

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): June 7, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

AcelRx Pharmaceuticals, Inc. (the “*Company*”) has prepared an investor presentation to be used in certain investor meetings, beginning June 7, 2017, a copy of which is attached hereto as Exhibit 99.1.

This information, including the Exhibit 99.1 referenced herein, is “furnished” and not “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Securities Exchange Act of 1934 or the Securities Act of 1933 only if and to the extent such subsequent filing specifically references the information herein as being incorporated by reference in such filing.

Item 8.01 Other Events.

The U.S. Food and Drug Administration has notified the Company that it no longer plans to hold an advisory committee meeting in connection with its review of the Company’s New Drug Application (NDA) for DSUVIA™ (sufentanil sublingual tablet, 30mcg) for the treatment of moderate-to-severe acute pain. The decision does not alter the Prescription Drug User Fee Act (PDUFA) goal date for completion of the review of the NDA, which remains October 12, 2017.

Forward-Looking Statements

Statements made in this Current Report on Form 8-K, other than statements of historical fact, are forward-looking statements, including, for example, statements relating to the timing of completion and outcome of FDA review of the Company’s NDA for DSUVIA™. Forward-looking statements are subject to a number of known and unknown risks and uncertainties that might cause actual results to differ materially from those expressed or implied by such statements. For example, the Company cannot assure you with respect to the timing of completion and outcome of the FDA’s review of the Company’s NDA with respect to DSUVIA or any other product candidate. These and other risk factors are set forth in the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 and subsequent SEC filings. The Company disclaims any intention or duty to update any forward-looking statement made in this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Investor Presentation

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: June 7, 2017

ACELRX PHARMACEUTICALS, INC.

By: /s/ Jane Wright-Mitchell

Jane Wright-Mitchell

Chief Legal Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Investor Presentation

AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX)

Vincent Angotti, CEO
Corporate Overview

Jefferies 2017 Healthcare Conference
Grand Hyatt, New York

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 AcetRx'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; AcetRx'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 AcetRx's product candidates, including potential market opportunities for DSUVIA, ARX-04 and ZALVISO. These forward-looking statements are based on AcetRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcetRx 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 AcetRx 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; AcetRx'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 AcetRx's product candidates; the accuracy of AcetRx's estimates regarding expenses, capital requirements and the need for financing; and other risks detailed in the Risk Factors and elsewhere in AcetRx's US Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on May 8, 2017. AcetRx 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.

Late Stage Pipeline of Sublingual Sufentanil Products for Acute Moderate-to-Severe Pain

DSUVIA™ (in US)

PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA FILED	APPROVED
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ARX-04 (in EU)

PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	MAA FILED	APPROVED
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Zalviso® (in US)

PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA FILED	APPROVED
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Zalviso® (in EU)

PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	MAA FILED	APPROVED
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The AcelRx Difference: Proprietary 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 now¹)
- **Low GI bioavailability²** 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



Department of Defense Provided 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/w2fR0>
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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Pharmaceuticals, Inc.

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.

MRC-0137 05JUN17

NDA and MAA Submitted for the Treatment of Moderate-to-Severe Acute Pain in a Medically Supervised Setting

NDA accepted for filing by the FDA on Feb 10, 2017 • PDUFA date is Oct 12, 2017
MAA validated by EMA on March 23, 2017 • CHMP opinion expected first half 2018

