highly by healthcare professionals for its ease of use.

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Commercial Opportunity

Gina Ford, RPh, MBA

Commercial Opportunity

Market for Novel Pain Therapies

Strategy and Opportunity

Tactical Rollout

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Market for Novel Pain Therapies

Situation Analysis

US Commercial Strategy Insights Gained from Multiple Sources

2016 Completed Market Research

n = 479 HCP Surveys

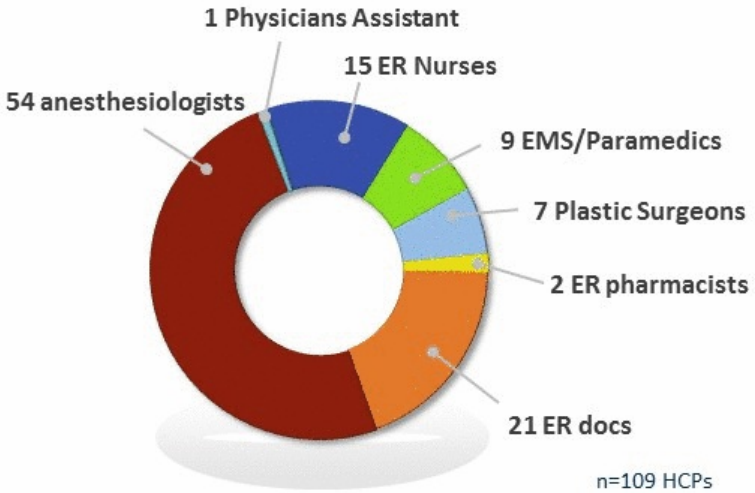
Pre-hospital n=47	•Landscape assessment •Buying Process •Paramedic Qualitative
Emergency Department n=65	•Landscape assessment •Buying process •Physicians Qualitative •Nurse Qualitative •Positioning
Ambulatory Surgery n=32	•Landscape assessment •Buying Process •Surgeon/Anesth Qualitative
In Progress	•Validated Forecast (n=335) •Market Access Strategy •Brand Identity and Packaging

EU work included Forecast and Market Access

2016 KOL Engagement

Completed 9 Advisory Boards

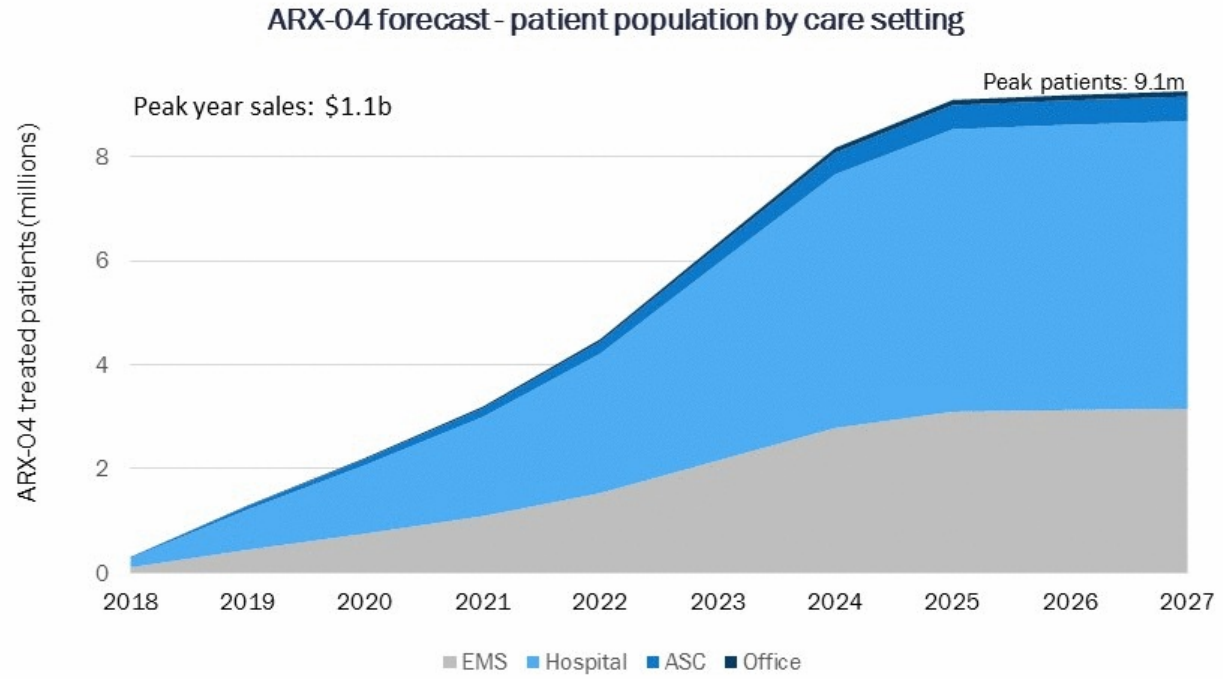
3 Anesthesiology, 2 ER Physician, 1 ER Nurse, 1 Paramedic, 1 Multi-disciplinary, 1 Plastic Surgeon



n=109 HCPs

- Engaged ARX-04 Educational Outreach Advisory Board on 3 occasions

ARX-04 Represents a $1.1b Opportunity at Peak Assuming Treatment of an Estimated 9.1 Million Patients with Moderate to Severe Acute Pain

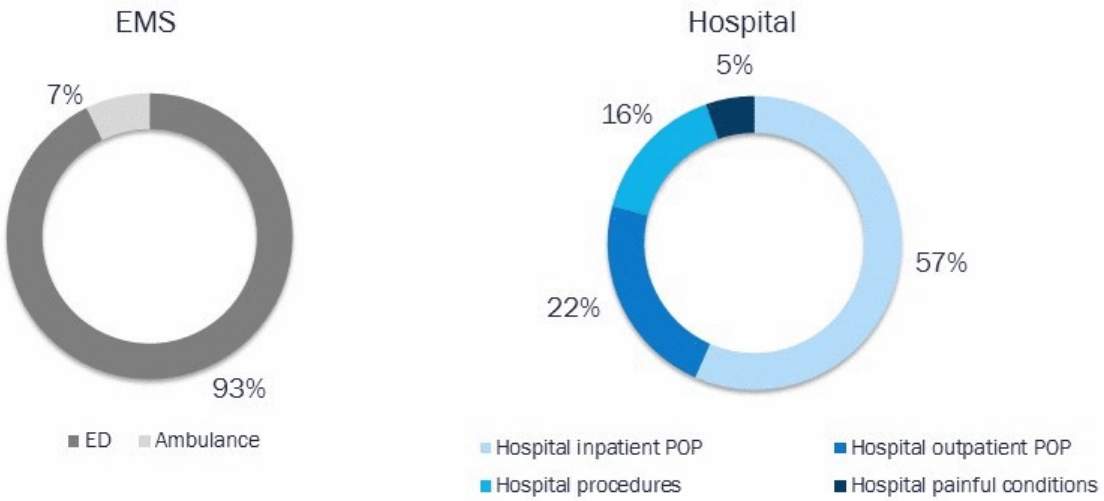


Assuming receipt of a final product label that closely aligns with the company's proposed label submitted to FDA (treatment of moderate-to-severe acute pain severe enough to require an opioid agonist and for which alternative treatments are inadequate, in adult patients in a medically supervised setting).

