

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): October 2, 2015

**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 Regulation FD Disclosure.**  
**7.01.**

AcelRx Pharmaceuticals, Inc. (the “Company” or “AcelRx”) hosted an Analyst & Investor Day on Friday, October 2 in New York from 12:00pm – 2:00pm ET. Members of the management team will discuss the AcelRx late-stage product candidates, Zalviso™ and ARX-04. A comprehensive update was also provided on ARX-04, including recently reported and updated clinical results, anticipated market size and regulatory plans. An update was also provided on Zalviso, which was recently approved for sale in the European Union. 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 is also available in the “Investor Relations” section of AcelRx Pharmaceuticals, Inc.’s website, located at [www.acelrx.com](http://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 Financial Statements and Exhibits.**  
**9.01.**

(d) Exhibits.

**Exhibit**  
**Number Description**

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99.1 Slide presentation entitled, “AcelRx Pharmaceuticals, Inc. New York Analyst Day Presentation October 2, 2015”

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**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: October 2, 2015

ACELRX PHARMACEUTICALS, INC.

By: /s/ Jane Wright-Mitchell

Jane Wright-Mitchell

Chief Financial Officer

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## INDEX TO EXHIBITS

<b>Exhibit Number</b>	<b>Description</b>
99.1	Slide presentation entitled, "AcelRx Pharmaceuticals, Inc. New York Analyst Day Presentation October 2, 2015"



New York  
Analyst Day Presentation  
October 2, 2015

# 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, Zalviso and ARX-04, including AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the U.S., anticipated resubmission of the Zalviso NDA to the FDA including the scope of the resubmission and the timing of the resubmission, and FDA review time; the anticipated timing of the Phase 3 SAP302 study for ARX-04; ability to fund ARX-04 development from the contract with the Department of Defense; financial guidance and cash forecast; the status of the Collaboration and License Agreement with Grunenthal or any other future potential collaborations, including potential milestones and royalty payments under the Grunenthal agreement; and the therapeutic and commercial potential of AcelRx's product candidates, including Zalviso and ARX-04.

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 finalize the pathway towards a resubmission of the Zalviso NDA to the FDA; potential additional clinical studies, Human Factor studies and/or additional data analysis necessary in order to resubmit the Zalviso NDA; AcelRx's ability to receive regulatory approval for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso and ARX-04 in the United States and Europe; AcelRx's ability to receive any milestones or royalty payments under the Grunenthal agreement; 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 planned Phase 3 ARX-04 SAP302 trial and the fact that FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 SAP301 study of ARX-04; AcelRx's ability to complete Phase 3 clinical development of ARX-04 and support ARX-04 development under the contract with the Department of Defense; 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 Pharmaceuticals' U.S. Securities and Exchange Commission filings and reports including its Quarterly Report on Form 10-Q filed with the SEC on August 3, 2015. AcelRx Pharmaceuticals undertakes no duty or obligation to update any forward-looking statement contained in this release as a result of new information, future events or changes in its expectations.

# Agenda

Introduction	Howie Rosen, Interim CEO
Zalviso Update	Howie Rosen, Interim CEO
ARX-04	
Introduction	Pamela Palmer, CMO
Abdominal Surgeries (SAP301)	Harold Minkowitz, M.D.
Emergency Room (SAP302)	James Miner, M.D.
Commercial Opportunity	Gina Ford, VP Commercial Strategy
Physician Discussion	Pamela Palmer, James Miner, Harold Minkowitz
Closing Remarks	Howie Rosen, Interim CEO

## AcelRx Representatives

Howie Rosen	Interim Chief Executive Officer
Pamela Palmer, M.D.	Co-Founder, Chief Medical Officer
Tim Morris	Chief Financial Officer, Head of Business Development
Anil Dasu	Chief Engineering Officer
Jane Wright-Mitchell	Chief Legal Officer
Gina Ford	Vice President Commercial Strategy
Brenda Lemus, M.D.	Senior Director Medical Affairs

# Principal Investigators



**Harold S. Minkowitz, M.D.**

Memorial Hermann Memorial City Medical Center  
Board Certified American Board of Anesthesiologists  
Clinical research expert in post operative pain  
+10 years experience in running pain trials



**James R. Miner, M.D.**

Hennepin County Medical Center  
Chief, Emergency Medicine  
Board Certified Emergency Medicine  
Professor of Emergency Medicine at University of Minnesota  
Clinical research expert pain management and procedural sedation

# AcelRx Mission

Founded in 2005 by Pamela Palmer, M.D. Medical Director of UCSF Pain Management Center

IV-PCA  
(Intravenous Patient Controlled Analgesia)