DSUVIA™
Sufentanil Sublingual
Tablet 30 mcg Ⓢ

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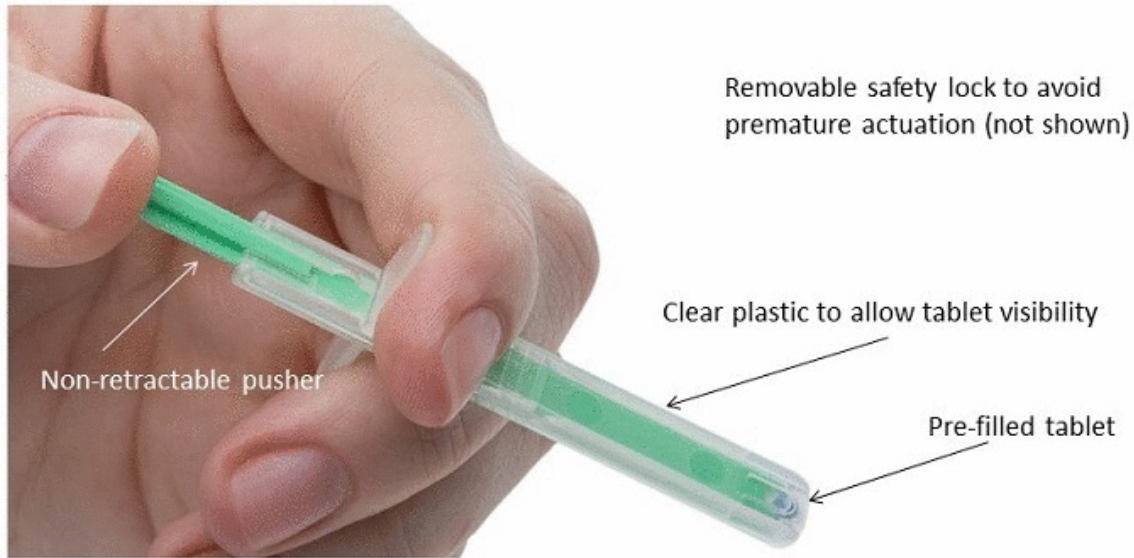
MRC-0137 05JUN17

6

DSUVIA: Single-Dose Applicator (SDA)

Designed in Collaboration with the DoD

(Light-Weight, Extreme-Environment Tested, Easily Handled with Gloves)¹



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

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Sufentanil Sublingual Tablets 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

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1. ZALVISO patients who dosed two 15-mcg tablets within 25 minutes were included in the ARX-04 safety database

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9

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

SAP202: ASC

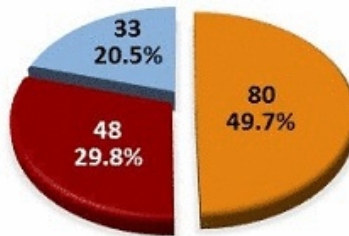


Surgery Type

- Bunionectomy

100 Total patients

SAP301: ASC

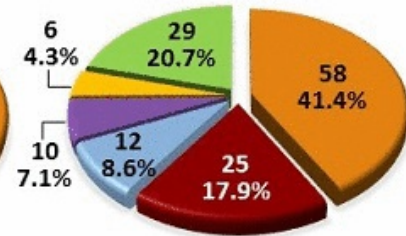


Surgery Type

- Abdominoplasty
- Laparoscopic Abdominal
- Hernioplasty

161 Total patients

SAP303: Hospital



Surgery Type

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

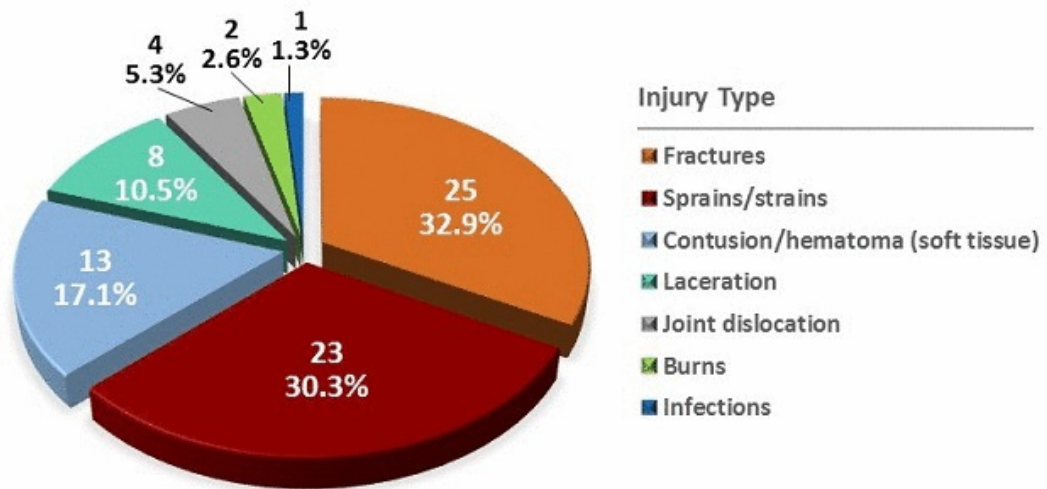
140 Total patients

Most Common Adverse Events:^{*} All Sufentanil Sublingual Tablets 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