Source: QuintilesIMS Consulting Services 2016 analysis

The Emergency Department and Hospital POP Present the Greatest Opportunities for ARX-04

ARX-04 revenue forecast – top care settings breakdown by % of revenue



Administration limited to medically supervised settings

AcelRX Pharmaceuticals, Inc.

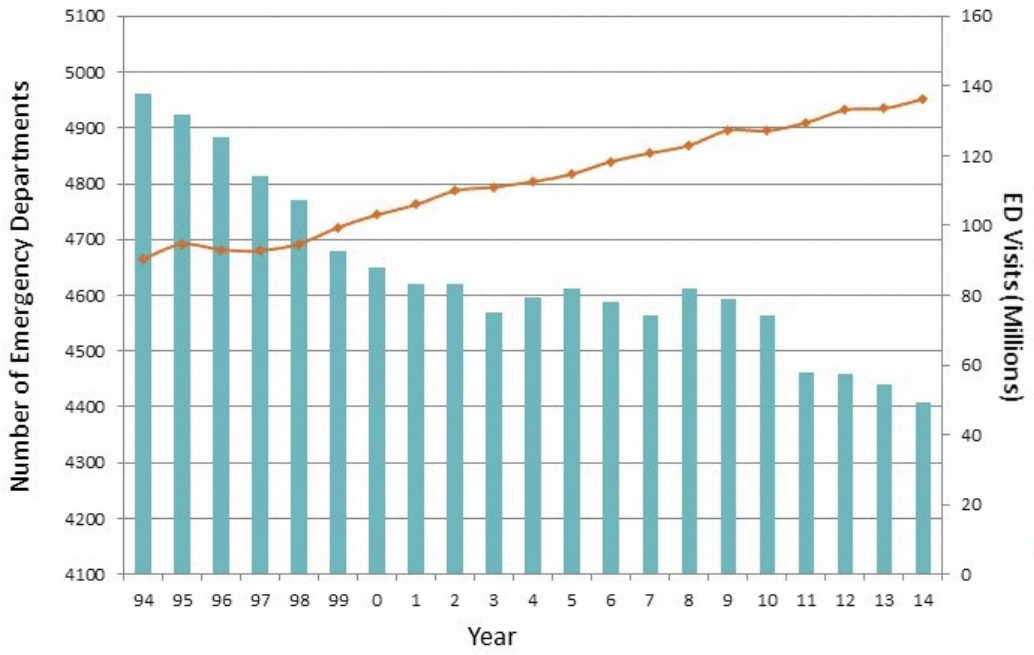
Source: QuintilesIMS Consulting Services 2016 analysis

Market for Novel Pain Therapies

The Unmet Need

- Emergency Department (ED) Crowding and Waiting
- Inefficient ED Pain Management

Number of EDs Shrinking While Annual Visits On the Rise – Making Efficiency Important



- Hospital closures linked to lack of profits particularly in areas of high competition or those serving higher populations in poverty[2]
- Urban hospitals are responsible for 84% of total ED visits[3]

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1. American Hospital Association (2016, November 23) http://www.aha.org/research/reports/tw/chartbook/2015/15chartbook.pdf (Graph)
2. RAND Corporation (2016, November 23) http://www.rand.org/pubs/external_publications/EP20110092.html
3. American Hospital Association Annual Hospital Survey - purchased May 2016

ED Patient Crowding & Waiting Are Critical Issues

Compromises care quality

"Emergency department crowding is clearly linked to worse patient care and worse outcomes, including higher mortality rates, higher rates of complications, and errors." -- *Jesse M. Pines, M.B.A., M.D*

Reported by hospitals as measures to the Centers for Medicare & Medicaid Services (CMS)

"With implementation of the Affordable Care Act and pressure to reduce health care costs, crowding will likely continue to worsen. We know there are effective interventions that can mitigate crowding, now is the time to develop best practices to reduce emergency department crowding so that we can provide the highest-quality patient care."

– *Leah S. Honigman Warner, M.D., M.P.H.*

Can be mitigated by improving patient flow throughout the hospital

Compromises community trust

Costly

- Improving Patient Flow and Reducing Emergency Department Crowding: A Guide for Hospitals. Content last reviewed October 2014. Agency for Healthcare Research and Quality, Rockville, MD. (2016, November 23) http://www.ahrq.gov/research/findings/final-reports/ptflow/executive-summary.html
- Study finds most crowded US hospitals did not adopt proven interventions. George Washington University, Dec. 7, 2015 (2016, November 23) https://www.eurekalert.org/pub_releases/2015-12/gwu-sfm120715.php

