

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): January 8, 2017

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 2.02 Results of Operations and Financial Condition.

AcelRx Pharmaceuticals, Inc. (the “Company” or “AcelRx”) will be providing financial information about the Company’s cash and outstanding loan balances as of December 31, 2016 in the Company’s presentation handout to be utilized in various meetings with securities analysts and investors during the J.P. Morgan Healthcare Conference from January 9, 2017 through January 12, 2017 in San Francisco, and The Trout Group Annual 1x1 Management Access Event from January 10, 2017 through January 13, 2017, also in San Francisco. The aforementioned financial information is included on slides #36 and #39 of the presentation handout, as furnished in Exhibit 99.1 to this Current Report and is incorporated herein by reference.

The information contained in this Item 2.02 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 Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The information contained in this Item 2.02 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 7.01. Regulation FD Disclosure.

AcelRx will participate in various meetings with securities analysts and investors during the J.P. Morgan Healthcare Conference from January 9, 2017 through January 12, 2017 in San Francisco, and The Trout Group Annual 1x1 Management Access Event from January 10, 2017 through January 13, 2017, also in San Francisco, 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.ace.rx.com.

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

Item 8.01. Other Events.

On January 8, 2017, the Company issued a press release entitled “AcelRx Pharmaceuticals Announces DSUVIA™ as Brand Name for ARX-04” a copy of which is attached as Exhibit 99.2 to this Report.

Also on January 8, 2017, the Company issued a press release entitled “AcelRx Pharmaceuticals Provides Guidance on 2017 Milestones for ARX-04, now known as DSUVIA™ in the United States, for the Treatment of Moderate-to-Severe Acute Pain” a copy of which is attached as Exhibit 99.3 to this Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Slide presentation entitled, “AcelRx Pharmaceuticals Corporate Overview January 2017”
99.2	Press release dated January 8, 2017 entitled, “AcelRx Pharmaceuticals Announces DSUVIA™ as Brand Name for ARX-04 in the United States”
99.3	Press release dated January 8, 2017, entitled “AcelRx Pharmaceuticals Provides Guidance on 2017 Milestones for ARX-04, now known as DSUVIA™ in the United States, for the Treatment of Moderate-to-Severe Acute Pain”

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: January 9, 2017

ACELRX PHARMACEUTICALS, INC.

By: /s/ Jane Wright-Mitchell

Jane Wright-Mitchell
Chief Legal Officer

INDEX TO EXHIBITS

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AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX)

Corporate Overview
January 2017

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, DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as ARX-04 outside the United States, and ZALVISO® (the sufentanil sublingual tablet system), including U.S. Food and Drug Administration, or FDA, review of the New Drug Application, or NDA, for DSUVIA; the potential approval by the FDA of the NDA for DSUVIA; the ARX-04 and DSUVIA clinical trial results; AcelRx's pathway forward towards gaining approval of ZALVISO in the United States, 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 DSUVIA, 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' DSUVIA and ARX-04 development program, including the FDA review of the DSUVIA NDA in the United States and the possibility that the FDA may dispute or interpret differently clinical results obtained from the Phase 3 DSUVIA and ARX-04 studies; the ZALVISO development program, including successful 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 DSUVIA in the United States, ARX-04 in 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.

Anticipated Launch of a New Approach for Treating Moderate-to-Severe Acute Pain

DSUVIA Highlights

- NDA submitted December 12, 2016
 - Sublingual sufentanil tablet pre-filled in a disposable single-dose applicator
 - 505(b)2 with 4 clinical studies and 900+ patient safety database
- US market Opportunity >\$1 billion in multiple settings¹:
 - EMS - Pre-hospital and Emergency Departments
 - Short-stay and In-patient Surgeries
 - Ambulatory Surgery Centers
 - Interventional and Office-based Procedures
- CII with Distribution Control
 - Label: "Medically Supervised Settings"
 - No Retail Distribution (REMS)



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1. Data on file. In-house commissioned market research. QuintilesIMS, "ARX-04 and ZALVISO US forecast" December 2016

MRC-0106 06JAN17

Department of Defense Provides up to \$22M in Support for the Development of DSUVIA

Battlefield

- IM morphine standard of care¹
- IM dosing often ineffective due to shock and lack of circulation to muscles; death can occur due to oxygen desaturation upon reperfusion²
- IV lines time-consuming and challenging to start
- DoD Needs: Rapid onset with predictable offset and minimal cognitive effects



Civilian Equivalent = EMS/ED

- Guidelines support opioids for moderate-to-severe acute pain³
- IV lines can be challenging to start in field or in moving ambulances⁴
- Can take 30 minutes or more to have an IV line inserted in ED⁵



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/18Xpa2>
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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DSUVIA is funded in part by the Clinical and Rehabilitative Medicine Research Program (CRMRRP) of the U.S. Army Medical Research and Materiel Command (USAMRMC) under contract No. W81XWH-15-C-0046.

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The AcelRx Difference: Proprietary¹ Sufentanil Sublingual Tablets Have Unique Properties

Sufentanil

- **Lipophilic** absorbed sublingually
- **Potent** 30 mcg in small tablet possible (4-8 mg liquid morphine in syringe often used IV now²)
- **Low GI bioavailability³** minimizes delayed effect of swallowed drug

