

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

FORM 8-K

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

Date of Report (Date of earliest event reported): December 4, 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” or “AcelRx”) will participate in various meetings with securities analysts and investors on Monday, December 4, 2017, and will utilize a presentation during those meetings. The presentation is furnished as Exhibit 99.1 to this Current Report and is incorporated herein by reference. The presentation will also be made available in the “Investor Relations” section of AcelRx Pharmaceuticals, Inc.’s website, located at www.acelrx.com.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Slide presentation entitled, “Corporate Overview December 2017”

SIGNATURES

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

Date: December 4, 2017

ACELRX PHARMACEUTICALS, INC.

By: /s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer

Corporate overview

December 2017

AceIRx
Pharmaceuticals, Inc.

Exploring innovative solutions for acute pain



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; evaluation of the CRL and AcelRx's plans for resubmission of the NDA for DSUVIA with the FDA; 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; 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 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; and projected cash flows. These forward-looking statements are based on AcelRx's current expectations and inherently involve significant risks and uncertainties. AcelRx's 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's DSUVIA and ARX-04 development programs, including EMA review of the ARX-04 MAA, and the possibility that EMA may dispute or interpret differently clinical results obtained from the ARX-04 Phase 2 and 3 studies; the possibility that the FDA may dispute or interpret differently the results of the ZALVISO development program, including the results from the IAP312 clinical trial; 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, including adverse events; the success, cost and timing of all development activities and clinical trials; 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 9, 2017. 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.

Key leadership

Vincent Angotti
Chief Executive Officer



- Appointed Chief Executive Officer and a member of the Company's Board of Directors in March 2017
- Over 25 years of experience leading executive and commercial teams at public and private life sciences companies
- Previous positions: CEO of XenoPort, Inc. , SVP Sales & Marketing of Reliant Pharmaceuticals, Inc., Career began at Novartis Pharmaceuticals where he held various roles of increasing responsibility

Raffi Asadorian
Chief Financial Officer



- Appointed Chief Financial Officer effective August 2017
- Over two decades of finance, strategy and corporate development experience at publicly traded and private equity owned companies
- Previous positions: CFO of Amyris, Unilabs, and PLIVA. Career began at PricewaterhouseCoopers where he was a Partner in its Transaction Services group

Pamela P. Palmer, MD, PhD
Chief Medical Officer



- Co-founded AcelRx in July 2005 and serves as Director and Chief Medical Officer
- Director of the UCSF Pain Center for Advanced Research and Education (PainCARE) from 2005 to 2009; Co-founded Omeros Corporation in 1994
- Dr. Palmer has a medical degree and a doctorate in neuroscience from Stanford University, and continued on to the University of California, San Francisco for her anesthesia residency



Acute



Chronic



**Medically
Supervised**



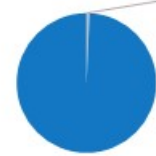
**Patient
Retail
Script**



0.7%

Of sustained opioid use originates from an inpatient experience ⁽¹⁾

Patients with sustained opioid use



0.70%

■ Inpatient experience
■ No inpatient experience

OUR FOCUS

Treatment for moderate-to-severe acute pain within a medically supervised environment

Late-stage pipeline of sufentanil sublingual products for moderate-to-severe acute pain

DSUVIA

- Single dose sufentanil sublingual 30 mcg tablet in a pre-filled applicator
- HCP administered in a Medically Supervised Setting
- US/EU large potential market opportunity in multiple settings¹



Zalviso™

- Multiple doses sufentanil sublingual 15 mcg tablets in a 40-count cartridge
- Patient administered in a Medically Supervised Setting
- Approved and Marketed in EU
- US: potentially complementary market opportunity with DSUVIA



Current IV opioids on the market do not fully address the patient or healthcare professional needs