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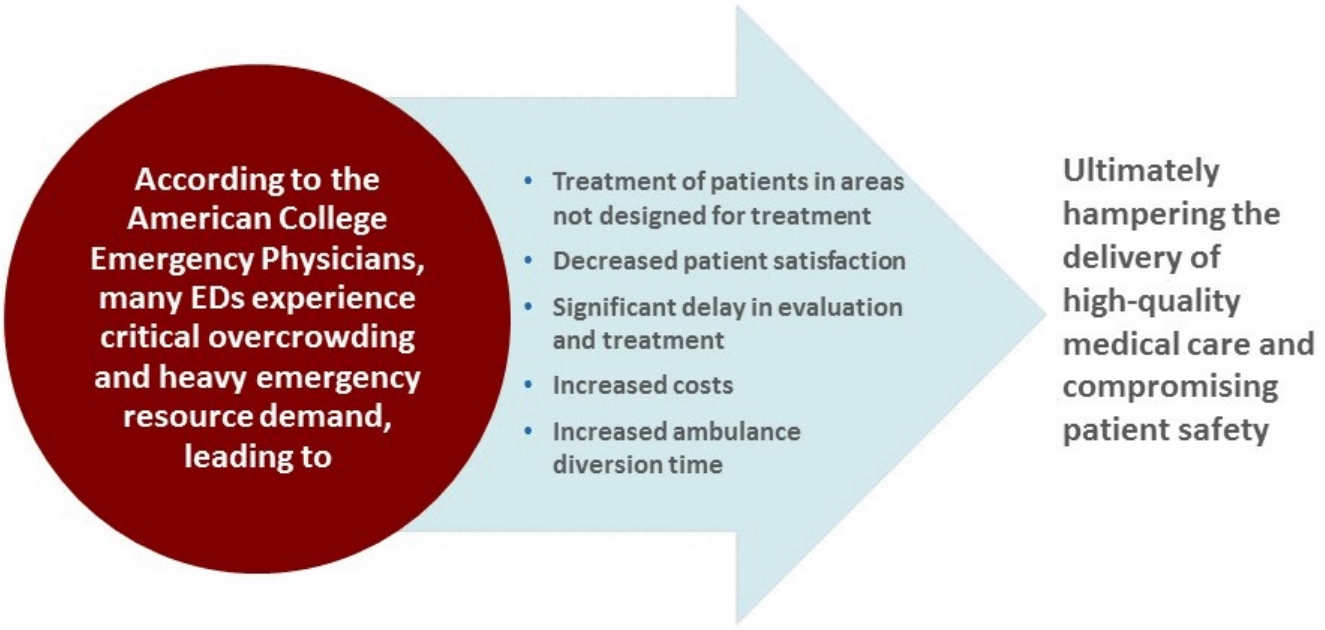
ED Patient Crowding & Waiting are Critical and Compound Issues



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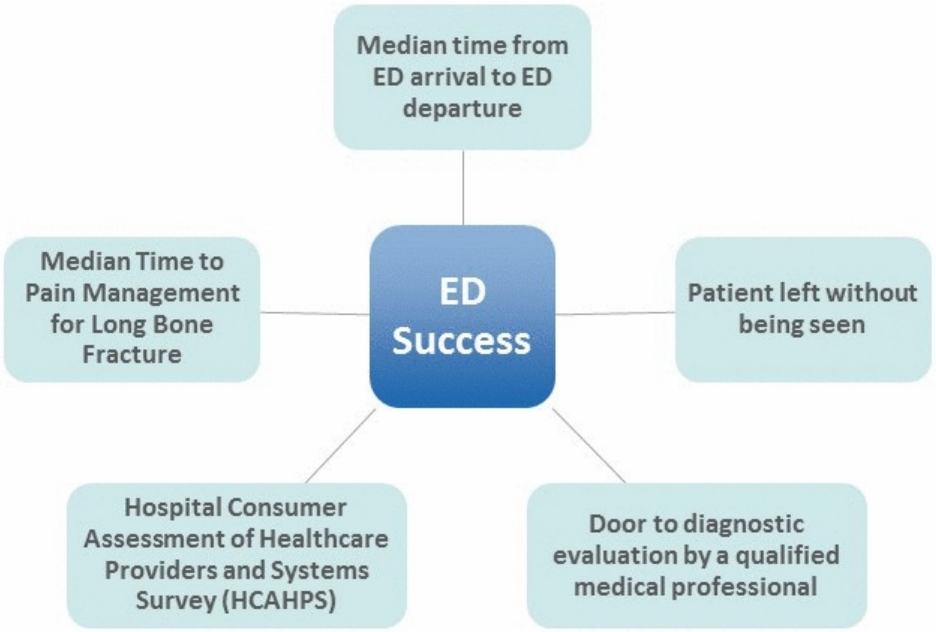
ACEP Policy Statements, Clinical & Practice Management. Revised and approved by the ACEP Board of Directors February 2013. Originally approved by the ACEP Board of Directors January 2006. (2016, November 23) https://www.acep.org/clinical---practice-management/crowding/

Many ED Success Measures Focus on Efficiency and Patient Satisfaction



- 2016 Hospital Measure Summary Minnesota Statewide Quality Reporting and Measurement System (SQRMS) and FY2018 for Center for Medicare and Medicaid Services (CMS) (2016, November 23) https://www.stratishealth.org/documents/2016-CMS-State-measures-20150115.pdf
- Improving Patient Flow and Reducing Emergency Department Crowding: A Guide for Hospitals. Content last reviewed October 2014. Agency for Healthcare Research and Quality, Rockville, MD. (2016, November 23) http://www.ahrq.gov/research/findings/final-reports/ptflow/section3.html

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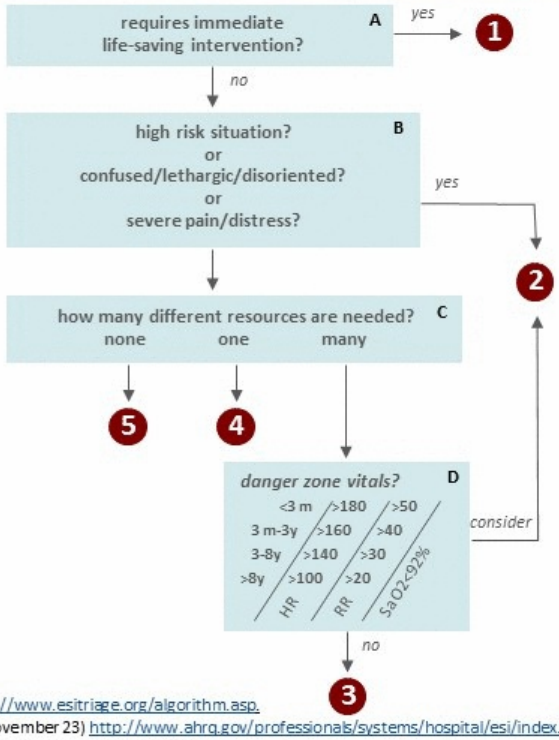
Emergency Severity Index (ESI): Unique Tool Developed to Efficiently Triage Patients In the ED to Help Control "Crowding"[1]

- ESI takes into account both[2]
  - Patient acuity
  - Required resources
- More patients are triaged using the ESI than any other triage acuity system in the US[3]
- ESI levels are loosely associated with physician evaluation and management codes[4]



1. Emergency Severity Triage (2016, November 23) http://www.esitriage.org/algorithm.asp.
2. Agency for Healthcare Research and Quality (2016, November 23) http://www.ahrq.gov/professionals/systems/hospital/esi/index.html.
3. Acad Emerg Med. 2012 Jan;19(1):106-9. doi: 10.1111/j.1553-2712.2011.01240.x.
4. Gilboy N, Tanabe T, Travers D, Rosenau AM. Emergency Severity Index (ESI): A Triage Tool for Emergency Department care, Version 4. Implementation Handbook 2012 Edition. AHRQ Publication No. 12-0014. Rockville, MD. Agency for Healthcare Research and Quality. November 2011.