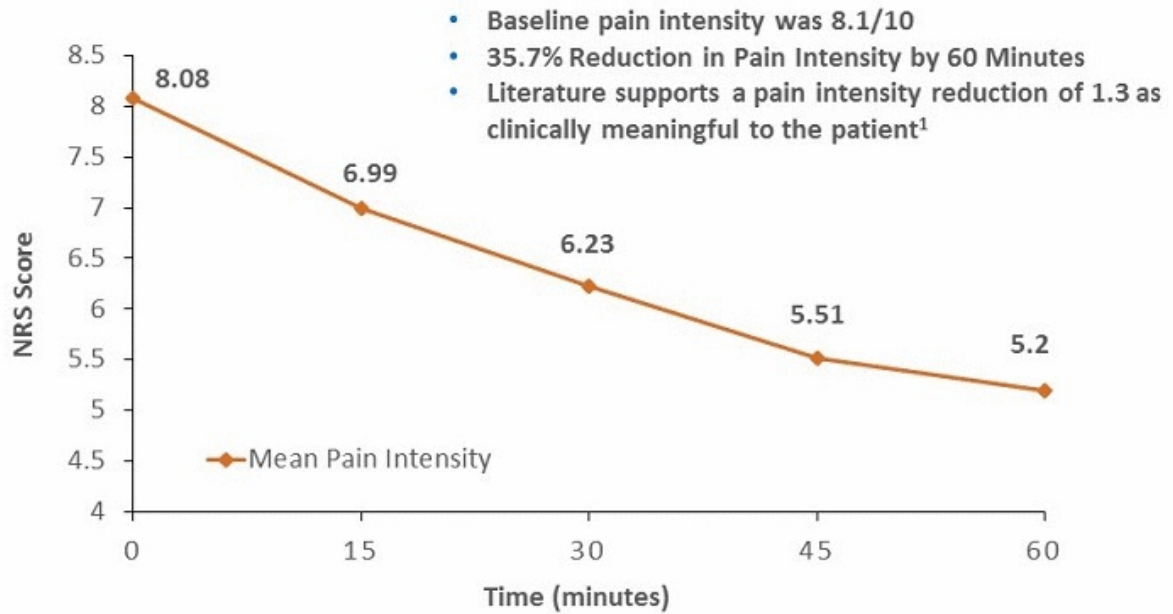
SAP302 Emergency Department: Demographics (n=76) Included Multiple Injury Types

Trauma classifications



76 Total patients

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

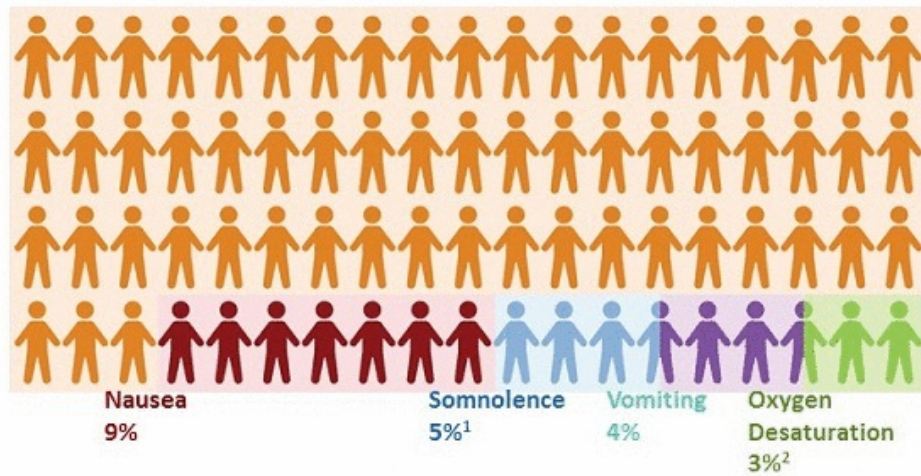


SAP302 Emergency Department: 79% of Patients in SAP302 Reported no Side Effects

Adverse Events (> 2% of patients)