*Slower acting opioids
(IV morphine)*

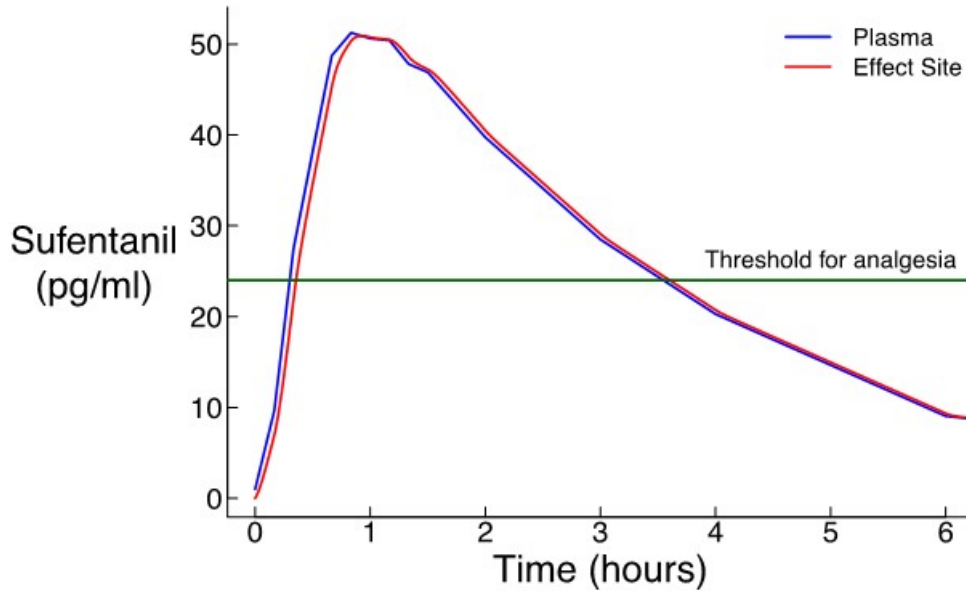


*Fast acting, but fast offset opioids
(IV fentanyl/sufentanil)*



Sufentanil sublingual addresses an unmet need in acute pain management

Sufentanil Sublingual (30 mcg)



Clinical trials show analgesia as early as 15 minutes and with a duration of ~3 hours

Proprietary sufentanil sublingual tablets have unique properties



Small size dissolves in minutes



Sublingual absorption potentially maintains therapeutic levels for 3 hours



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 mitigate risk of diversion with clear liquids



DSUVIA
(sufentanil)
sublingual tablet 30 mcg

DSUVIA designed in collaboration with the Department of Defense

Light-Weight, Extreme-Environment Tested, Easily Handled with Gloves¹



DSUVIA has an opportunity to address unmet needs for patients and hospitals



**Patient
experience**



Ease of use



**Hospital/ER
efficiency**



**No risk of IV
infection**



**Lower total
cost**

NDA and MAA submitted for the treatment of moderate-to-severe acute pain in medically supervised settings



- CRL received on October 11, 2017
- FDA Type A meeting end of January 2018
 - Label: “Medically Supervised Settings”
 - Administered by Healthcare Professional
 - No retail distribution
 - REMS program



- CHMP opinion expected first half of 2018



Data

Collection

*Collect patient data to support
max daily dose*

HF

Human Factors study

*Validate revised Directions
For Use*

- In-person Type A meeting set for end of January 2018
- New data combined with existing ZALVISO and DSUVIA data/analysis included in the briefing book supporting proposed maximum dosing
- HF study protocol proposed and expected to take less than 1 month to complete