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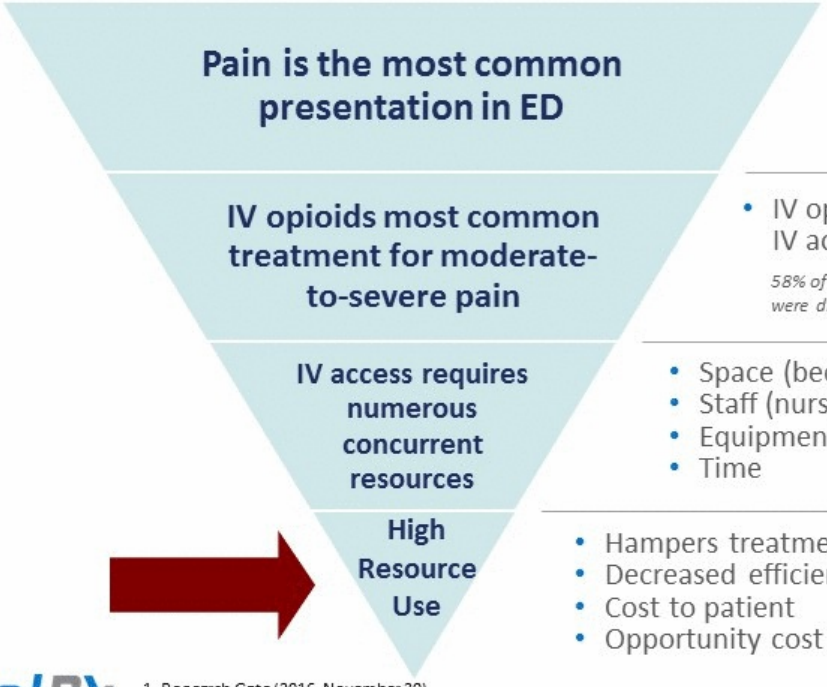
Despite New Strategies, Many Patients Utilize Significant ED Resources Primarily to Address Pain Issues



- ED pain prevalence throughout the world ranges from 52 to 79% [1]

- IV opioids often sole reason for IV access

58% of pts were not admitted to the hospital and were discharged to home from the ED. Palmer et al

- Space (bed, room)
- Staff (nurses, physicians)
- Equipment
- Time

- Hampers treatment of more critical patients
- Decreased efficiency & patient flow
- Cost to patient
- Opportunity cost to ED

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1. Research Gate (2016, November 30) https://www.researchgate.net/publication/6197282_Pain_prevalence_and_pain_relief_in_trauma_patients_in_the_Accident_and_Emergency_Department

A Viable IV-alternative for Moderate-Severe Acute Pain Could Reduce the Resource Demand

- **There is an unmet need for patients with moderate to severe pain who present in the ED**
  - That don't require IV access for other reasons or for which IV access is difficult to establish
  - With a means to address pain in a timely fashion
  - And with minimal need for resources

Market for Novel Pain Therapies

Prevalence of Acute Pain

- Moderate-to-Severe Acute Pain (m-s aP)

ARX-04 Annual Eligible Population Is Significant in Hospital and Non-hospital Settings

Moderate-to-severe acute pain segmentation varies across different care settings

in millions	Emergency medical services (EMS)		Hospital				Ambulatory surgery centers (ASC)		Office	
	Pre-hospital	Emergency department	Inpatient surgery	Inpatient conditions	Outpatient surgery	Procedure	Outpatient surgery	Procedure	Surgery	Procedure
2017 adult patient pop.	25.4	111.8	12	2.8	18.0	72.7	8.8	9.6	3.4	46.4
2017 adult m-s aP pop.	11.7	51.4	7.8	1.8	7.2	14.5	3.5	1.9	1.4	2.3
	51.4		31.4				5.4		3.7	
Tot. m-s aP patients	91.9M									

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Source: Medical literature review- see full report for details, QuintilesIMS primary market research, QuintilesIMS analysis

ARX-04 Strategy

- ARX-04 Positioning
- ARX-04 Launch Plan
- ARX-04 Opportunity
- ARX-04 Reasons to Believe

POSITIONING

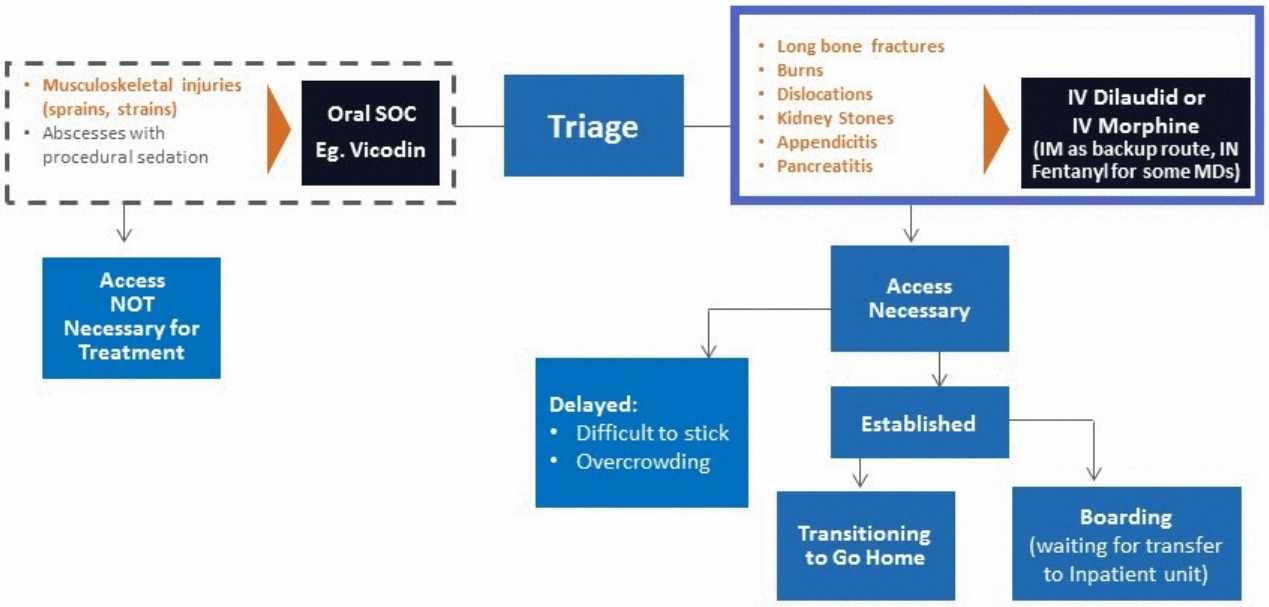
ARX-04 Presents an Efficient Option That Works to Optimize Resources and May Help Address Patient Overcrowding

ARX-04 may provide a treatment option for ED healthcare providers to use for patients who require opioids to address their moderate-to-severe acute pain, but do not require IV access and the associated resources.