SST (30 mcg)
n=76

No
Adverse
Event
79%



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1. All 4 patients reporting 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)

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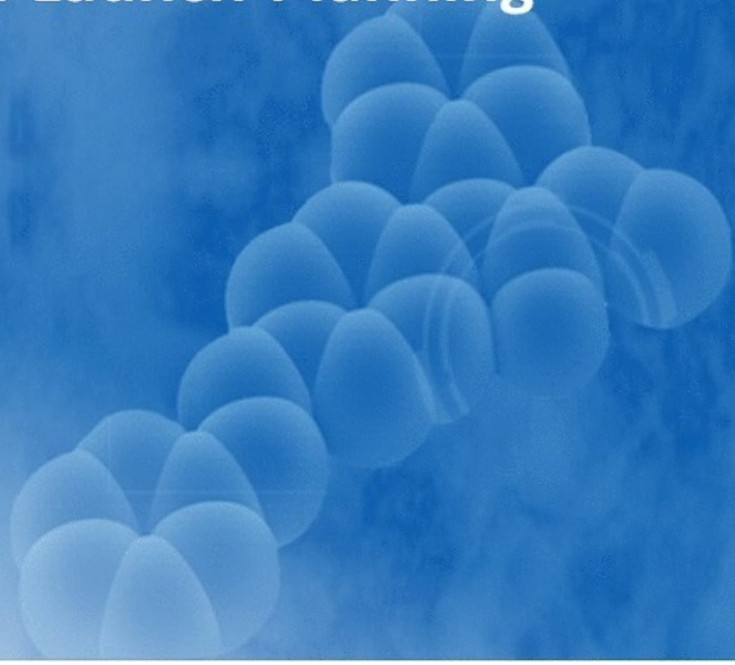
Additional Results from Clinical Program Provide Support for Safety, Efficacy and Ease of Use for SST 30 mcg

- 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.