Human programming errors

Mechanical malfunction

Morphine produces active metabolites

Zalviso™ System

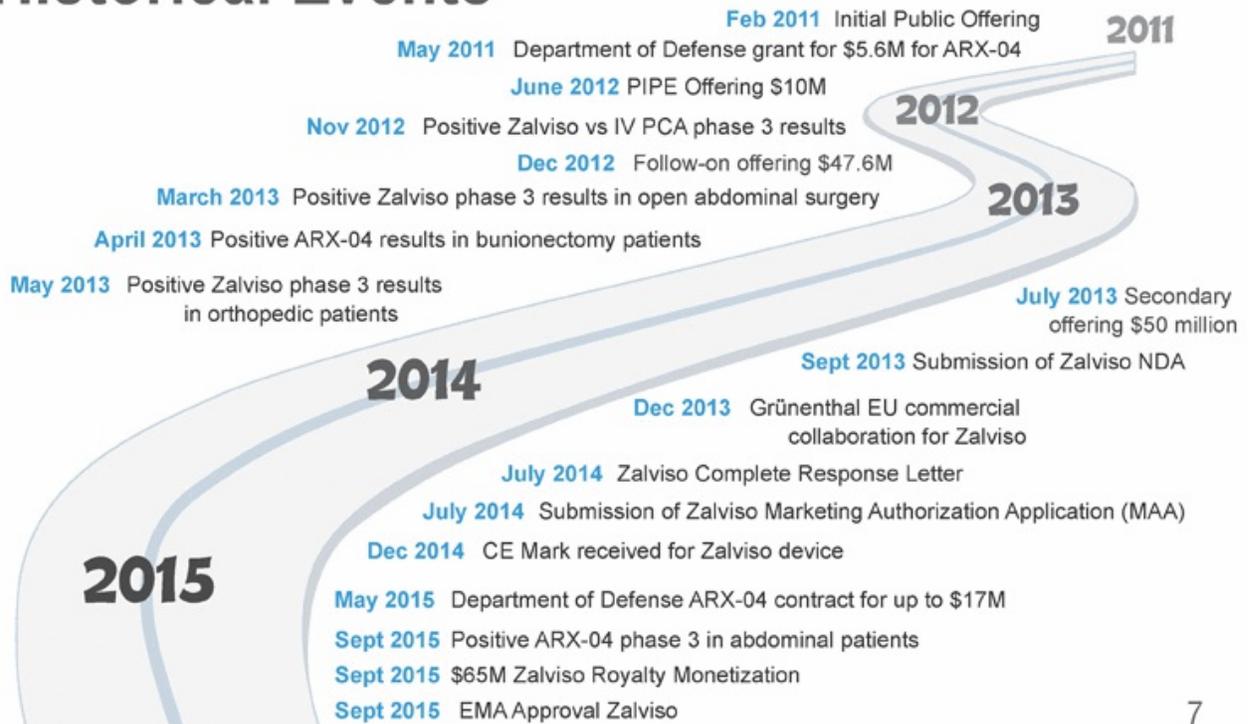


Pre-programmed

non-invasive

No active metabolites

# Historical Events



# Sufentanil Platform

Targets Pain in Multiple Hospital and HCP Settings



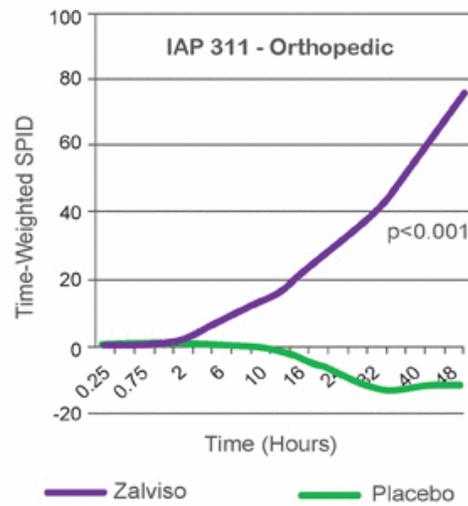
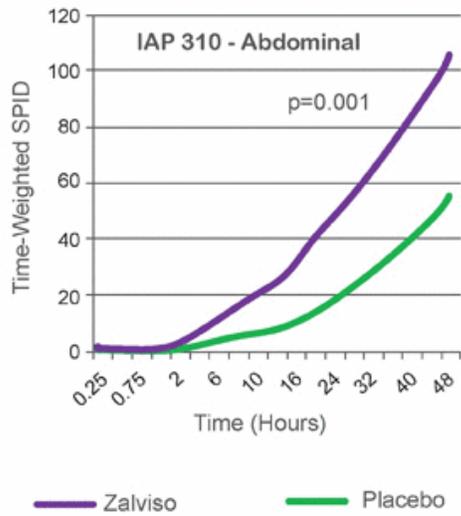
**Zalviso™**

High Therapeutic Index Opioid  
High Lipophilicity  
No Active Metabolites  
Sublingual Delivery  
IV use approved in US & EU



**ARX-04**

# Zalviso Phase 3 Data



# Grünenthal Zalviso Collaboration

Commercial rights to European Union

Total collaboration

- \$30M upfront received
- \$5M on MAA filing received
- \$15M on MAA approval, to be received Q4 2015
- \$28.5 in R+D milestones remain
- \$166 commercial milestones remain (20% of first four worth \$44.5 in total retained as part of PDL deal)
- royalties from mid teens to mid twenties expected over life of agreement (25% retained as part of PDL deal)
- peak revenues expected to be \$150M US



# European Pain Federation Conference

September 2-5, 2015 in Vienna, Austria



# Zalviso Regulatory Update

FDA conference call early September

Attended by senior FDA staff

Expecting meeting minutes soon

Finalizing plans for an additional clinical study to begin in Q1 2016, if needed

## Financial Summary

DoD contract signed May 2015	up to \$17 million
Cash on hand at June 2015	\$51 million
Proceeds from Royalty Monetization Sept. 2015	\$65 million
EU approval milestone (expected Q4 2015)	\$15 million
Projected cash balance Dec 31, 2015	\$100+ million
Outstanding under Hercules Loan	\$23 million
Estimated Operating Cash Burn 2015	~\$40 million

# Milestones

## Upcoming:

Commencing ER Study (SAP-302) for ARX-04	Q4 2015
ARX-04 Pre NDA Meeting	Dec 2015
ER Study Results	H1 2016
ARX-04 NDA Submission	H1 2016

## Completed:

ARX-04 DoD Contract Executed	May 2015
CHMP Positive Opinion	July 2015
ARX-04 SAP301 Topline Data	Sept 2015
Completed \$65M Royalty Deal	Sept 2015
Zalviso MAA Approval	Sept 2015

# ARX-04

Sufentanil Sublingual Tablet, 30 mcg  
Healthcare Professional Administered



## Why Sublingual Sufentanil?

**Sufentanil first synthesized by Janssen in 1974**

**First approved in US for IV delivery in 1984**

Approved for induction of anesthesia

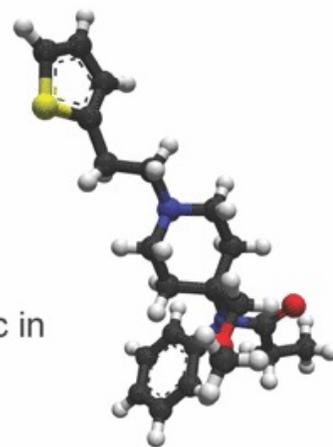
Later approved for epidural delivery as an analgesic in  
combination with bupivacaine