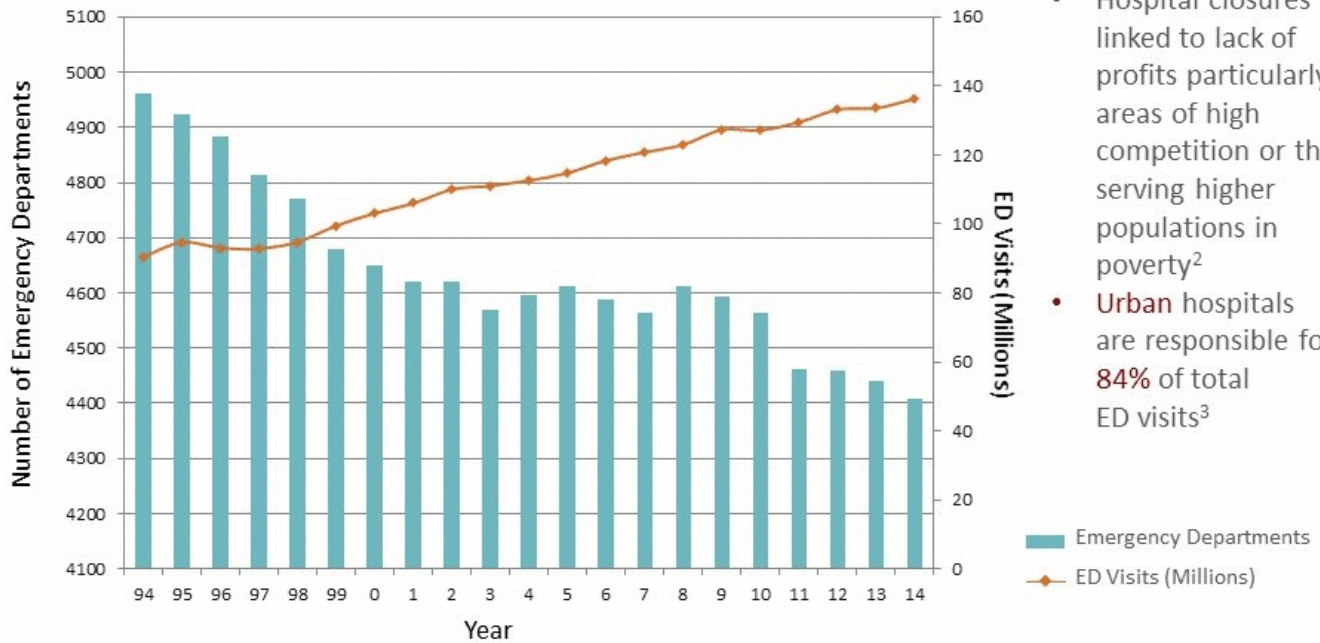


Tablet

- **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



Number of Emergency Departments 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 poverty²
- **Urban** hospitals are responsible for **84%** of total ED visits³

■ Emergency Departments
—●— ED Visits (Millions)

1. Aha.org [Internet] TrendWatch Chartbook 2015;c2015. Available from <http://www.aha.org/research/reports/tw/chartbook/2015/15chartbook.pdf> (Graph) (accessed 2016, November 23)
 2. Rand.org [Internet] Factors Associated with Closures of Emergency Departments in the United States. Available from http://www.rand.org/pubs/external_publications/EP20110092.html (accessed 2016, November 23)
 3. American Hospital Association Annual Hospital Survey - purchased May 2016

Emergency Department Patient Crowding and Wait Times are Becoming More Critical



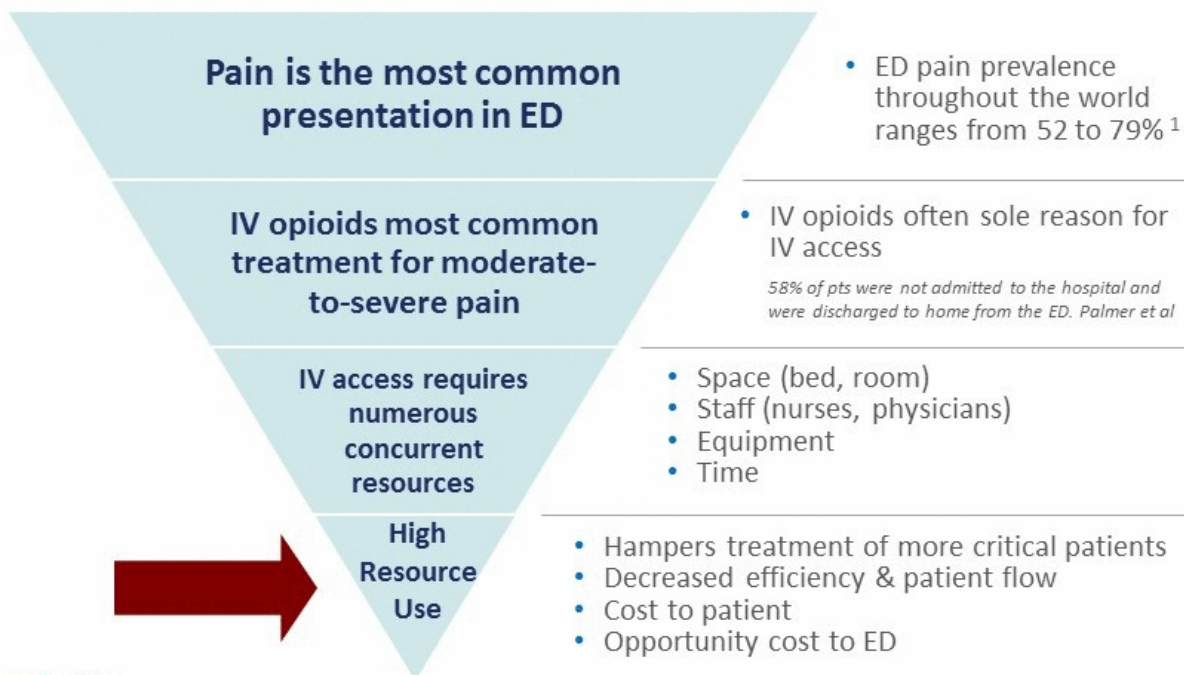
American College of Emergency Physicians Recognizes the Impact of ED Crowding

According to the ACEP, many EDs experience critical overcrowding and heavy emergency resource demand, leading to

- Treatment of patients in areas not designed for treatment
- Decreased patient satisfaction
- Significant delay in evaluation and treatment
- Increased costs
- Increased ambulance diversion time

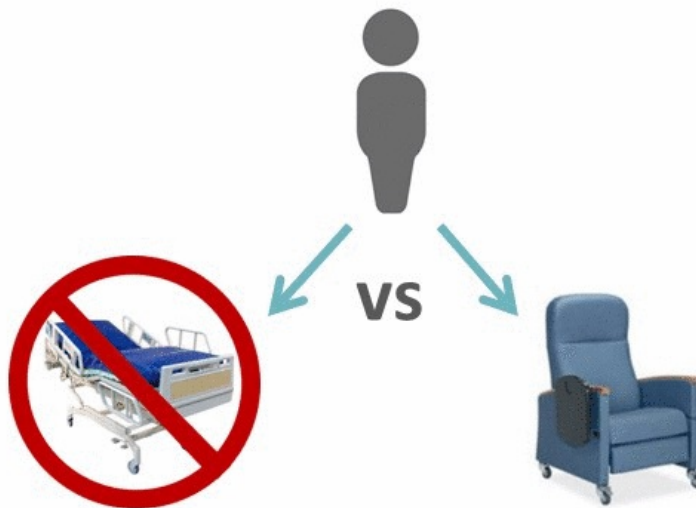
Ultimately hampering the delivery of high-quality medical care and compromising patient safety

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



DSUVIA May Provide Treatment Option That Works to Optimize Resources and May Help Address Patient Overcrowding

DSUVIA 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.