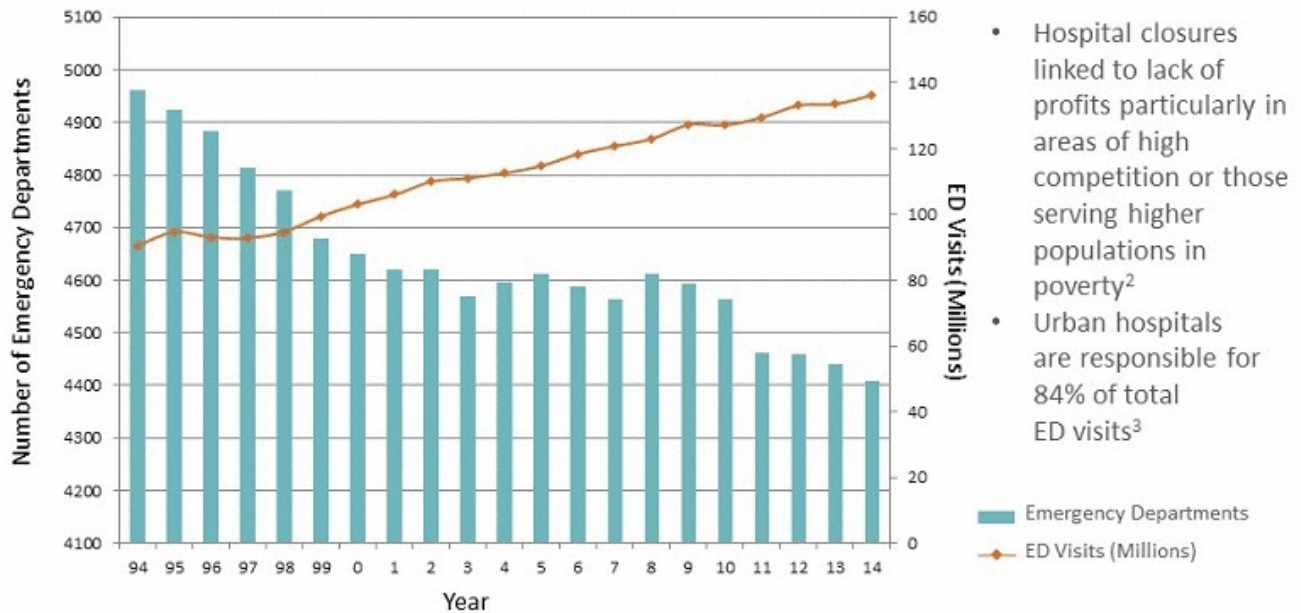


US Commercial Launch Planning

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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] Trend Watch 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/EP_20110092.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



Wait Times Following Initial Evaluation in the Emergency Department

Why am I waiting?

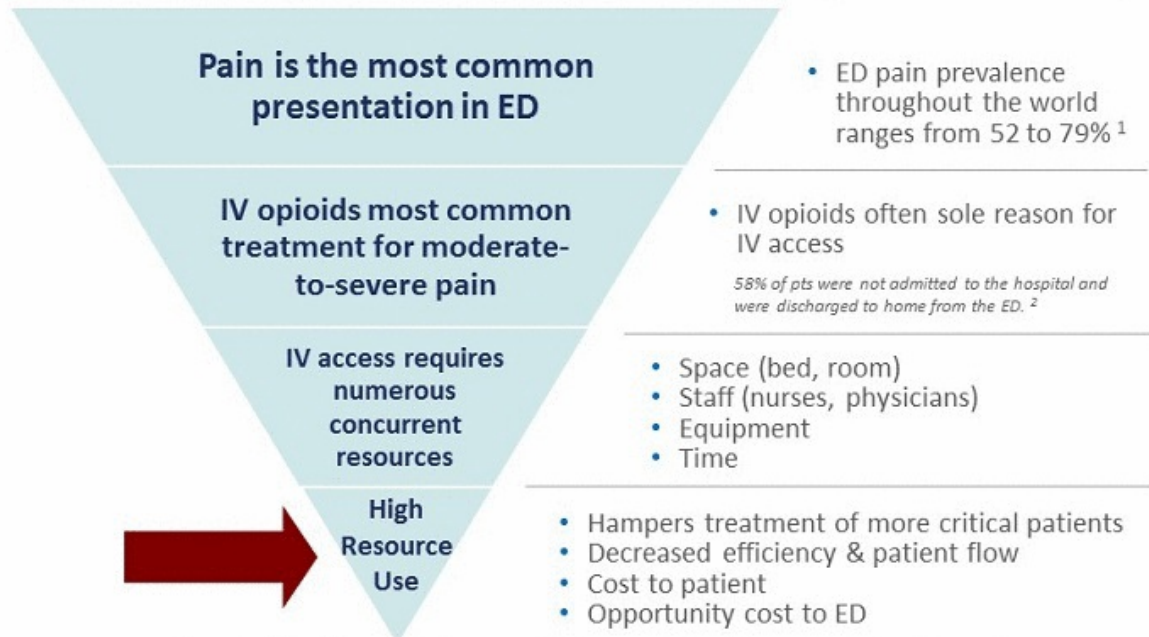
Some aspects of your care may take time. Conditions change quickly in the Emergency Department and we will do our best to accurately predict your waiting time.

APPROXIMATE TESTING TIMES	HOURS
 Routine Blood Work	2
 X-Rays	2
 CT Scans	4-5
 MRI	5-6

ED staff will keep you informed about next steps and waiting times.