### **Molecular Properties**

Lipophilic –1500 times more fat-soluble than morphine

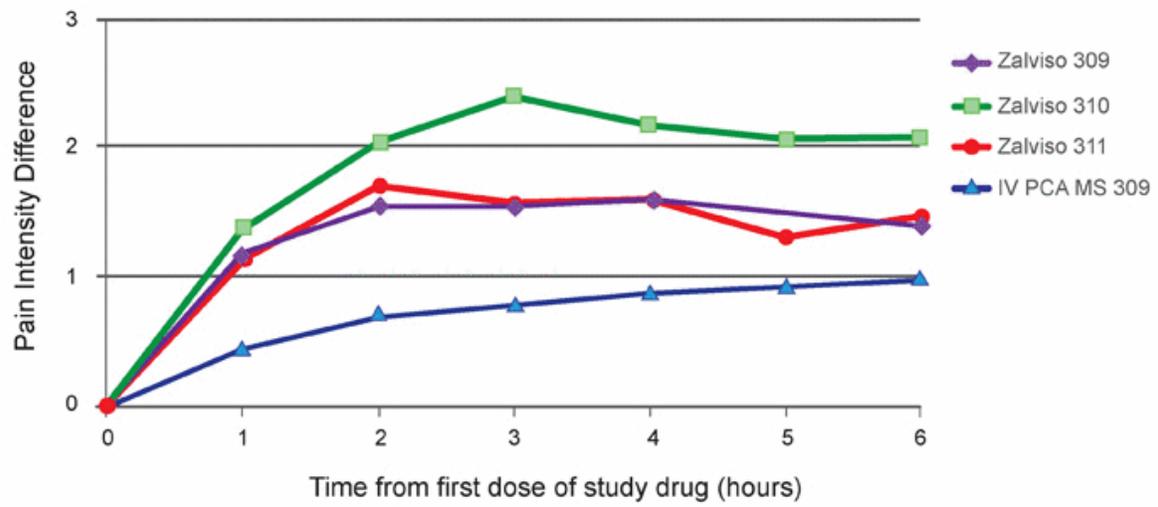
20% non-ionized at physiological pH (fentanyl only 8%)

**Fat-soluble, non-ionized molecules = Fast Brain Penetration**



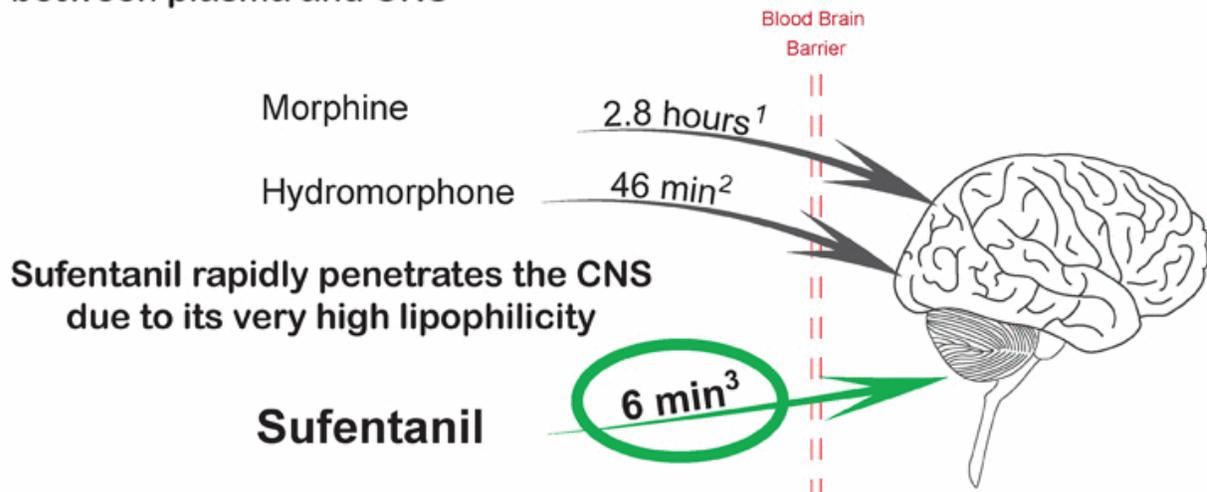
# Sublingual Sufentanil

## Data Shows Consistent Onset



# Sufentanil Transit Time to the Brain

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



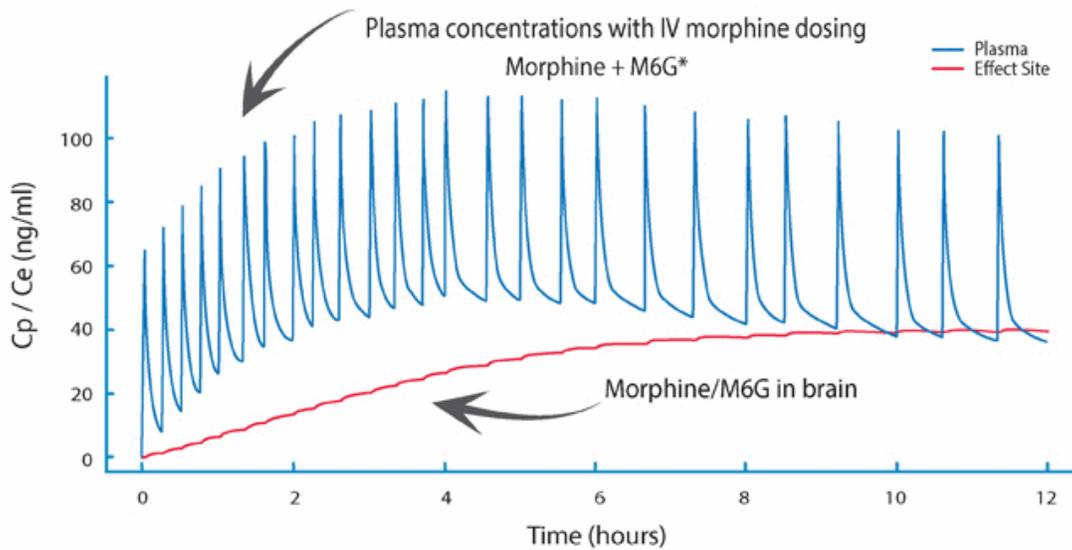
<sup>1</sup> Lotsch et al., Anesthesiol 95:1329-38, 2001