904 total patients in DSUVIA database across a variety of surgery / injury types

904

Total Patients

SAP202: Post-operative musculoskeletal

SAP301: Post-operative soft tissue

SAP302: ER setting, multiple injury types

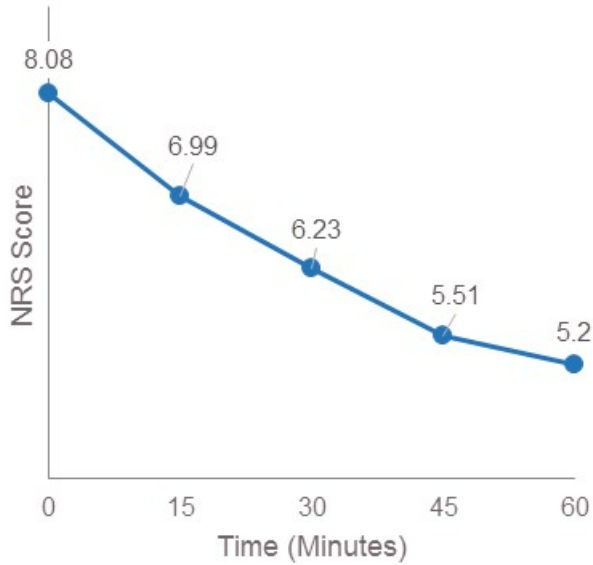
SAP303: Post-operative older population, co-morbidities

Select Zalviso patients

- Pivotal trials demonstrated statistically significant pain reduction compared to placebo (SAP202, $p=0.005$; SAP301, $p<0.001$)
- Combined clinical studies showed no meaningful differences in Adverse Events compared to placebo

In emergency settings, DSUVIA showed clinically meaningful pain reduction with a single dose

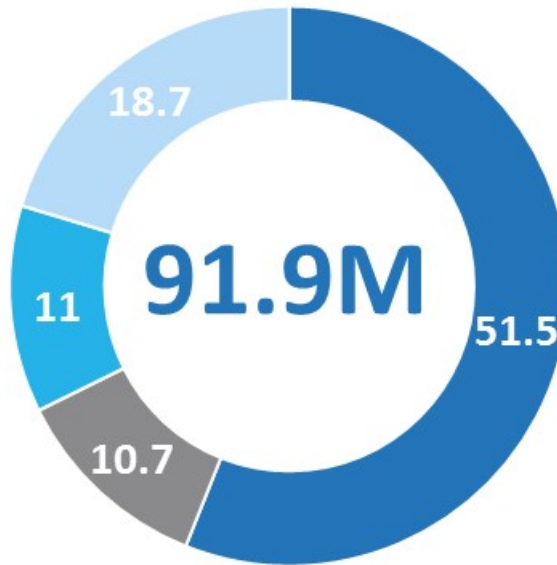
Mean Pain Intensity (SAP302)