Sign posted in the Emergency Department at Beth Israel Deaconess Medical Center in Boston

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



1. Researchgate.net [Internet]. Pain Prevalence and Pain Relief in Trauma Patients in the Accident and Emergency Department. Available from https://www.researchgate.net/publication/6197282_Pain_prevalence_and_pain_relief_in_trauma_patients_in_the_Accident_and_Emergency_Department (accessed 2016, November 30)

2. Cost of Intravenous Analgesia for the Management of Acute Pain in the Emergency Department is Substantial in the United States
Authors: Pamela P. Palmer et al. JHEOR 2017;5(1):1-15

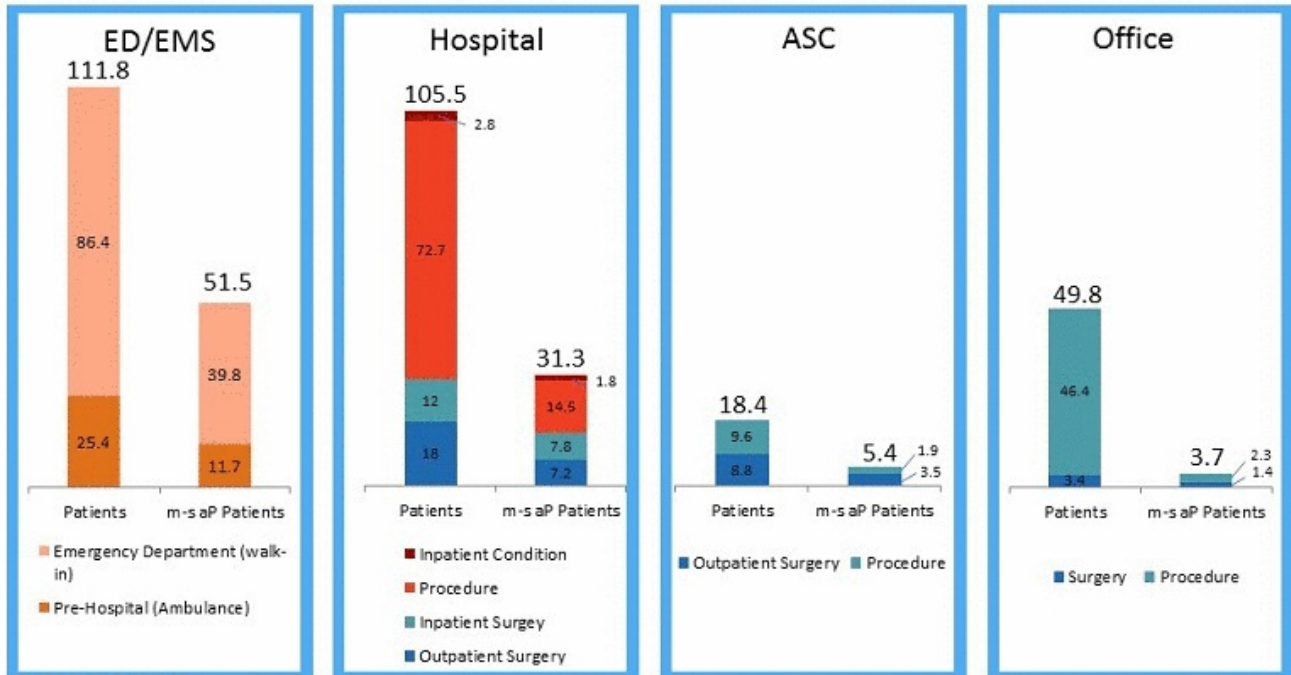
3. Data on file. In-house market research. Conducted at American College of Emergency Physicians (ACEP) November 2015

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.



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



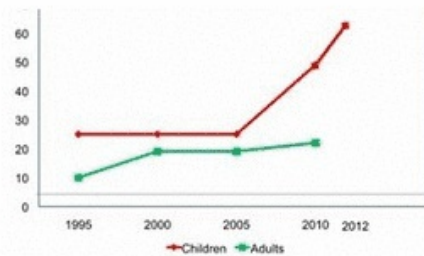
Market Research has Identified Additional Patient Populations that May Benefit from DSUVIA