<sup>2</sup> Shafer et al., Geriatric Anesthesiology, 2nd ed. New York, NY: Springer, Chapter 15:209-28, 2007

<sup>3</sup> Scott et al., Anesthesiol 74:34-42, 1991

# Plasma versus Brain Morphine Concentrations

Delayed brain uptake leads to disconnect between IV dosing and effect<sup>1</sup>



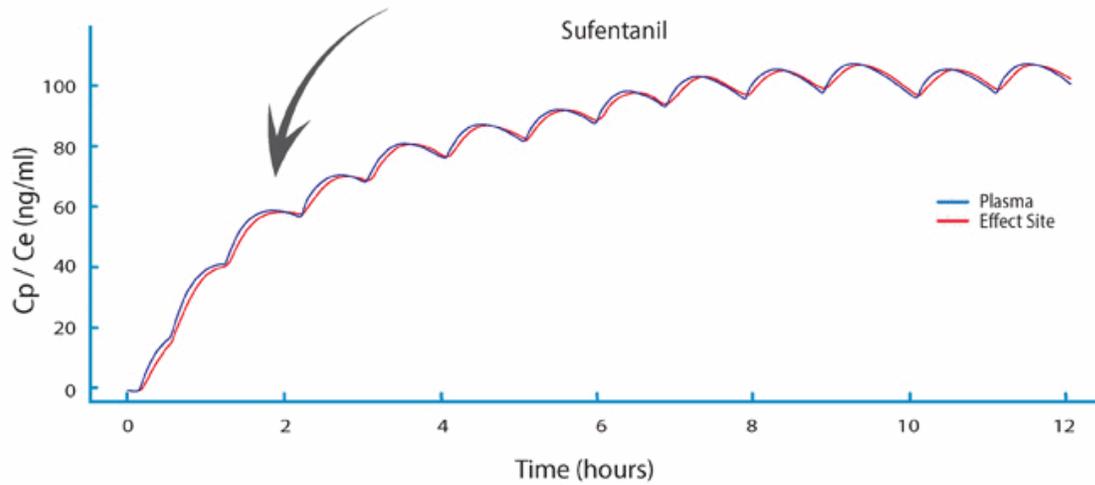
\* Assumes equipotency of morphine and M6G; other potency ratios achieved similar results

<sup>1</sup> IV PCA dosing frequency based in IAP309 Phase 3 study; plasma and brain concentrations modelled from published plasma and CNS equilibration values by Fisher - consultant to AcelRx

# Sufentanil Concentrations

Uptake of sublingual sufentanil leads to potential for real-time tracking Between dosing and effect<sup>1</sup>

Sublingual sufentanil plasma and brain concentrations track together



<sup>1</sup> Plasma and brain concentrations modelled from SST5 PK data and from published CNS equilibration values D. Fisher - consultant to AcelRx

# Sufentanil - High Therapeutic Index

Opioid therapeutic index = lethal dose (LD<sub>50</sub>)/effective dose (ED<sub>50</sub>)

Opioid	Therapeutic Index
Meperidine	5 <sup>1</sup>
Methadone	12 <sup>1</sup>
Morphine	71 <sup>1</sup>
Hydromorphone	250 <sup>2</sup>
Fentanyl	277 <sup>1</sup>
<b>Sufentanil</b>	<b>26,716<sup>1</sup></b>

<sup>1</sup> Mather, Clin Exp Pharmacol Physiol 1995; 22:833.

<sup>2</sup> Kumar, Eur J Pharmacol 2008; 597:39 (ED50) and Purdue Pharma MSDS, 2009 (LD50)

# Sufentanil Lacks Active Metabolites

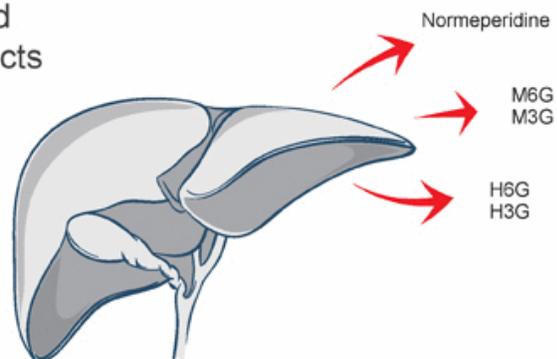
## Commonly used opioids have active metabolites

Meperidine is metabolized to normeperidine which can cause seizures<sup>1</sup>

Morphine and hydromorphone metabolites can accumulate with renal insufficiency following surgery<sup>2</sup>

M3G and H3G can reach high levels and have been linked to neuroexcitatory effects

M6G and H6G can produce delayed opioid-induced adverse events

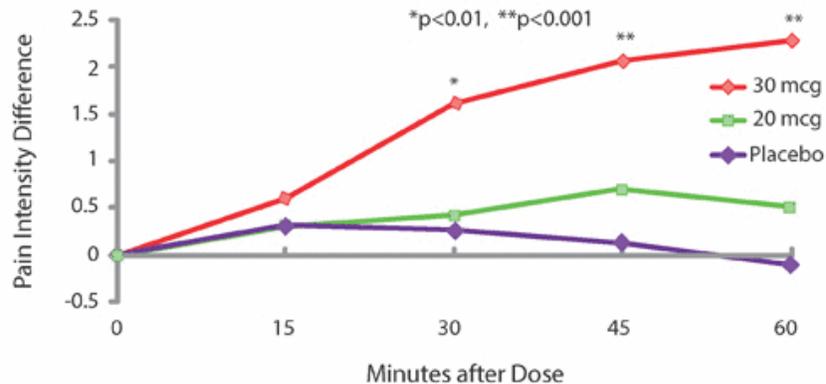


<sup>1</sup> Clark et al., J Emerg Med 13:797-802, 1995  
<sup>2</sup> Mayo Clin Proc 84(7):613-624, 2009