DSUVIA: Sufentanil Sublingual Tablet (SST) 30 mcg Clinical Summary

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SST 30 mcg Clinical Program Included More Than 900 Patients

Study	Number of Patients	Study Design	Mean # 30 mcg Doses / Study Period	Efficacy Endpoint	Efficacy
SAP202	100	Multi-center, randomized, placebo-controlled, postoperative	4.9 / 12h	SPID12: ARX-04 vs placebo	SST 30 mcg demonstrated pain relief over placebo
SAP301	161	Multicenter, randomized, placebo-controlled, postoperative	7.0 / 24h	SPID12: ARX-04 vs placebo	SST 30 mcg demonstrated pain relief over placebo
SAP302	76	Multicenter, Open-Label, Emergency Department	1.1 / 2h	Drop in pain intensity from baseline	SST 30 mcg patients had >35% drop in pain at one hour after a single dose
SAP303	140	Multicenter, Open-Label, postoperative	3.3 / 12h	Drop in pain intensity from baseline	SST 30 mcg patients had 57% drop in pain
Select ZALVISO® Patients ¹	427	Varied, postoperative	N/A	SPID48: SS vs. placebo or IV PCA morphine	Sublingual sufentanil patients demonstrated pain relief over placebo and morphine

**TOTAL
904**

SPID12 = summed pain intensity difference to baseline over 12 hours

Postoperative Studies: SST 30 mcg Studied in Postoperative Pain Across a Variety of Surgery Procedures in Multiple Surgical Settings

SAP202: ASC

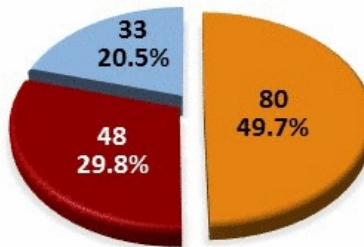


Surgery Type

- Bunionectomy

100 Total patients

SAP301: ASC

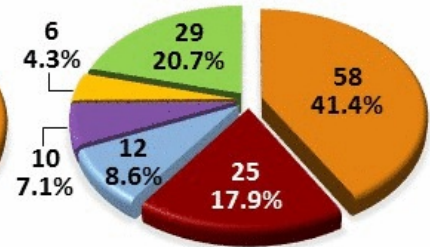


Surgery Type

- Abdominoplasty
- Laparoscopic Abdominal
- Hernioplasty

161 Total patients

SAP303: Hospital



Surgery Type

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

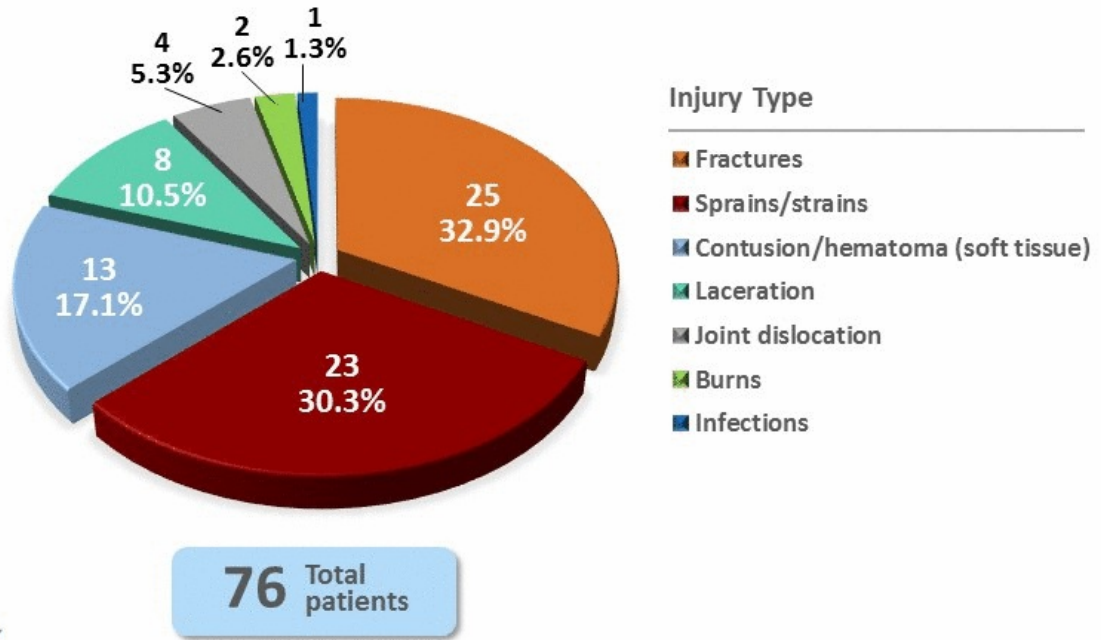
140 Total patients

Most Common Adverse Events:^{*} All SST 30 mcg Phase 2 and 3 Studies Demonstrate No Meaningful Difference Compared to Placebo