- 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



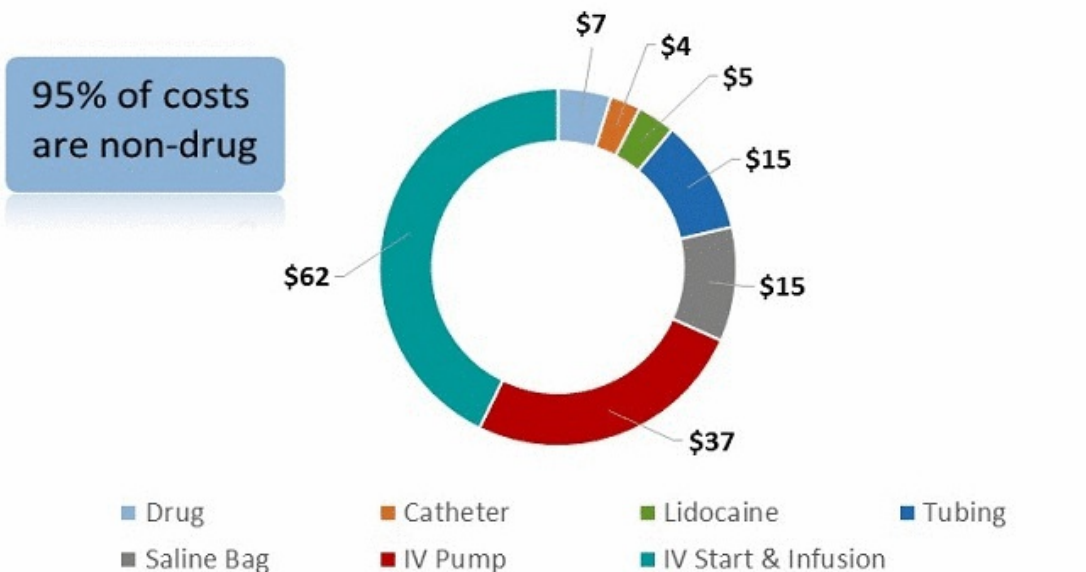
- Needle-phobia population over time³



1. Pubmed <https://www.ncbi.nlm.nih.gov/pubmed/17636457> (accessed 2016, November 23)
 2. Hcup.net [Internet] HCUFnet: 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



Sublingual Sufentanil Under Review for Treating Moderate-to-Severe Pain

DSUVIA™ (US) Highlights

- NDA accepted for filing by FDA February 10, 2017
 - 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"
 - Administered by HCP
 - No Retail Distribution
 - REMS program



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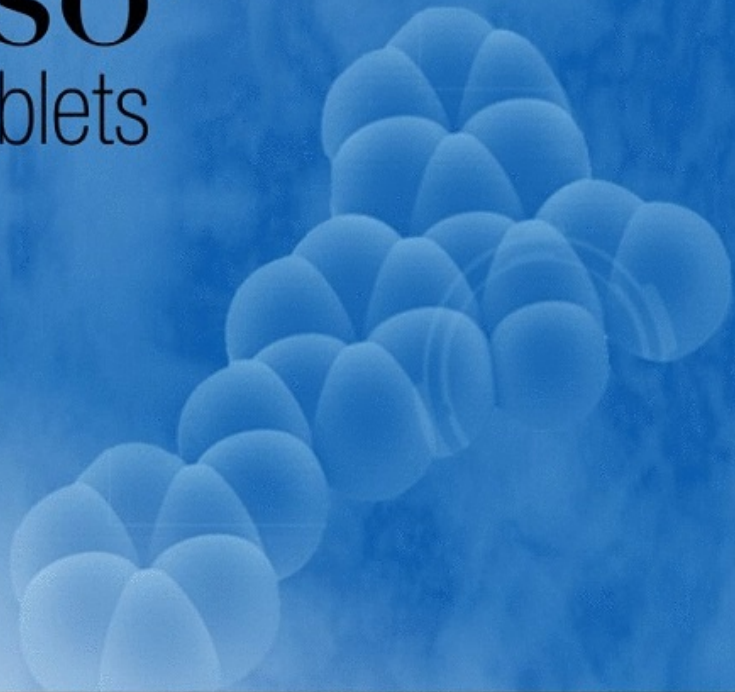
1. Data on file. In-house commissioned market research. QuintilesIMS, "ARX-04 and ZALVISO US forecast" December 2016