# ARX-04: Dose Finding Study

Successful Phase 2 Bunionectomy Study

Counts as pivotal trial (SPID12,  $p=0.003$ )



## Take Aways:

- ✓ Early onset at 15 minutes
- ✓ Dose Response
- ✓ Highly Statistically Significant
- ✓ Minimal Placebo Response

## ARX-04: SAP301 Phase 3



Announced September 9th, 2015

Pivotal Phase 3 Results

Proposed Indication of Moderate to Severe Acute Pain

Ambulatory Abdominal Surgery

Met all Endpoints (Primary: SPID-12)

Highly Statistically Significant

# ARX-04: Regulatory Progress

## End of Phase 2 Meeting with FDA held December 2013

Confirmed 505(b)(2) submission

500 Patient safety database, 100 multiple dose, 400 single dose

Inclusive of patients from Zalviso database and SAP302

## Work Completed

Secured final DoD funding for phase 3, May 2015

Single & repeat dose definitive PK study

Completed Phase 3 SAP301 study

Initiated open-label study in ER patients SAP302

## DoD History with ARX-04

Approached by US Army to provide alternative to IM morphine in 2011

Battlefield injuries results in significant blood loss and hypovolemic shock

IM morphine and subsequent reperfusion of wounded soldiers suggests sublingual dosing may offer beneficial dosing option

DoD grant award May 2012 for ARX-04 phase 2 studies \$5.6m

DoD contract awarded in May 2015 for up to \$17m anticipated to take ARX-04 to NDA filing

# Intellectual Property

## IP Strategy

Drug-device combination allows  
for broad patent coverage

Integrated IP and regulatory  
strategy designed to minimize  
ANDA exposure

## ARX-04 IP Portfolio

11 US patents issued on NanoTab  
7 US patents issued on Devices  
Coverage through 2027 - 2031

3 EU patents issued on NanoTab  
2 EU patents issued on device  
Coverage through 2027 - 2029

19 issued patents in other territories

11 US applications plus 30+ foreign  
applications in late stage prosecution

## ARX-04: Anticipated Timeline

Pre-NDA Meeting	Q4 2015
ER (SAP 302) Study Completion	Q1 2016
Submit NDA	H1 2016
NDA PDUFA Date	H1 2017



# ARX-04

Sufentanil Sublingual Tablet, 30 mcg  
Healthcare Professional Administered



# **SAP301 Topline Data**

**Harold Minkowitz, MD  
Principal Investigator  
Memorial Hermann Memorial City  
Medical Center, Houston TX**

## SAP301 Study Design

- **Postoperative ambulatory surgery patients following abdominal surgery**
  - open herniorrhaphy
  - abdominoplasty
  - any laparoscopic abdominal surgery
- **Randomized 2:1, active:placebo**
  - Total of 163 randomized and 161 dosed (ITT population)
- **Study completed at 24 hours after first dose**
  - dosing could extend out to 48 hours if needed
- **Primary endpoint: Sum of the pain intensity difference to baseline over the first 12 hours (SPID12)**

# SAP301 Demographics

Category	SAP301			
Sex	Female: 68%			
Age	Mean: 41 years			
Race/ethnicity	Caucasian: 40%	Hispanic: 38%	Afric-Amer: 19%	Asian: 3%
Surgery	Abdominoplasty: 50%	Laparoscopic: 30%	Open Hernia: 20%	
ASA status	ASA 1: 64%	ASA 2: 32%	ASA 3: 4%	
BMI	< 30: 70%			

## SAP301 Patient Disposition

- ITT population: 107 active: 54 placebo
- Completed 24 hr: 102 active: 41 placebo

Reason for Early Termination	ARX-04	Placebo
Adverse Event	0%	3.7%
Lack of Efficacy	3.7%	18.5%
Protocol Violation	0%	1.9%
Withdrawal by Subject	0.9%	0%

## **Primary Endpoint: Time-weighted SPID-12**

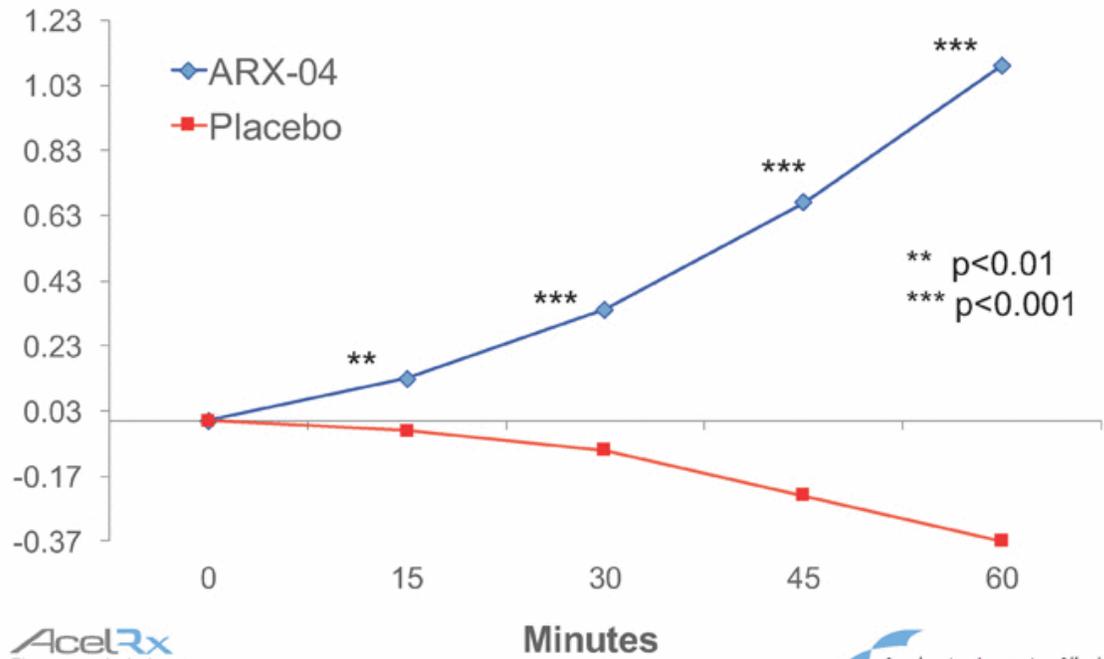
- **SPID = Sum of Pain Intensity Difference to Baseline**
- **Essentially an area under the curve measurement of the drop in pain intensity from baseline over the first 12 hours of the study**
- **SPID12 reflects shorter duration of use compared to SPID48 for Zalviso™ studies**
- **These types of surgery are usually outpatient and the patient is usually discharged by 12 hours**
- **Patients kept overnight for up to 48 hours for the purposes of this study**