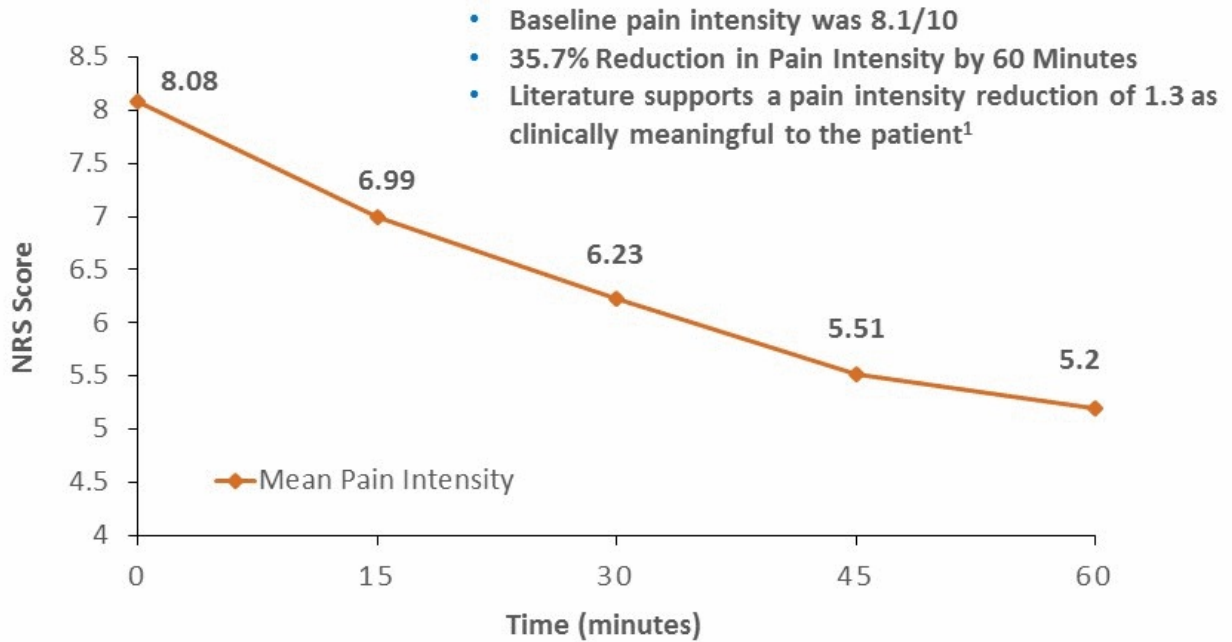
Adverse Event, n(%)	Combined Sufentanil (N=363)	Combined Placebo (N=74)	Treatment p-value
Nausea	105 (28.9)	16 (21.6)	NS
Vomiting	26 (6.3)	1 (1.4)	NS
Headache	29 (8.0)	10 (13.5)	NS
Dizziness	21 (5.8)	3 (4.1)	NS
Somnolence	15 (4.1)	2 (2.7)	NS
Pruritus	11 (3.0)	2 (2.7)	NS
Hypotension	8 (2.2)	1 (1.4)	NS
Flatulence	4 (1.1)	4 (5.4)	0.031
Procedural nausea	3 (0.8)	3 (4.1)	NS

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

Trauma classifications



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

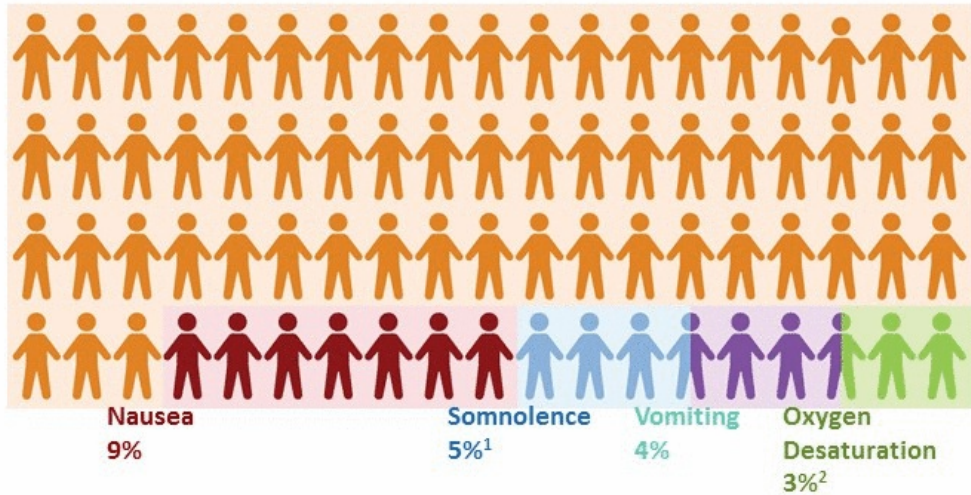


SAP302 Emergency Department: 79% of Patients in SAP302 Reported no Side Effects

Adverse Events (> 2% of patients)

SST (30 mcg)
n=76

No
Adverse
Event
79%



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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)

Additional Results from Clinical Program Provide Support for Safety, Efficacy and Ease of Use for SST 30 mcg

- 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 SST 30 mcg 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.
- Six-Item Screener demonstrated no effect on cognition by SST 30 mcg in SAP302.

DSUVIA Commercial Launch Planning

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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) (completed Dec 2016)
- Market Access Strategy
- Brand Identity and Packaging

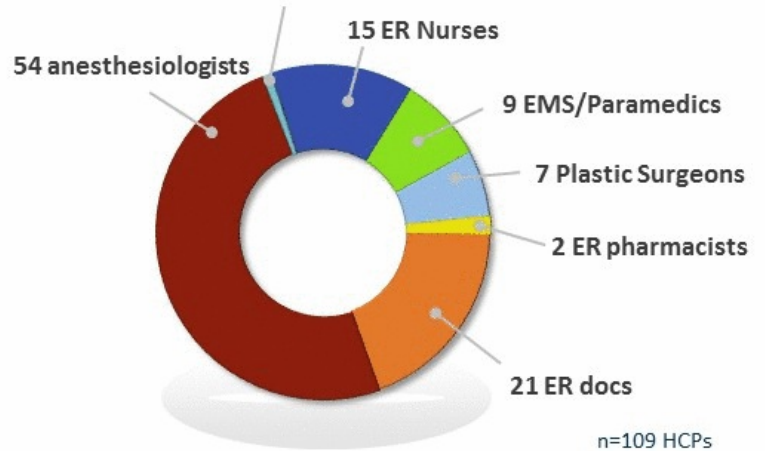
EU work included Forecast and Market Access