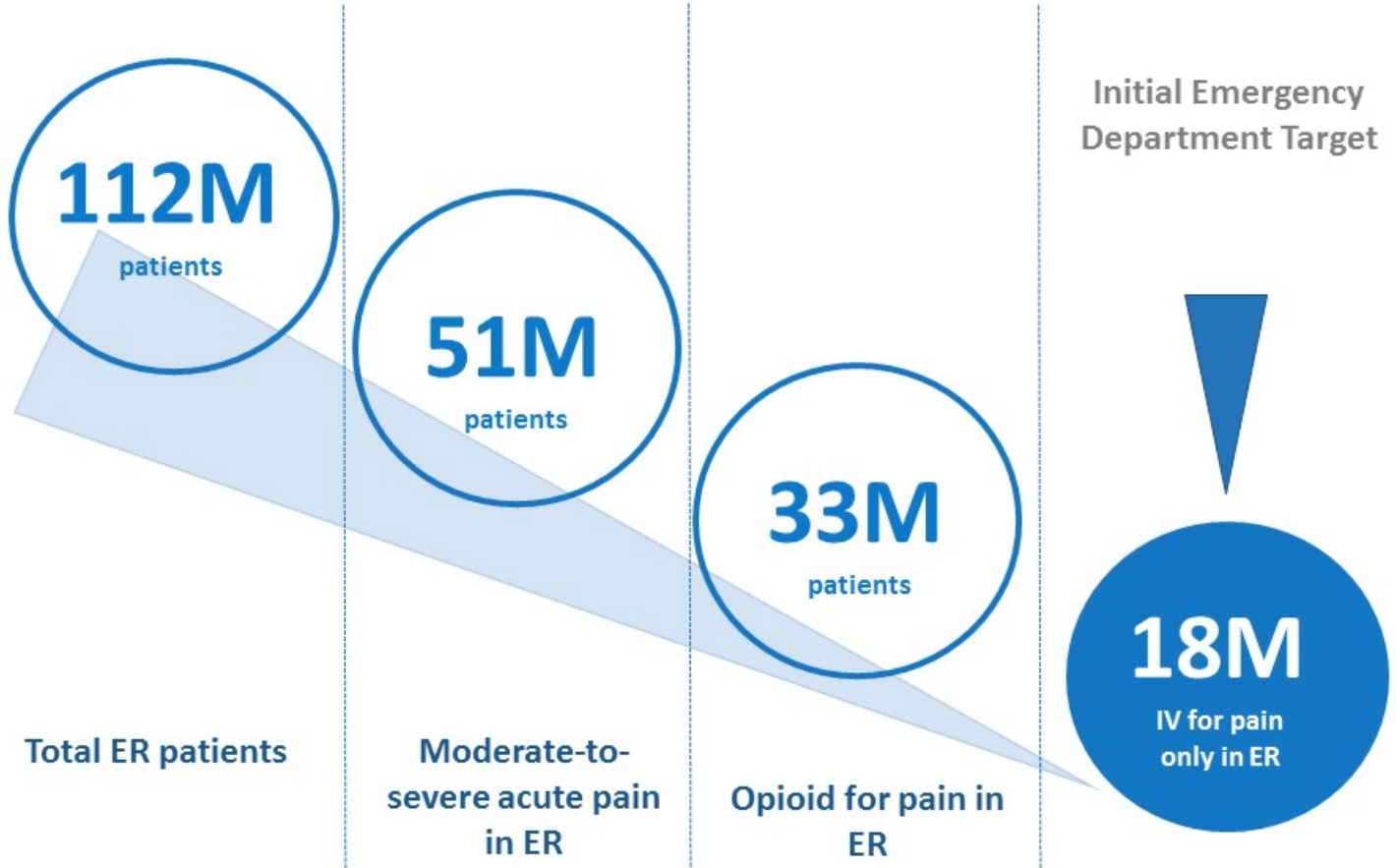
- Baseline pain intensity was 8.1/10
- 35.7% Reduction in Pain Intensity by 60 Minutes
- Literature supports a pain intensity reduction of 1.3 as clinically meaningful to the patient¹

~92 million adult moderate-to-severe acute pain patients in medically supervised settings