## Primary Endpoint: SPID-12

- Pain intensity measured on a scale of 0 – 10  
(0 = no pain, 10 = worst pain imaginable)

Assessment	ARX-04	Placebo	P-Value
Baseline	5.6	5.5	NS
SPID-12	25.8	13.1	p<0.001

# SPID Over First Hour of Treatment



## Secondary 12-Hour Endpoints

Endpoint	ARX-04	Placebo	P-Value
TOTPAR-12	21.2	15.4	p<0.001
SPRID-12	47.0	28.6	p<0.001

TOTPAR: total pain relief as measured on a 0-4 scale (summed)  
SPRID: summed pain intensity/pain relief composite measure

## Secondary 24-Hour Endpoints

Endpoint	ARX-04	Placebo	P-Value
SPID-24	58.0	37.3	p<0.001
TOTPAR-24	45.8	35.5	p=0.001
SPRID-24	103.9	73.1	p<0.001
PGA-24	80.4%	51.9%	p<0.001
HPGA-24	80.4%	53.7%	p<0.001

PGA: patient global assessment ratings of "good" or "excellent"

HPGA: healthcare professional global assessment ratings of "good" or "excellent"

## Number of ARX-04 Tablets Dosed

Time Period	Number [median (range)]	Interdosing Interval [mean]
0 – 12 Hours	4 (1 – 9)	185 minutes
0 – 24 Hours	7 (1 – 15)	221 minutes

## Rescue IV Morphine Use

	ARX-04	Placebo	P-Value
Patients Using Rescue (%)	27.1%	64.8%	p<0.001

## Adverse Events

- **Total of 2 Serious Adverse Events (SAEs): hemiparesis and syncope**
  - Both related to study drug, in placebo group, and caused drop-out prior to 24 hours
- **There was one patient in the ARX-04 group that dropped out due to an adverse event during the extension period after 24 hours due to “oxygen saturation decreased” rated as mild and not related to study drug**

## Adverse Events (>3% in either group)

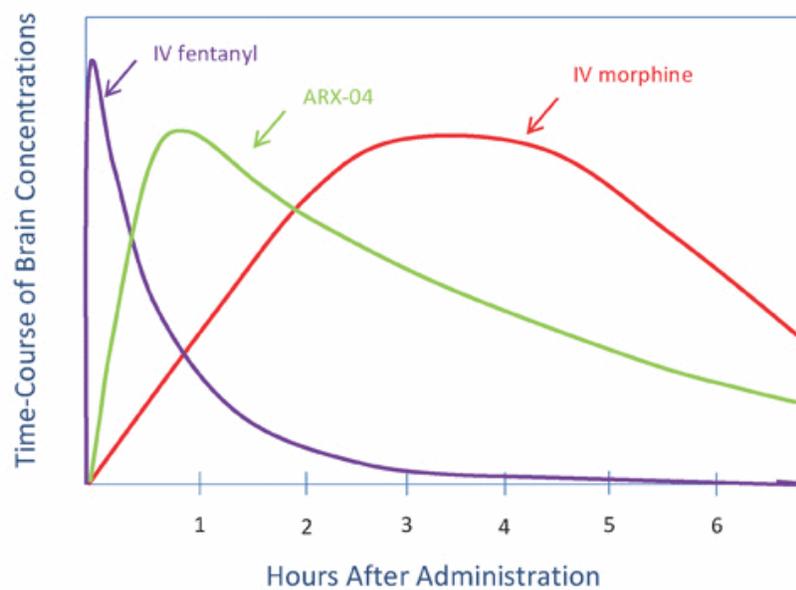
- No statistical difference for ARX-04 compared to placebo

Adverse Event	ARX-04	Placebo
No Adverse Event	42.1%	37.0%
Nausea	32.7%	29.6%
Headache	19.6%	18.5%
Vomiting	7.5%	1.9%
Dizziness	5.6%	3.7%
Hypotension	4.7%	3.7%
Flatulence	3.7%	7.4%
Somnolence	2.8%	3.7%
Procedural nausea	2.8%	5.6%
Pruritus	1.9%	3.7%

# **ARX-04 in the Emergency Room**

**James Miner, MD  
Principal Investigator, SAP302  
Chief of Emergency Medicine  
Hennepin County Medical Center,  
Minneapolis, MN**

# ARX-04



## SAP302 Study Design

- **ARX-04 single-dose treatment, open-label, evaluating safety and efficacy in patients presenting to the ER with trauma or injury associated with moderate-to-severe pain**
- **Exclusions:**
  - pregnancy
  - opioid-tolerant (taking more than 15 mg oral morphine equivalent daily)
  - dependent on supplemental oxygen
- **Primary efficacy endpoint: SPID1**
  - Summed pain intensity difference to baseline over first hour after receiving ARX-04

# SAP302 Study Design

- **Key safety endpoints**
  - Six-Item Screener (cognitive impairment test): pre-dose and one-hour post-dose
  - Adverse events
  - Vital signs
- **The novel single dose applicator along with the sublingual dosage form of sufentanil provide potential benefits in many clinical settings:**
  - Paramedic/military use
  - Emergency rooms
  - Ambulatory surgery recovery rooms

## SAP302 Timeline

- **Study initiation** **September 2015**
- **Additional clinical sites initiated** **Q4 2015**
- **Final visits planned** **January 2016**
- **Top line results** **Q1 2016**