This treatment alternative may have a positive impact on ED patient flow, productivity and hospital costs.

OPPORTUNITY

Current State of Moderate-to-Severe Acute Pain Management in ED Requires an IV for Opioid Treatment



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American Family Physician (2016, November, 23) http://www.aafp.org/afp/2013/0601/p766.html

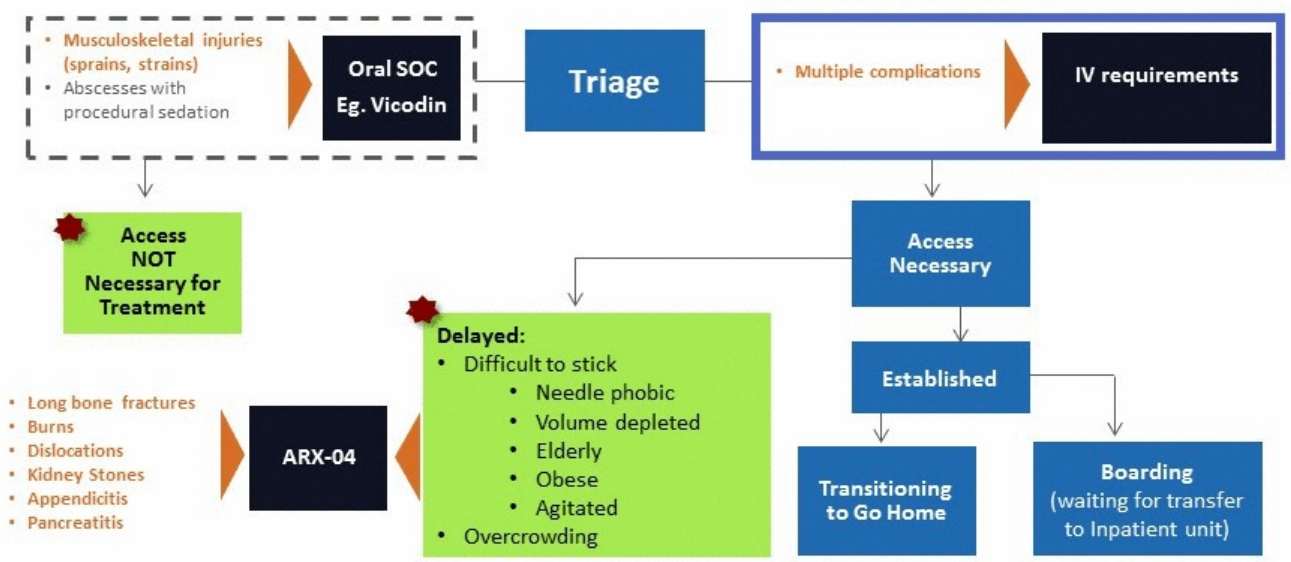
Current

MRC-0104 30NOV16

OPPORTUNITY

ARX-04 May Reduce the Number of IVs Placed for Pain Management

A viable IV alternative for the treatment of moderate-to-severe acute pain could be beneficial



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Current Future

Multiple Pitfalls and Challenges of IV Access Have Been Well Documented in the Literature[1]

- Failure rates of IV access reported as high as **40%**
- **Average time** to establish IV access ranges from **2.5 to 16 minutes**
- Significant delays in care when IV access requires HCP intervention
  - **difficult access** may require **30 minutes**
- **Physician time** devoted to obtaining IV access ranging from **22 to 57 minutes**

Patients with **difficult IV access** are subject to repeated attempts by multiple practitioners and are more likely to experience **treatment delays, more pain,** and **decreased patient satisfaction**

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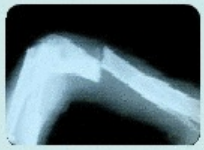
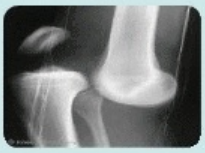
1. Emergency Nurses Association (2016, November 23) https://www.ena.org/practice-research/research/CPG/Documents/DifficultIVAccessCPG.pdf

Long Bone Fractures, Dislocations, and Abdominal Pain Show Opportunities Beyond Difficult to Stick Patients



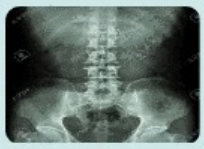
Long bone fractures

- 2.3% of ED patients; 3+ million



Sprains / strains / dislocations

- 4.8% of ED patients; almost 6.5 million (Dislocations = .4% of ED patients; 500,000+)



Abdominal pain

- 4.7% of ED patients; 6 million

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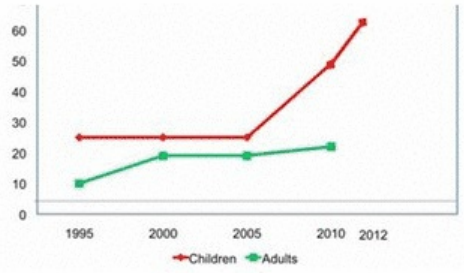
"HCUPnet: A Tool For Identifying, Tracking, And Analyzing National Hospital Statistics". Hcupnet.ahrq.gov. N.p., 2016. Web. 10 Nov. 2. 2016. "Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality, US Department of Health and Human Services". http://hcupnet.ahrq.gov/

Difficult to Stick Patients Alone Offer Shift Away from Using IV Opioids

- **Difficult venous access** is present in approximately **1 out of every 9 to 10** people undergoing IV access in an urban academic ED.[4]

- **Needle phobic** patients = **10%** of population; **13.5 million** ED patients[1]
  - Potentially **1.5 million ARX-04** ED patients[2]

- Needle-phobia population over time[3]



1. Pubmed (2016, November 23) https://www.ncbi.nlm.nih.gov/pubmed/7636457
2. "HCUPnet: A Tool For Identifying, Tracking, And Analyzing National Hospital Statistics". Hcupnet.ahrq.gov. N.p., 2016. Web. 10 Nov. 2016. "Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality, US Department of Health and Human Services". http://hcupnet.ahrq.gov/
3. Connecticut by the Numbers (2016, November 23) http://ctbythenumbers.info/2013/12/15/pediatricians-invention-stop-pain-injections-improve-public-health/
4. Pub Med (2016, November 23) https://www.ncbi.nlm.nih.gov/pubmed/25171796

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ARX-04 Strategy

- Reasons to Believe

ARX-04 Is A Potential Alternative Treatment Option for Moderate-Severe Acute Pain Patients in the ED Not Requiring an IV

ARX-04 means ED staff, time and space could be more readily available for patients with higher ESI scores who require these limited resources.