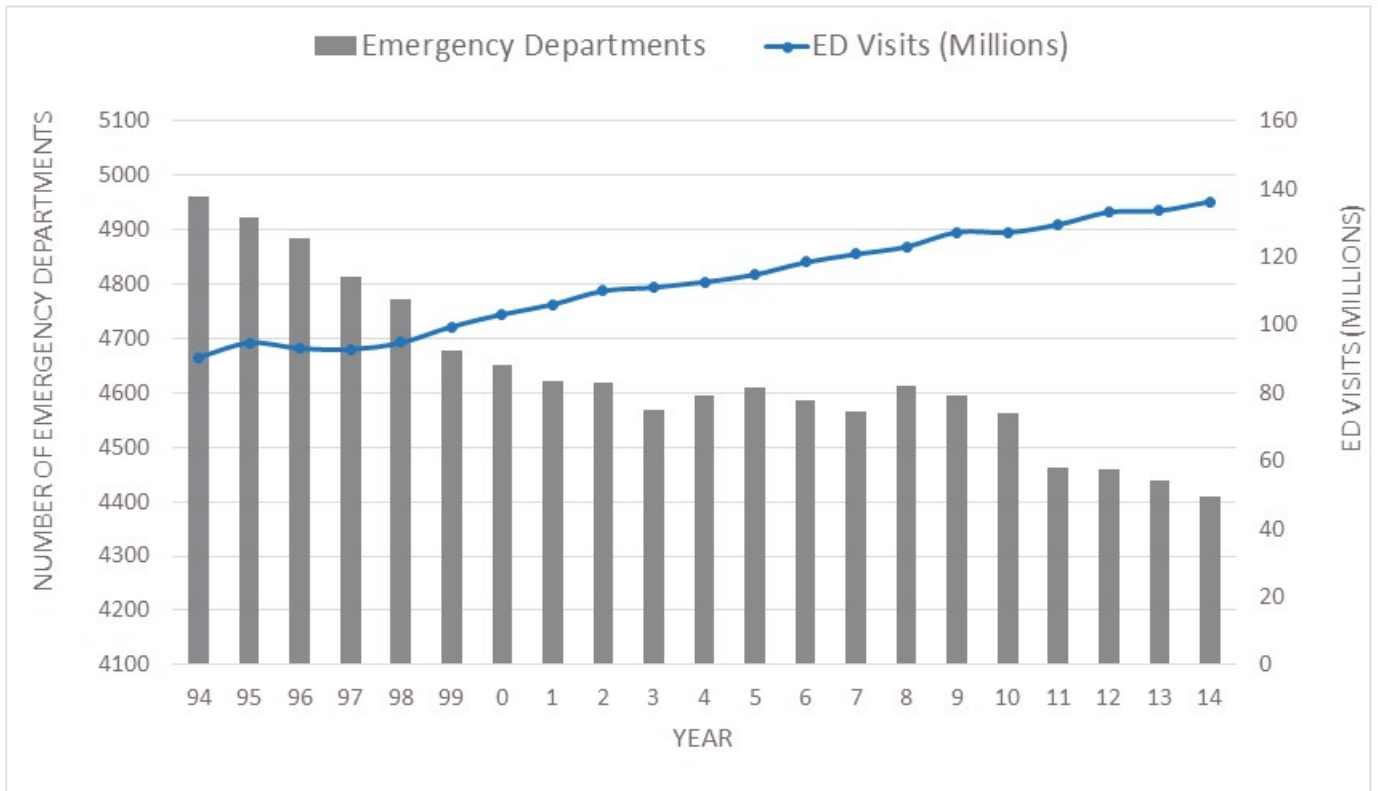
- Emergency department
- Outpatient surgery
- Inpatient/other surgery
- Other procedures



Initial emergency department target of 18 million adult patients annually receiving IVs exclusively for pain meds



The number of emergency departments is declining while annual visits are on the rise