MRC-0137 05JUN17 25

Zalviso™

(sufentanil) tablets

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



Proposed Indication

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

Dosing

Dose utilized was 15 mcg tablet

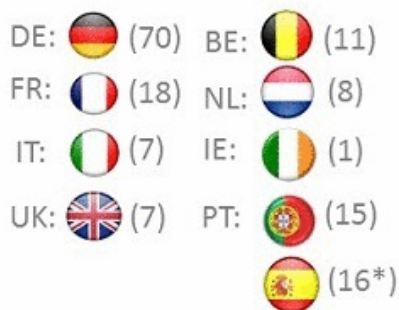
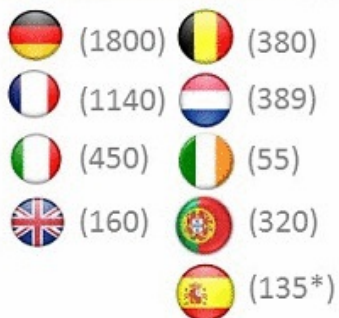
Development Status

- Clinical Study in life portion completed
- NDA resubmission anticipated by end of 2017
- Type II resubmission – 6 month Review
- Launched in Europe April 2016 by Grünenthal

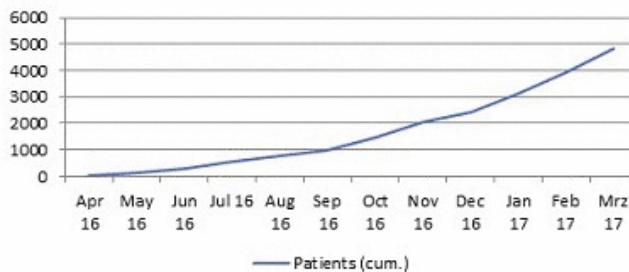
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MRC-0137 05JUN17 27

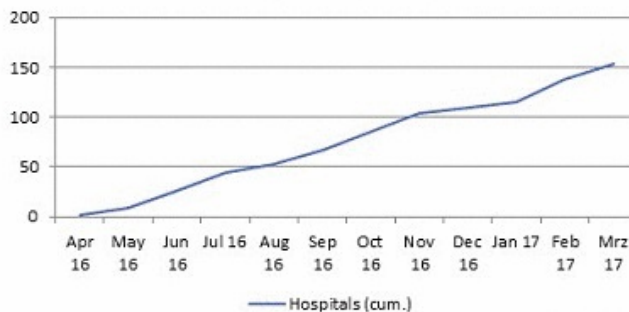
Zalviso Launch Update – Approximately 4,800 Patients Treated in 153 Hospitals



Patients (cum.)



Hospitals (cum.)



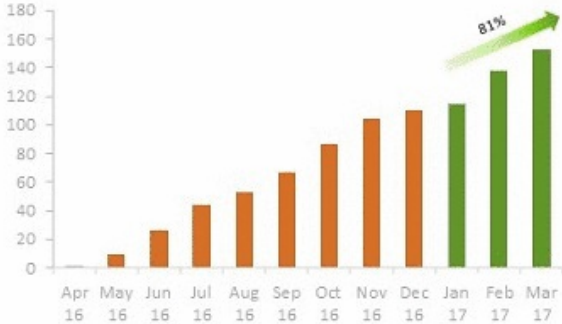
Monthly Zalviso Total Patients and Hospital Accounts

First quarter of 2017 showed a significant increase in exposures and hospital accounts over the three previous quarters combined

Patients



Hospital Accounts



Cash on Hand at March 31, 2017 was \$72M

Cash balance March 31, 2017	\$72 million
Outstanding Loan Amount	\$21 .5 million
Shares Outstanding	45 million
Headcount at March 31, 2017	38

AcelRx is Developing and Commercializing Sublingual Sufentanil for Treating Moderate-to-Severe Acute Pain

AcelRx Highlights

- NDA accepted for filing by FDA for DSUVIA on February 10, 2017
 - PDUFA October 12, 2017
 - US market Opportunity >\$1 billion in multiple settings¹
 - Initial US launch being planned in Emergency Medicine
- ZALVISO launched by Grünenthal in Europe
 - 4,800 patients in 153 hospitals
 - Potential follow-on product to DSUVIA in US
 - >€500 million potential in Europe
- \$72 million cash as of March 31, 2017



For more information, visit:
www.acerx.com

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Pharmaceuticals, Inc.