# Same Molecule Different Opportunities

## US Product Opportunities for Sublingual Sufentanil Tablets



**Zalviso  
Market Potential**



**ARX-04  
Market Potential**

<sup>1</sup>Recent Zalviso analyst estimates  
<sup>2</sup>ZS Associates 2014 and Millennium 2010

# ARX-04 Key Points

**ARX-04 leverages our knowledge of sublingual sufentanil**

Utilization - multiple settings across a range of physician specialties

Largest opportunity for ARX-04 is the US Emergency Departments

Ambulatory Surgery Centers (ASC) are a key target

Other Hospital and Office Based Procedures present additional opportunity

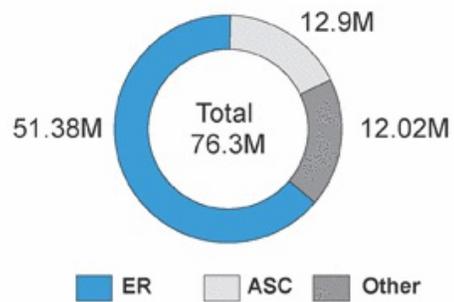


# Potential ARX-04 Market

175M Patients Annually



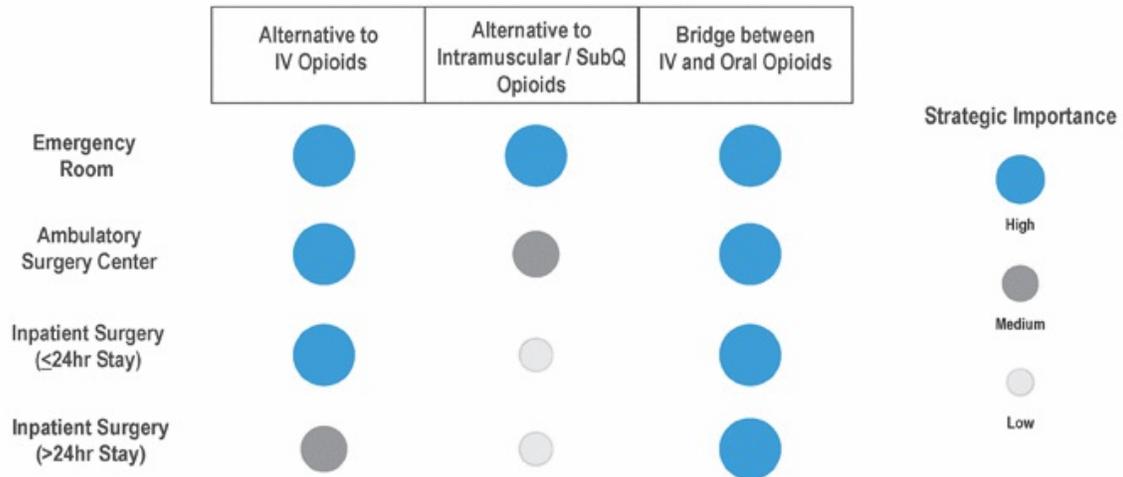
Moderate to Severe  
Pain Patients



Data on file. In-house commissioned market research. ZS Associates "Opportunity Assessment, US & EU" Study dated August 8, 2014  
Ambulatory Surgery Center Association and Ambulatory Surgery Foundation, History of ASCs, [www.advancingsurgicalcare.com](http://www.advancingsurgicalcare.com)  
Emergency Medicine Network, National Emergency Department Inventory, [www.emnet-usa.org](http://www.emnet-usa.org)  
Data on file. In-house commissioned market research. Millennium Research Group "US Market Opportunity Study for Sublingual Sufentanil" Study dated March 24, 2010

# ARX-04 Potential

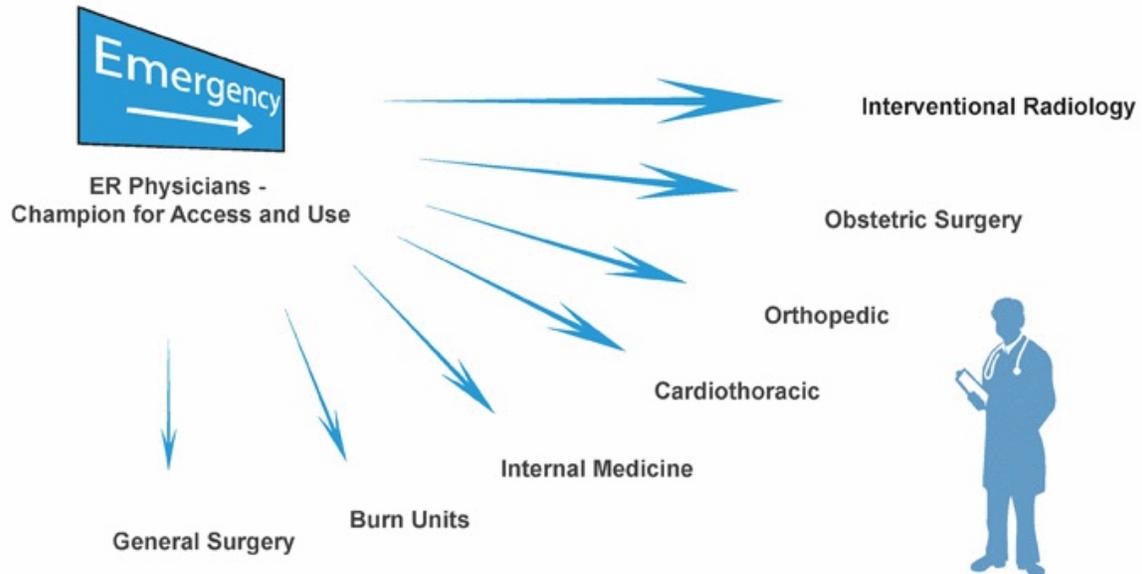
ARX-04 Place in Treatment Algorithm



Note: Assessment is based on ARX-04's ability to replace current treatment, and the likelihood of that treatment being used in each setting. Market Research indicates likely ability to succeed in the ER segment as high.