Administration	Onset	Duration	Recognized Adverse Event Profile
Sublingual dose provides non-invasive route eliminating the time and resources associated with IV	Clinically meaningful relief in 15-20 minutes[1]	1 tablet every 60 minutes as needed 75% of patients did not require or request 2nd dose	79% of patients did not experience side effects

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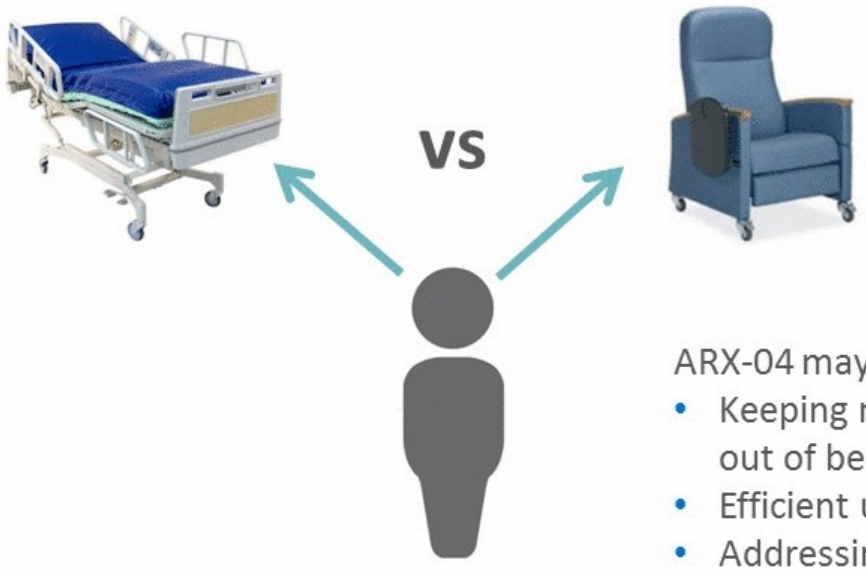
1.Bijur, Polly E., et al.. Validation of a Verbally Administered Numerical Rating Scale of Acute Pain four Use in the Emergency Department. Academy Emergency Medicine. 2003;10: 390-392.

ARX-04 Has the Potential to Assist ED Physicians in Managing Resources



ARX-04 may assist with:

- Keeping non-critical patients out of beds
- Efficient use of ED space
- Addressing RN resources

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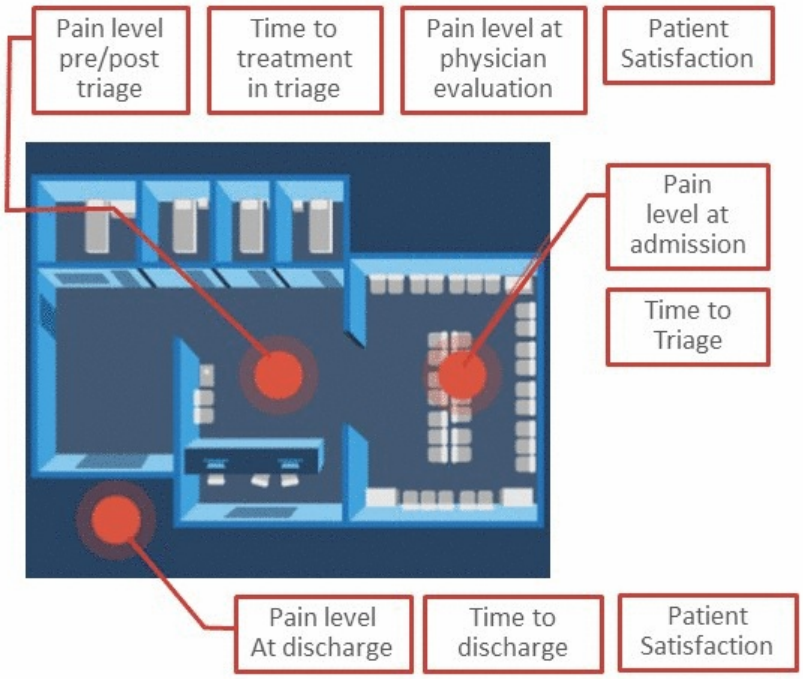
AcelRx Intends to Complete a Comprehensive Phamacoeconomic Model that will Continue to Support the Uses of ARX-04 in the ED

- **Value-based Outcomes and Real World Evidence (RWE)**
  - Outcomes at different points of ED flow
  - Time & motion
  - Patient satisfaction survey
  - Patient Reported Outcomes
  - Longitudinal post ED discharge survey
  - Societal cost of m-s aPain
  - Cost benefit analysis
  - Cost effectiveness modeling
  - Budget impact modeling



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MHA@GW Blog. State of Emergency: Overcrowding in the ER [Infographic]. July 15, 2014 by Emily Newhook. (2016, November 23) https://mha.gwu.edu/overcrowding-in-the-er/

ARX-04 REMS Program Will Promote the Use of ARX-04 Only in Medically Supervised Settings

- **Fundamentals of ARX-04 REMS Program, include;**
  - Use in medically supervised settings only
  - Not available via retail pharmacy
  - Not for home use
- **The product is presented,**
  - In a tamper-evident pouch,
  - As a single-dose applicator, that cannot be reused

Tactical Rollout

- Key Initiative
- Launch Readiness and Timing

KEY INITIATIVE

Pilot Program will help Establish Best Practices prior to Full deployment and Commercial launch

Objectives

- Generate real world experience with ARX-04 in medically supervised settings
- Establish best practices in adoption and utilization of ARX-04 in EDs and EMS

Output

- **Clinical**
  - Baseline #s for benchmarking studies
  - Database of key data – utilization, treatment patterns, etc.
- **Economic**
  - Outcomes at different points of ED flow
    - Time & motion
    - Patient satisfaction
    - Cost benefit analysis
- **Operational**
  - Protocols
  - Policies & Procedures
  - Formulary kits
  - Sequential selling roadmap
  - Best-practice tools and turn-key programs for national launch & post