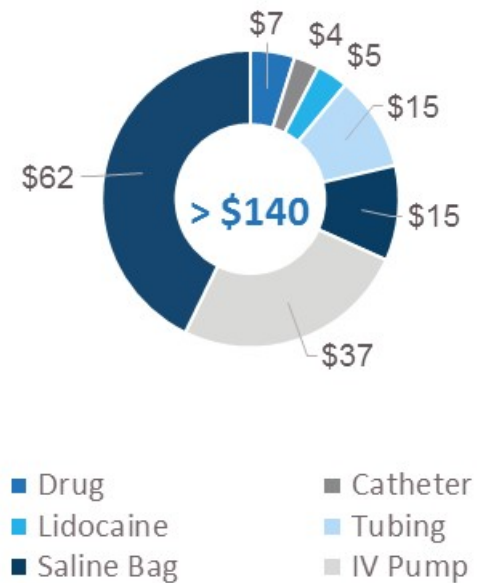


IV administration is resource and cost intensive

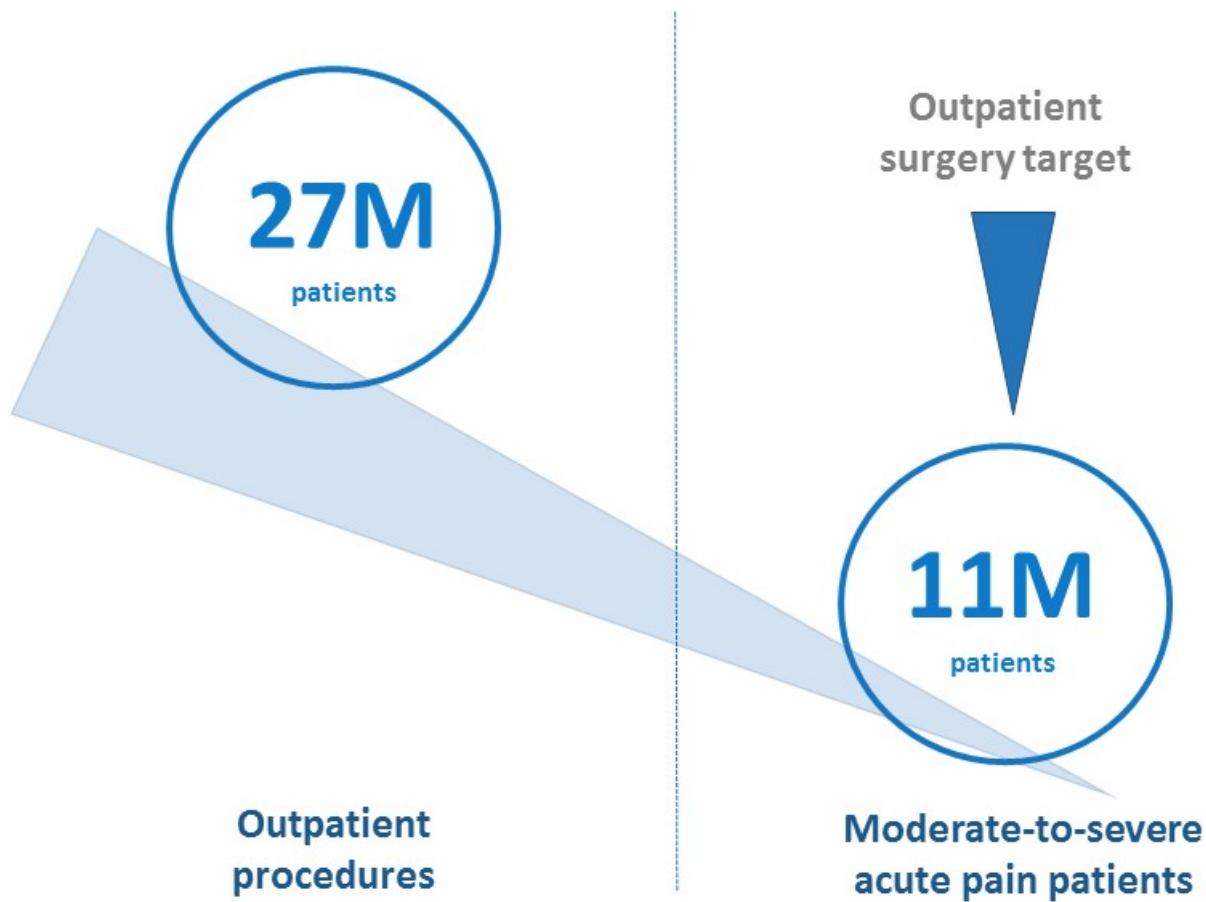
Efficiency Costs of Initiating IV^{1,2}

- Lack of bed space, HCP availability decreases patient flow
- Failure rates of IV access reported as high as **12-26%**
- Difficult IV access may require advanced techniques, such as ultrasound guidance, increasing time to IV placement by **118 – 135 minutes**