2016 KOL Engagement

Completed 9 Advisory Boards

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

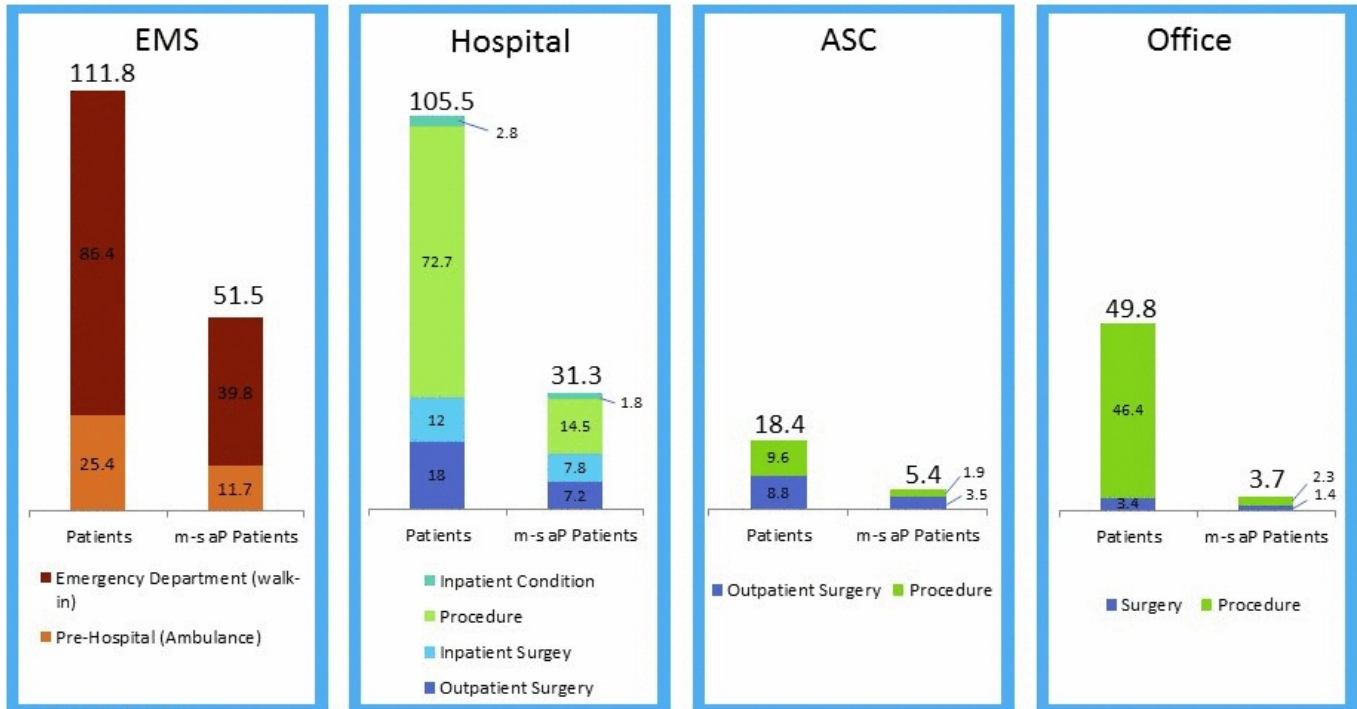
1 Physicians Assistant



- Engaged DSUVIA Educational Outreach Advisory Board on 3 occasions

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Estimated 2017 DSUVIA Eligible Adult Moderate-to-Severe Acute Pain (m-s aP) Population is 91.9 Million in Hospital and Non-hospital Settings



Market Research has Highlighted Some Potential Emergency Department Applications for DSUVIA



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

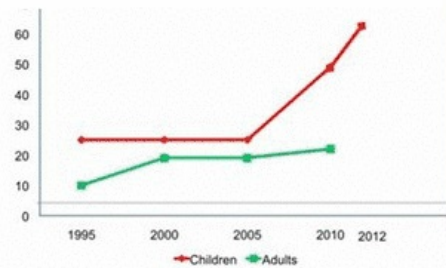
Market Research has Identified Additional Patient Populations that May Benefit from DSUVIA

- **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 patients¹
 - Potentially **1.5 million DSUVIA** ED patients²



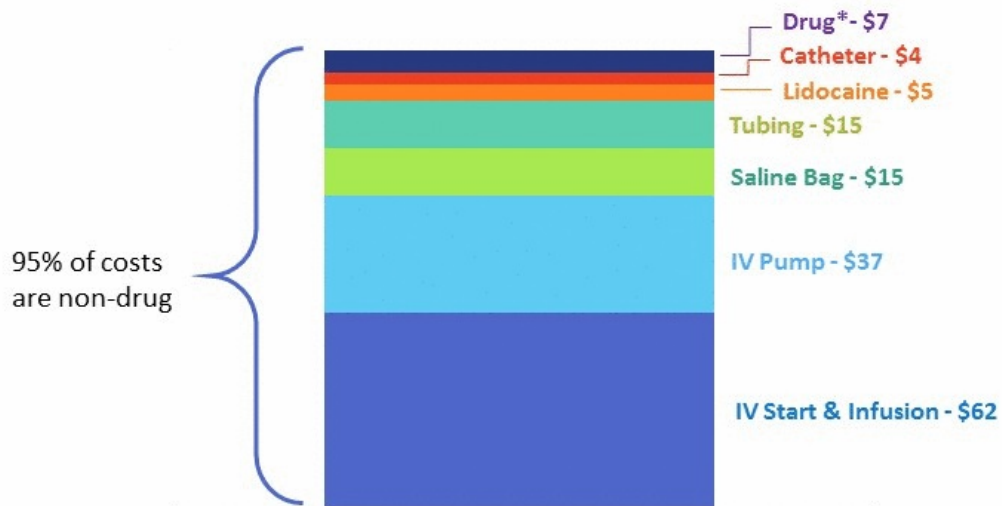
- Needle-phobia population over time³



1. Pubmed <https://www.ncbi.nlm.nih.gov/pubmed/7636457> (accessed 2016, November 23)
2. Hcup.net [Internet] HCUPnet: A Tool For Identifying, Tracking, And Analyzing National Hospital Statistics". Available from Hcupnet.ahrq.gov (accessed 2016, November 2)
3. Connecticut by the Numbers <http://ctbythenumbers.info/2013/12/15/pediatricians-invention-stop-pain-injections-improve-public-health/> (accessed 2016, November 23)
4. Pub Med <https://www.ncbi.nlm.nih.gov/pubmed/25171796> (accessed 2016, November 23)

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

Component Costs of IV Opioid Dose



Pilot Program Will Help Establish Best Practices Prior to Full Deployment and Commercial Launch



Objectives

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

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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

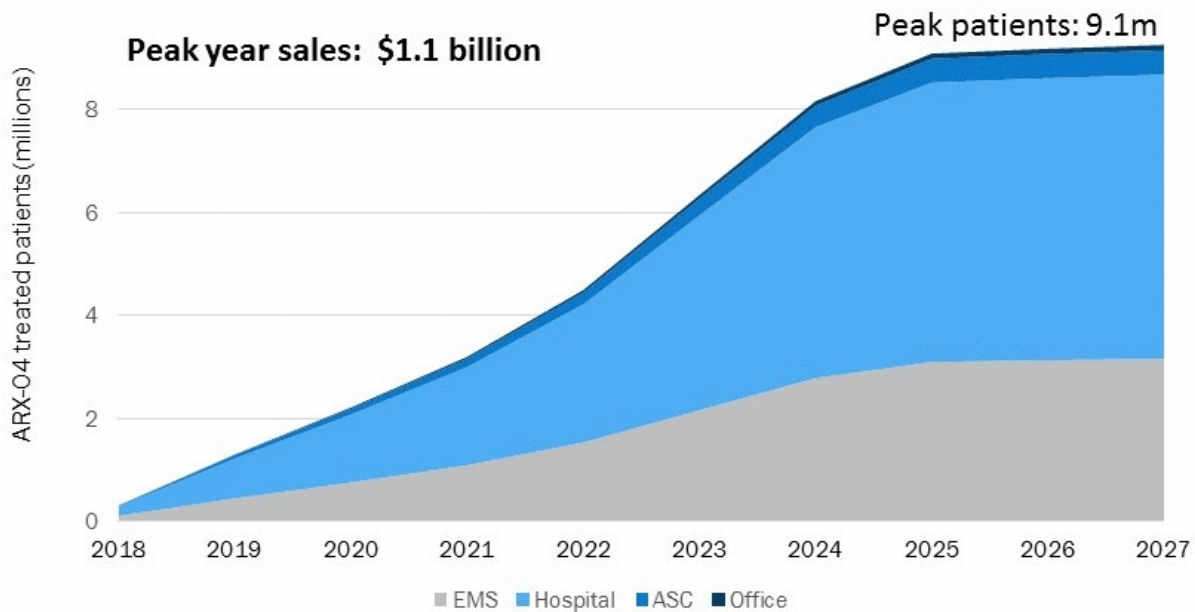
DSUVIA Emergency Department Launch and Beyond