Data on file. In-house commissioned market research. ZS Associates "Opportunity Assessment, US & EU" Study dated August 8, 2014

# ER: Hospital Front Door



Data on file. In-house commissioned market research. ZS Associates "Opportunity Assessment, US & EU" Study dated August 8, 2014  
Data on file. In-house commissioned market research. Millennium Research Group "US Market Opportunity Study for Sublingual Sufentanil" Study dated March 24, 2010

# ER Pain Management Gap

## **No Entrenched Standard of Care**

### **Protocols are not standardized**

Assessing route of administration is often the first step

Is IV Administration required?

Is the PO (Oral) route available?

Is IV administration possible?

# Emergency Room Market

Highest number of eligible patients

Opportunities for use

Alternative to IV or IM opioid

Bridge to oral therapy

Acute exacerbation of painful chronic condition

Straight forward sales targeting

Geographically, highest tiered potential

Contract based call point – ER Specialty

Formulary adoption

ER physicians demonstrate high willingness  
to support formulary adoption



## US ER Market Potential

**\$2B +**

Total ER US Patients	110M
Patients with M/S-aP	51M
Patients on ARX-04 (range)	5.4M - 6.7M
ARX-04 Doses (range)	12M - 14.7M

8

# Ambulatory Surgery Care (ASC) Market

AcelRx expected to launch ARX-04 in ASC in addition to ER

ASC's include corporations, hospitals, and physicians

Highly concentrated ownership among ASC

Top-down approach

Establish corporate partnerships with 3-5 large systems<sup>1</sup>

Formulary Approval Process

Medical affairs to present clinical data to secure formulary position

Pharmaco-economic considerations

Committee Review and Approval

Sales team responsible for pull-through in ASC geography



<sup>1</sup> 639 ASC owned by 5 Corporations

# Ambulatory Surgery Center



Outpatient Surgical Discharges (2014)	31M
Potential Patients with M/S-aP	13M
Potential Patients treated with ARX-04	5.7M

Potential ARX-04 Doses

Base 17.2M

Low 13.8M    +/-20%    High 20.6M

## US ASC Market Potential

\$1B

Mean Doses	<u>12 hours</u>	<u>24 hours</u>
Sufentanil (30mcg)	4.4	7.0
Placebo	4.7	6.4

Data on file. In-house commissioned market research. ZS Associates "Opportunity Assessment, US & EU" Study dated August 8, 2014

# Commercial Access

ARX-04 will be subject to a formulary process

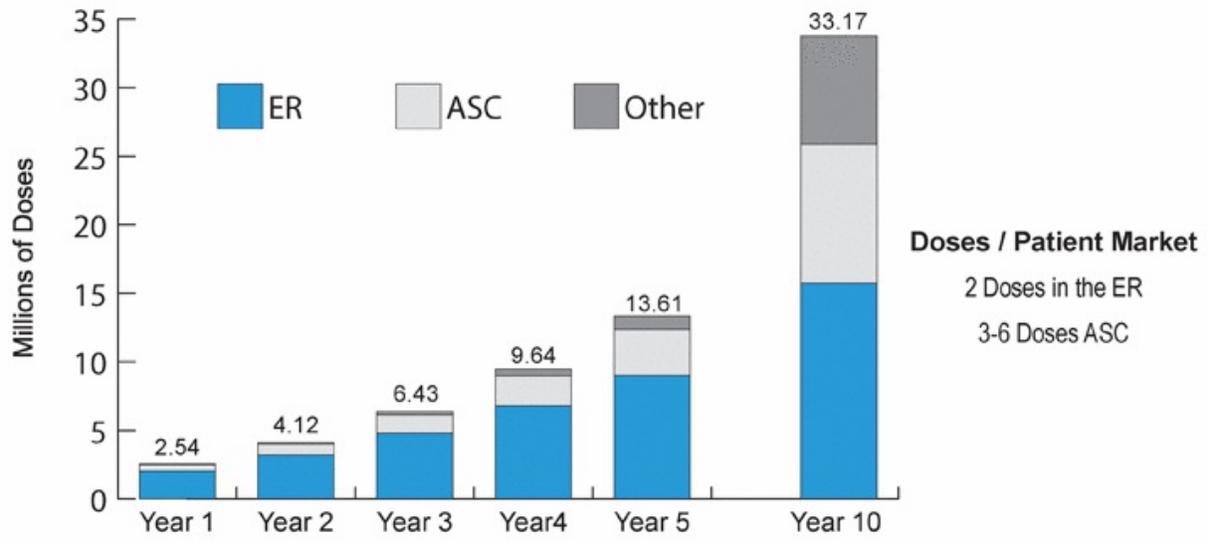
## Recent Conclusions

Payers have exhibited a positive reception for Sufentanil  
Expect hospitals to manage use based on cost

Payers stated that regardless of the site of care (ER vs inpatient, vs ASCs),  
sublingual Sufentanil is expected to be covered

Methods of payment include - J-code for outpatient, DRG for inpatient use,  
and line item in some situations

# ARX-04: Estimated Doses



Data on file. In-house commissioned market research. ZS Associates "Opportunity Assessment, US & EU" Study dated August 8, 2014

# DoD Contractual Relationship



United States Army Medical Research and Materiel Command (USAMRMC)

DoD has provided funding for the program since inception

Partial funding for phase 3 clinical, manufacturing, and regulatory activities

DoD initial purchase order for up to 200,000 commercial units at \$20 / unit

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# Commercial Path to Launch

## **Market Strategy**

- Single qualitative study completed
- Additional qualitative and quantitative research
- Hospital segmentation and targeting
- Demand / revenue model refinement

## **Market Access**

- Healthcare payer, ASC contracting, hospital formulary research
- Formal pricing study
- Distribution strategy crucial to reaching all settings

## **Creative Development**

- Positioning and value proposition
- Message development
- Core visual design and content

## Summary

Leverages sublingual sufentanil platform

ARX-04 utilization targets multiple settings of care

Emergency Department is the largest opportunity

Emergency Department use expected to drive additional hospital use

Ambulatory Surgery Centers are the next largest market

Other Hospital and Office-Based Procedures present additional opportunity



# AcelRx

Pharmaceuticals, Inc.