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ARX-04 ED Launch and Beyond

- Growth opportunities will leverage initial **ED work**, but require different strategies

- Launch market and clear opportunity vs. IVs
- Hospital
- Ambulatory Surgery Centers
- Office Surgeries & Procedures

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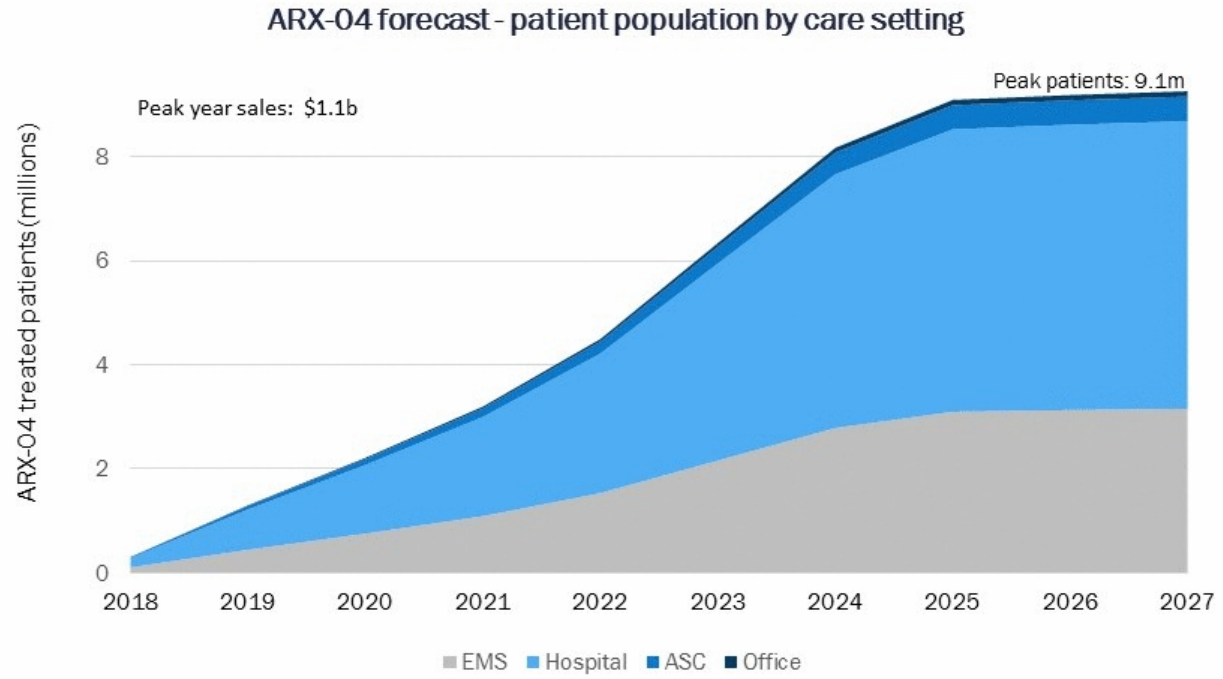
1. Commercial Strategy Support: Buying Processes Development, Deloitte, 2016.
2. EMS World. "9th Annual National EMS Systems Survey." Survey. www.emsworld.com. December 2011. Accessed online 28 November 2016.

ARX-04 Represents a $1.1b Opportunity at Peak Assuming Treatment of an Estimated 9.1 Million Patients with Moderate to Severe Acute Pain



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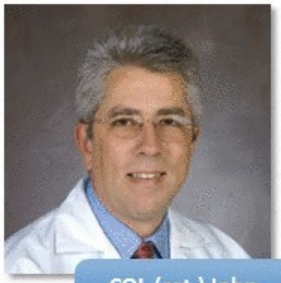
Assuming receipt of a final product label that closely aligns with the company's proposed label submitted to FDA (treatment of moderate-to-severe acute pain severe enough to require an opioid agonist and for which alternative treatments are inadequate, in adult patients in a medically supervised setting).

Source: QuintilesIMS Consulting Services 2016 analysis

Overall We are Excited About the Potential for ARX-04 Starting in the Emergency Department

Emergency Medicine Expert Panel

James Miner, MD, FACEP



COL (ret.) John B. Holcomb, MD, FACS

Michael Ritter, MD, FAAEM, FACEP

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James Miner, MD, FACEP

ARX-04 Primary Investigator
Chief of Emergency Medicine, HCMC

- Dr. James Miner earned his medical degree in 1996 from Mayo Medical School. He completed his residency in emergency medicine at Hennepin County Medical Center (HCMC) in 1999, and joined the HCMC Emergency Department staff.
- Currently, Dr. Miner is the Chief of Emergency Medicine at HCMC. He previously served as director for physician development for HCMC, and research director of the Department of Emergency Medicine. He also serves as professor of emergency medicine at the University of Minnesota Medical School.
- Dr. Miner is board certified in emergency medicine, and has conducted research in the areas of pain management and procedural sedation in the Emergency Department. He has edited and authored works on pain management and sedation, and is the senior associate editor of Academic Emergency Medicine.
- Dr. Miner was a primary investigator for the SAP302 clinical trial, and recruited a majority of study participants from his institution.

COL (ret.) John B. Holcomb, MD, FACS

Director, Center for Translational Injury Research
University of Texas Medical School

- Dr. John Holcomb graduated from the University of Arkansas Medical School and completed a general surgery residency and a fellowship in surgical critical care.
- Dr. Holcomb has served on the surgical staff at several US Army medical centers, and in 1993 as a member of Special Operations deployed to Somalia as a general surgeon during the Battle of Mogadishu. When he returned, he joined the US Army Institute of Surgical Research, where he led a DoD laboratory devoted to combat casualty care.
- During the current war in Southeast Asia he was the trauma consultant for the US Army Surgeon General and conceived and implemented the Joint Theater Trauma System and Damage Control Resuscitation. Since 2001, he has also served on the DoD's Committee for Tactical Combat Casualty Care.
- After retiring from the US Army, Dr. Holcomb joined Memorial Hermann Hospital as the division chief of acute care surgery. In addition, Dr. Holcomb holds several teaching positions, and serves as director of the University of Texas Medical School's Center for Translational Injury Research

Michael Ritter, MD, FAAEM, FACEP

Emergency Department Medical Director
Mission Hospital & Children's Hospital at Mission

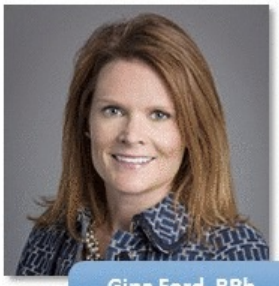
- Dr. Ritter received his medical degree from the University of California, Irvine and completed a residency in emergency medicine at the U.C. Irvine Medical Center, where he served as chief resident.
- He joined the staff of Mission Hospital and Children's Hospital at Mission in 1996 and is currently the medical director of the emergency department at Mission Hospital. He also served as former chairman of the pharmacy and therapeutics committee, credentials committee, and interdisciplinary committee at Mission Hospital. In addition, he is an assistant clinical professor of emergency medicine at UC Irvine.
- He also currently serves as the vice chairman of the Ocean County EMS Executive Committee, and chairman of the St. Joseph's Health System Physician Leadership Council. In 2011, Dr. Ritter received the Physician of the Year Award from the Ocean County Medical Association, and has been named Physician of Excellence by the Association yearly in 2009, 2010 and 2012-to-2015. He is also a recipient of the Joint Commission's Codman Award.