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



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

DSUVIA forecast - patient population by care setting



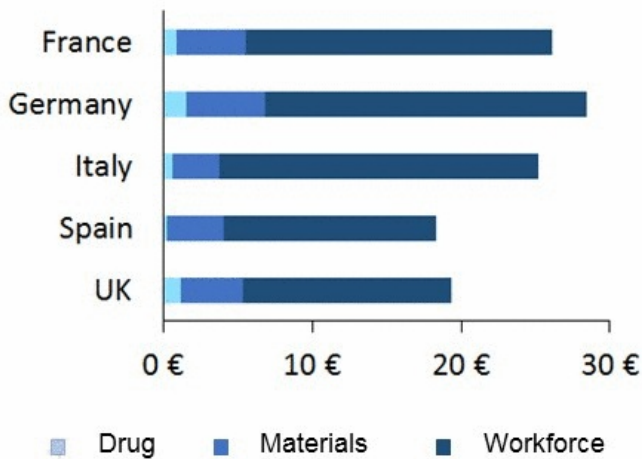
Assuming receipt of a final product label that closely aligns with the company's proposed label submitted to FDA (treatment of moderate-to-severe acute pain severe enough to require an opioid agonist and for which alternative treatments are inadequate, in adult patients in a medically supervised setting).

Source: QuintilesIMS Consulting Services 2016 analysis

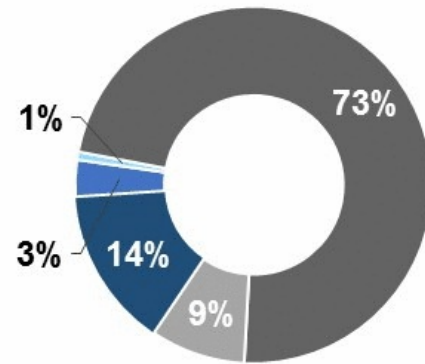
MRC-0106 06JAN17

ARX-04 Estimated to Have €500 Million Potential in the EU Where IV Morphine in the ED Inflicts a Substantial Economic Burden¹

Per-country breakdown of IV morphine drug administration by cost



EU5-average cost breakdown of total costs



ZALVISO® - Potential Follow-on Product in US is Already Marketed in Europe



Inpatient Surgeries requiring overnight stays

Proposed Indication

Management of moderate-to-severe acute pain in adult patients in a hospital setting.

Dosing

Maximum dose utilized was 15 mcg.

Development Status

- Launched in Europe April 2016 by Grünenthal
- Final US study started in 3Q 2016
- NDA resubmission planning in process

ZALVISO Final Phase 3 Study: IAP312 Open-Label, Single-Arm Designed to Evaluate Device Performance Initiated September 2016

IAP312 Multicenter Study

- Study designed specifically to address remaining FDA questions
- Protocol reviewed by FDA and revised based on FDA comments
- Currently enrolling; full enrollment ~315 patients
- 24- to 72-hour duration
- Single-arm, open-label, various postsurgical settings
- Multimodal analgesia allowed
- Per study protocol collecting device failure rate
- Per study protocol tracking incidence of dropped tablets
 - Expect more incidence than observed in Phase 3 studies


ZALVISO® European Launch
Update
2016 Year End Summary



ZALVISO

MRC-0106 06JAN17

8 EU Countries Treating Patients with ZALVISO® Most Recently in Ireland and Portugal; Successful P&R in Italy

Overview launch progress per country  = completed (Status 14.12.16)

Country	First use (pilot) of ZALVISO	Commercial launch
Germany	✓	Q1/17
France	✓	Q1/17
Belgium	✓	Q2/17
Netherlands	✓	Q1/17
Italy	✓	Q1/17
Portugal	✓	Q2/17
UK	✓	Q1/17
Ireland	✓	Q2/17
Spain	Jan 2017	Q2/17
Austria	Q1/17	Q2/17
Nordics	Q1/17	Q2/17

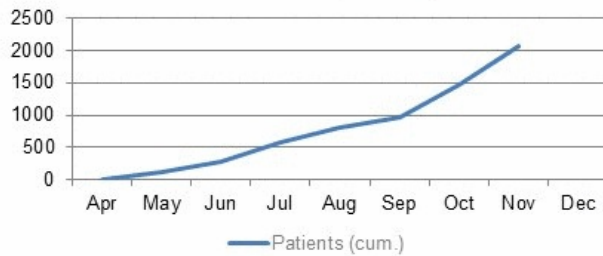
In October, for the first time, we succeeded in Italy a complete Pricing & Reimbursement process; details will be in the public domain by January 2017











ZALVISO
MRC-0106 06/JAN17

ZALVISO EU Launch Update – More Than 2,000 Patients Treated in 104 Hospitals in 8 Countries

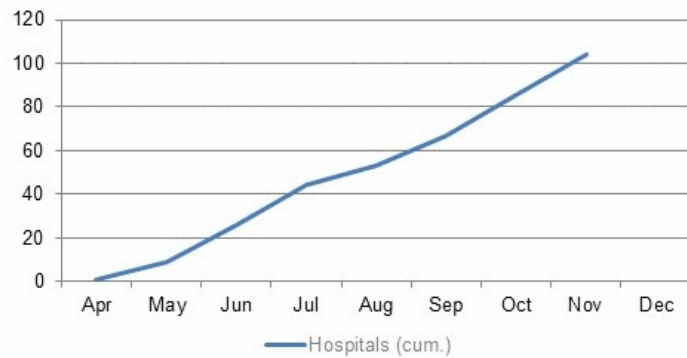
Patients (cum.)



Launch Countries

DE:  (54)	BE:  (6)
FR:  (24)	NL:  (3)
IT:  (7)	IE:  (1)
UK:  (5)	PT:  (4)

Hospitals (cum.)



Status: 30th Nov 2016



Market Feedback From First EU Commercial Experiences*



**“In general ZALVISO is perfect
for fast tracks”**

L. Eberhart, DE (Anesthetist)



**“No single issue with efficacy”
(using ZVO as monotherapy)**

Y. Leykin, IT

Positive First EU Clinical Experience

- ① Positive EU clinical experience so far confirmed by Int. AdBoard members*
 - Good pain relief both as monotherapy and as part of multimodal analgesic approach with rapid onset of action
 - Acceptable opioid-typical side effect profile
 - Easy to use for patient & nurse
 - Customers very pleased about clinical outcome in a broad range of surgical procedures

- ① So far none of the pilot hospitals has decided to terminate the collaboration

- ① “In all my years of pharmaceutical development, I have never seen a more positive clinical experience as ZALVISO.” – Dott. Alberto Grua, Chief Commercial Officer, Grünenthal Group

Cash on Hand at December 31, 2016 was \$80M

Cash balance December 31, 2016	\$80 million
Outstanding Loan Amount	\$21 .5 million
Shares Outstanding	45 million
Headcount at December 31, 2016	39

Strong Presence at Medical Meetings Planned for 2017

Date	Meeting	Date	Meeting
February 17 – 18	EMS State of the Sciences - The Gathering of Eagles XIX	August	Military Health Systems Research Symposium
March 16 – 20	American Academy of Emergency Medicine	September 6 – 9	Congress of European Pain Federation
March 21 – 24	International Symposium on Intensive Care and Emergency Medicine	September 13 – 17	Emergency Nursing 2017
April 30 - May 4	American Society of PeriAnesthesia Nurses	September 24 – 27	European Society of Emergency Medicine
May 4 – 6	Society for Ambulatory Anesthesia	October 21 – 25	American Society of Anesthesiologists
May 22 – 24	European EMS Meeting	October 29 - November 1	American College of Emergency Physicians
May 22 – 25	Special Operations Medical Association Scientific Assembly	November 16 – 18	American Society of Regional Anesthesia
June 3 – 5	European Society of Anaesthesiology - Euroanaesthesia	December 3 – 7	American Society of Health-System Pharmacists
April 30 - May 4	American Society of PeriAnesthesia Nurses	September 6 – 9	Congress of European Pain Federation

Significant Number of Key Milestones Anticipated in 2017

	Region	1H 2017	3Q 2017	4Q 2017
DSUVIA	US	NDA Review	AdComm	PDUFA
ARX-04	Europe	Submit MAA	EMA Review	
		Partnering Discussions		
ZALVISO	Europe	Market Expansion		
	US	Enrollment in IAP312	Prepare NDA	Resubmit NDA

AcelRx is Developing and Commercializing New Approaches for Treating Moderate-to-Severe Acute Pain

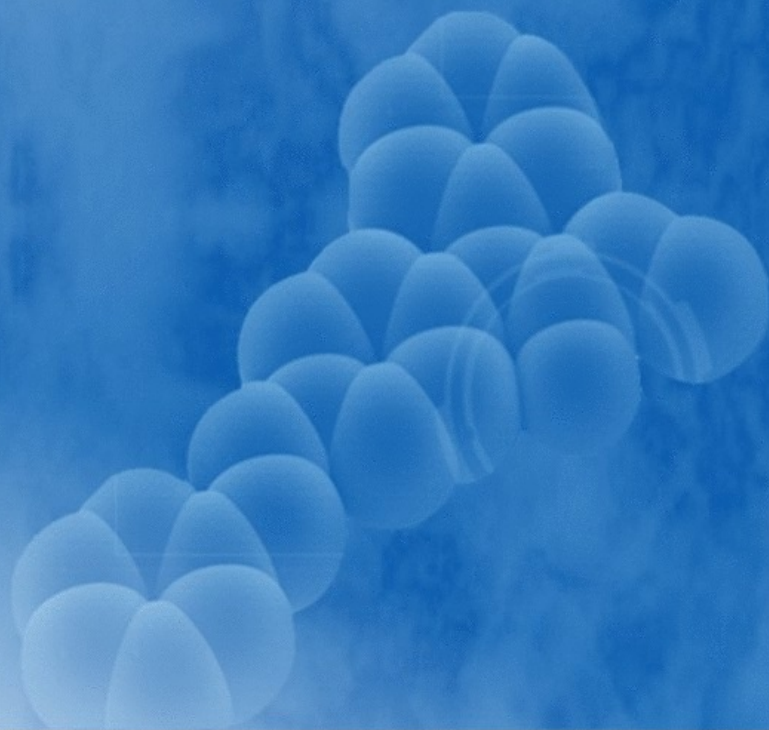
AcelRx Highlights

- NDA submitted for DSUVIA on December 12, 2016
 - US market Opportunity >\$1 billion in multiple settings¹
 - Initial US launch being planned in Emergency Medicine
 - >€500 million potential in Europe – partnering discussions
- ZALVISO launched by Grünenthal in Europe
 - Potential follow-on product to DSUVIA in US
 - ROW partnering discussions
- \$80 million cash as of December 31, 2016



For more information, visit:
www.acerlx.com

AceIRx
Pharmaceuticals, Inc.





AcelRx Pharmaceuticals Announces DSUVIA™ as Brand Name for ARX-04 in the United States

REDWOOD CITY, Calif., January 8, 2017 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain, announced that the U.S. Food and Drug Administration (FDA) has conditionally accepted the brand name, DSUVIA™ (sufentanil sublingual tablet, 30 mcg), for the company’s investigational product candidate, ARX-04. In addition, AcelRx has applied to the U.S. Patent and Trademark Office to obtain federal registration of the DSUVIA mark.

AcelRx recently announced the submission of a New Drug Application (NDA) with the FDA for DSUVIA for the treatment of patients experiencing moderate-to-severe acute pain in a medically supervised setting. This market is comprised of the adult emergency department setting, ambulatory and outpatient surgical settings, short-stay inpatient settings and certain office settings that serve patients undergoing painful procedures. In total, based on internal market research and published national surveys, AcelRx expects the peak market for DSUVIA in the U.S. to be an estimated \$1.1 billion.