General Q&A/Discussion

Howie Rosen, CEO

Pamela P. Palmer, MD, PhD, Cofounder, CMO

Timothy Morris, CFO & Head of Business Development



Gina Ford, RPh, MBA, VP, Commercial Strategy

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Howie Rosen

Chief Executive Officer and Director

- Mr. Rosen brings more than 25 years of experience in pharmaceutical and biotechnology leadership and strategy to AcelRx.
- Previously, he was vice president, commercial strategy at Gilead Sciences, Inc., and president of ALZA Corporation where he was responsible for all aspects of managing ALZA as an independent 1000-person operating company within the Johnson & Johnson Family of Companies.
- Mr. Rosen received a Master of Business Administration from the Stanford Graduate School of Business, where he graduated first in his class as the Henry Ford II Scholar. Mr. Rosen has a Master of Science in chemical engineering from MIT and he graduated with distinction from Stanford University with a Bachelor of Science in chemical engineering. Mr. Rosen was elected to the National Academy of Engineering in 2005.

Pamela P. Palmer, MD, PhD

Chief Medical Officer, Co-Founder, and Director

- Dr. Pamela Palmer co-founded AcelRx in July 2005, previous to which she was director of the UCSF Pain Center for Advanced Research and Education (PainCARE) from 2005 to 2009, where she gained extensive experience in the treatment of pain.
- Prior to PainCARE, she was medical director of the UCSF Pain Management Center, and worked as a faculty member at UCSF, where she conducted research on basic science mechanisms of pain transmission in her NIH-funded laboratory.
- In 1994 she co-founded Omeros Corporation, a biopharmaceutical company developing small-molecule and protein therapeutics aimed at improving pain management and clinical outcomes of patients.
- Dr. Palmer received a medical degree and a doctorate in neuroscience at Stanford University, and continued on to the University of California, San Francisco for her anesthesia residency.

Tim Morris

Chief Financial Officer & Head of Business Development

- Mr. Morris has served as chief financial officer since 2014 and assumed the additional role as head of business development in 2015.
- Previously, Mr. Morris served as a chief financial officer, senior vice president finance and global corporate development of VIVUS, Inc. from November 2004 to December 2013. At VIVUS Mr. Morris oversaw finance, corporate development, IT, human resources, legal, and investor relations functions.
- Prior to VIVUS, Mr. Morris was chief financial officer, senior vice president finance, manufacturing and administration from September 2001 to November 2004, and was a member of the Office of the President from August 2004 to November 2004 for Questcor Pharmaceuticals, Inc., a specialty pharmaceutical company. Mr. Morris graduated cum laude with a Bachelor of Science in business with an emphasis in accounting from California State University, Chico, and is a certified public accountant.

Gina Ford, RPh, MBA

Vice President, Commercial Strategy

- Gina Ford has worked with AcelRx since 2013 and brings more than 20 years of experience in marketing, sales and commercial strategy.
- Before joining AcelRx, Ms. Ford was principal and sole proprietor of One Joule, a commercial strategy consulting company. During her tenure at One Joule, Ms. Ford provided clients, including AcelRx, with strategic advice on commercial, marketing and market access strategy. She also led launch preparations, including forecasting, market sizing, launch training and communications, and sales territory alignment. Before founding One Joule, Ms. Ford held several leadership roles at Ipsen Pharmaceuticals including Head of Endocrinology Franchise and global market access responsibilities.
- In addition, she had leadership roles at Solstice Neuorsciences and Elan Pharmaceuticals in Market access and strategic business. Ms. Ford was a consultant with Boston Healthcare Associates and led numbers commercialization projects for pharmaceuticals, medical devices and molecular diagnostics.
- Ms. Ford received a Bachelor of Science in pharmacy from Southwestern Oklahoma State University and a Master of Business Administration from Capella University.

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For more information, visit:
www.acelrx.com

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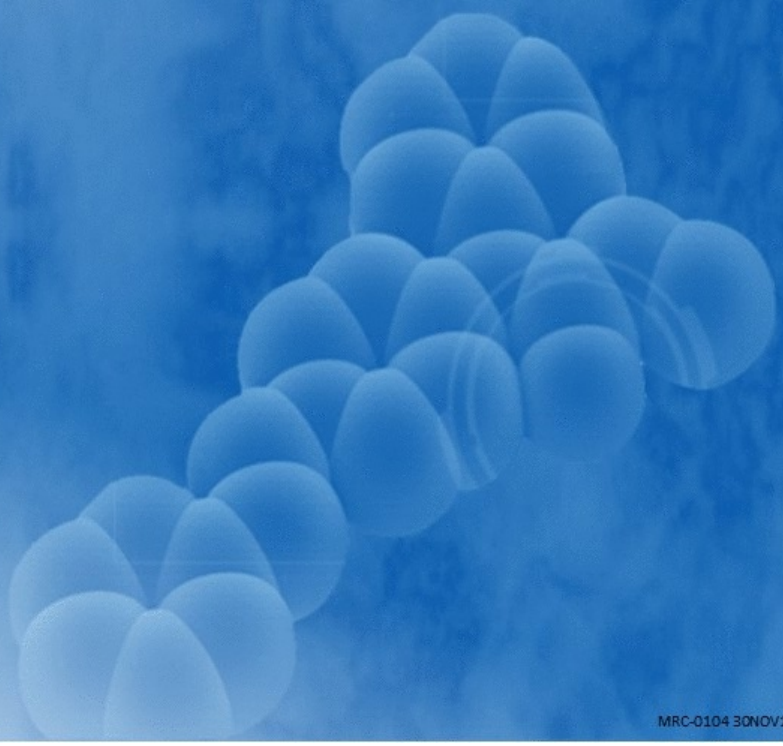

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