“Our initial target market will be the emergency medicine market,” commented Gina Ford, AcelRx’s vice president of commercial strategy. “Pending a favorable review by the FDA, we anticipate initiating a pilot launch program into identified centers of excellence around the country shortly after approval. During the next three quarters, we plan to add the necessary commercial staff and infrastructure to support these initial commercialization efforts.”

The FDA is expected to determine by mid-February 2017 whether the DSUVIA NDA is complete and acceptable for review. Should the Agency accept the NDA for review, a Prescription Drug User Fee Act (PDUFA) decision could be expected in the fourth quarter of 2017.



About DSUVIA (formerly known as ARX-04)

DSUVIA is a non-invasive investigational product candidate consisting of 30 mcg sufentanil tablets delivered sublingually by a healthcare professional using a disposable, pre-filled, single-dose applicator (SDA). Sufentanil is a synthetic opioid analgesic with a high therapeutic index and no known active metabolites.

Clinical and Rehabilitative Medicine Research Program (CRM RP)

DSUVIA is funded in part by the Clinical and Rehabilitative Medicine Research Program (CRM RP) of the U.S. Army Medical Research and Materiel Command (USAMRMC) under contract No. W81XWH-15-C-0046. The CRM RP was established in 2008 to foster research and technology advances for regeneration, restoration, and rehabilitation of traumatic injuries.

In accordance with USAMRMC guidelines, in the conduct of clinical research, AcclRx has adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects).

About AcclRx Pharmaceuticals, Inc.

AcclRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain. An NDA for DSUVIA (sufentanil sublingual tablet, 30mcg), known as ARX-04 outside the United States, with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised settings, was recently submitted to the FDA for review.

The Company's follow on product, ZALVISO® (sufentanil sublingual tablet system), designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting, is currently enrolling patients in a Phase 3 clinical trial, IAP312. ZALVISO delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. ZALVISO is approved in the EU and is investigational and in late-stage development in the U.S. Grunenthal Group holds the rights for ZALVISO in Europe, where a commercial launch has begun.

For additional information about AcclRx's clinical programs, please visit www.acclrx.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the process and timing of anticipated future development of AcclRx's product candidates, DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as ARX-04 outside the United States, and ZALVISO (sufentanil sublingual tablet system), including U.S. Food and Drug Administration, or FDA, review of the New Drug Application, or NDA, for DSUVIA; the potential approval of the DSUVIA NDA by the FDA; the DSUVIA and ARX-04 clinical trial results; AcclRx's pathway forward towards gaining approval of ZALVISO in the U.S., including successful completion of the IAP312 clinical study for ZALVISO; and the therapeutic and commercial potential of AcclRx's product candidates, including potential market opportunities and market size for DSUVIA, ARX-04 and ZALVISO. These forward-looking statements are based on AcclRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcclRx 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 AcclRx Pharmaceuticals' DSUVIA and ARX-04 development programs, including the FDA review of the DSUVIA NDA and the possibility that the FDA may dispute or interpret differently clinical results obtained from the DSUVIA Phase 3 studies; the ZALVISO development program, including successful 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 DSUVIA in the United States, ARX-04 in Europe and ZALVISO in the United States; the uncertain clinical development process; the success, cost and timing of all development activities and clinical trials; actual market size for AcclRx product candidates; and other risks detailed in the "Risk Factors" and elsewhere in AcclRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on November 2, 2016. AcclRx undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations.

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AcelRx Pharmaceuticals Provides Guidance on 2017 Milestones for ARX-04, now known as DSUVIA™ in the United States, for the Treatment of Moderate-to-Severe Acute Pain

- *Expected FDA Acceptance of the NDA*
- *Planned Submission of MAA in the EU*
- *Potential Approval and Commercialization in the U.S.*

REDWOOD CITY, Calif., Jan. 8, 2017 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain, provided guidance today on 2017 milestones for its lead product, ARX-04, known as DSUVIA™ (sufentanil sublingual tablet, 30 mcg) in the United States. Specifically, AcelRx's corporate milestones for DSUVIA and ARX-04 in the upcoming year are as follows:

- *Advance the NDA.* AcelRx submitted a 505(b)2 new drug application (NDA) for DSUVIA for moderate-to-severe acute pain in a medically supervised setting on December 12, 2016. The U.S. Food and Drug Administration (FDA) has 60 days to review an application and determine whether the NDA is acceptable for filing. AcelRx expects to receive this notification from the FDA in the first quarter of 2017. Assuming the FDA, through the Division of Anesthesia, Analgesia and Addiction Products (Division), accepts the NDA for filing, AcelRx will liaise with the Division and any advisory committees that may be convened during the review period.
- *Submit the European Regulatory Application.* AcelRx expects to submit a Marketing Authorization Application (MAA) under the Centralized Procedure for ARX-04 with the European Medicines Agency (EMA) in the first half of 2017.
- *Plan for U.S. Approval and Commercialization.* Should the Division favorably complete its review by the expected Prescription Drug User Fee Act (PDUFA) date, AcelRx anticipates being prepared to begin commercialization of DSUVIA as early as the fourth quarter of 2017.

"The most significant goals we accomplished in 2016 were with DSUVIA: The submission of the NDA; developing the DSUVIA commercial strategy; and establishing the supply chain. As a result, we are well positioned as we begin 2017 to advance DSUVIA in the U.S. and ARX-04 in Europe," stated Howie Rosen, CEO of AcelRx. "Of course, a positive FDA decision on our NDA has the potential to fully transform AcelRx and allow us to begin commercialization of DSUVIA into the emergency medicine market. As we presented in December, we believe the peak revenue potential across all settings for DSUVIA in the U.S. is \$1.1 billion. This forecast also reinforced our comfort with designating DSUVIA as our lead product and ZALVISO being a potential follow-on product in the U.S."

Tim Morris, CFO of AcelRx added, "We ended 2016 with \$80 million in cash and cash equivalents. We anticipate having about \$50 million in cash at the end of the 2nd quarter of 2017. Our spending in the 2nd half of 2017 will depend on the review process and PDUFA date set by the Division as well as the specific details of our commercial plans. The acceptance of the NDA for DSUVIA by April 1, 2017 also will allow us to refinance the \$21 million outstanding debt with Hercules. We expect to provide cash guidance for the full year as regulatory milestones and commercial plans become clearer."

Members of AcelRx senior management will be participating in The Trout Group Annual 1x1 Management Access Event in San Francisco, January 10 – 13, 2017.

About AcelRx Pharmaceuticals, Inc.

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