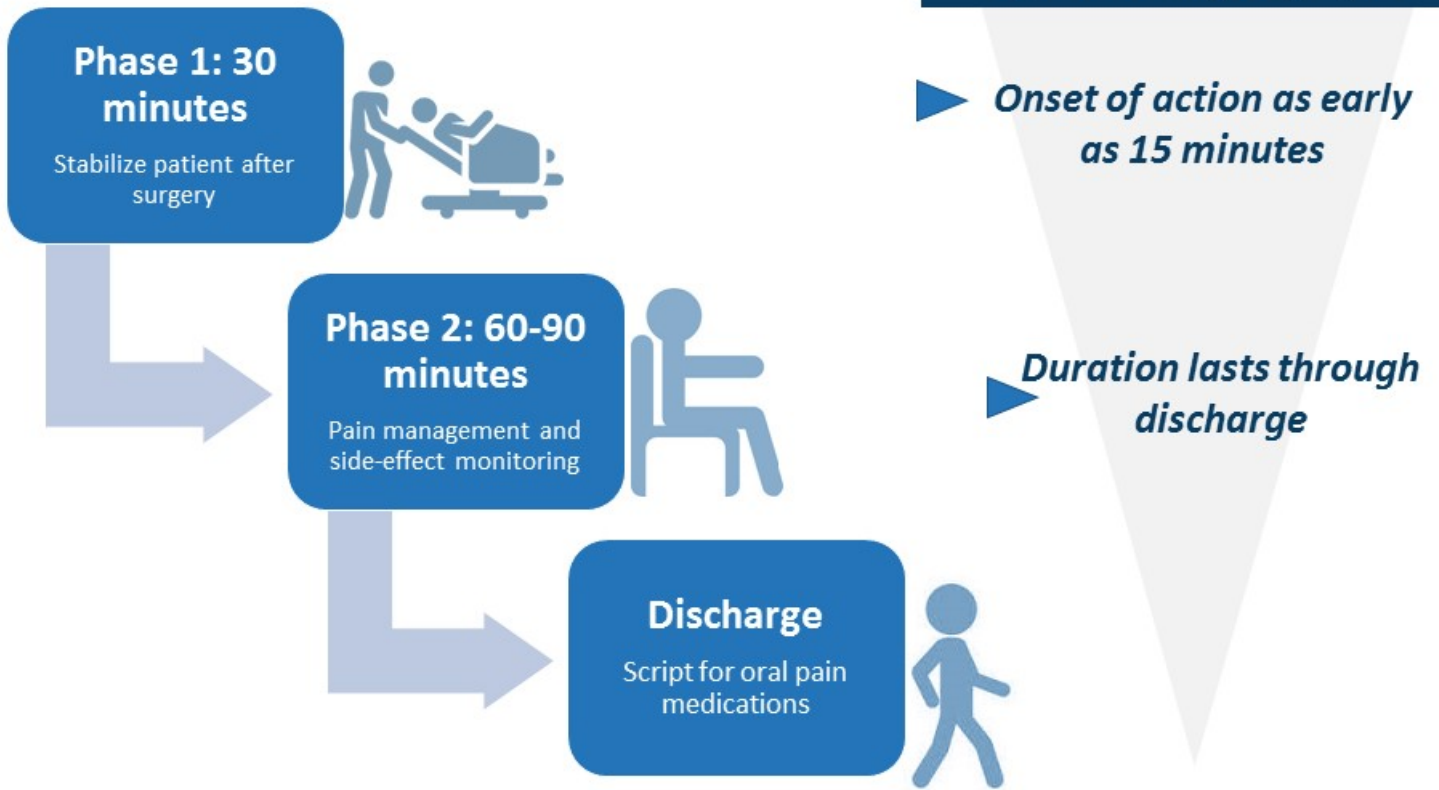
Component Costs of IV Dose³



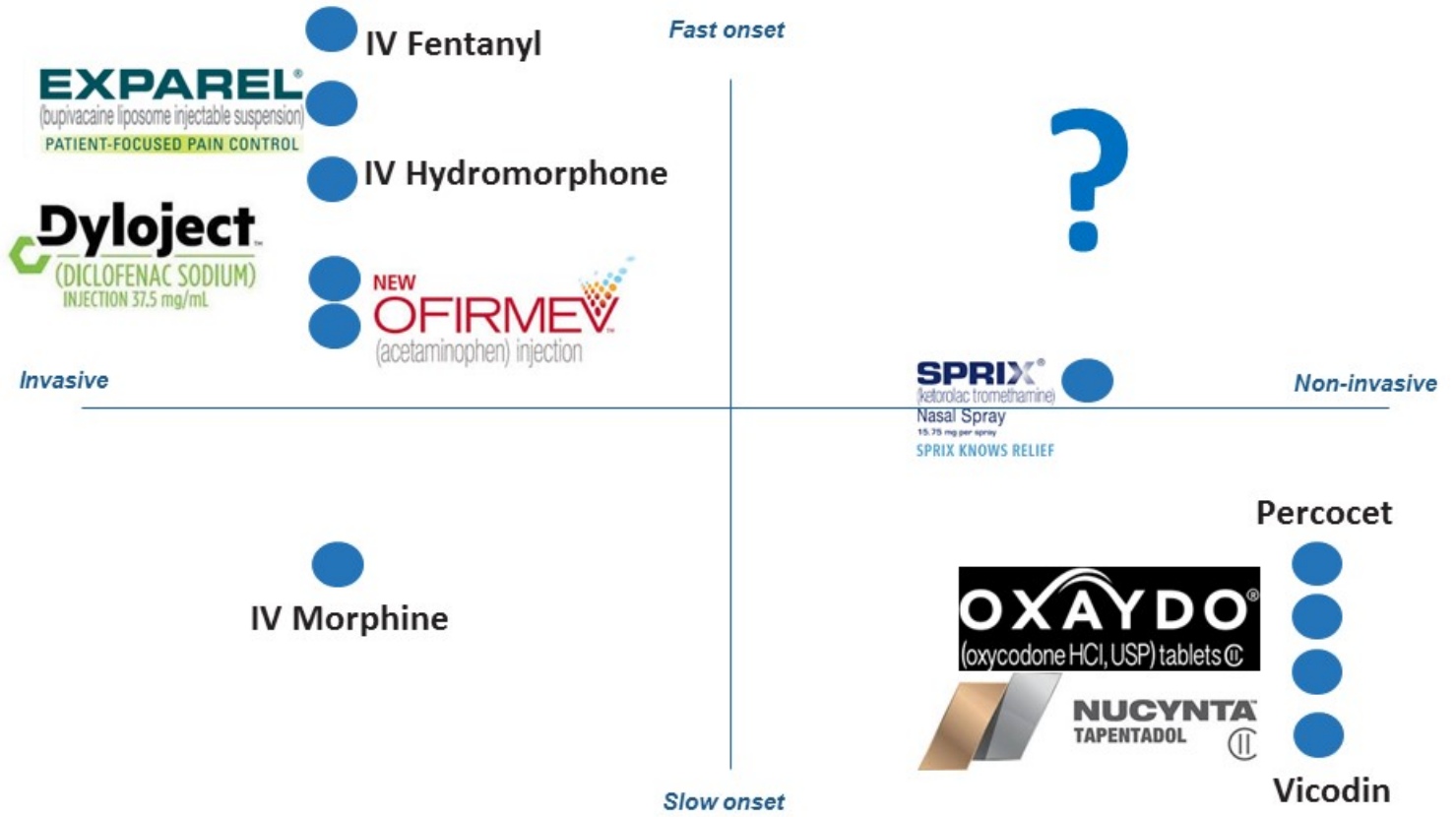
DSUVIA outpatient surgery opportunity is estimated at 11M adult patients annually



Outpatient surgery recovery is time-sensitive to ensure patient throughput

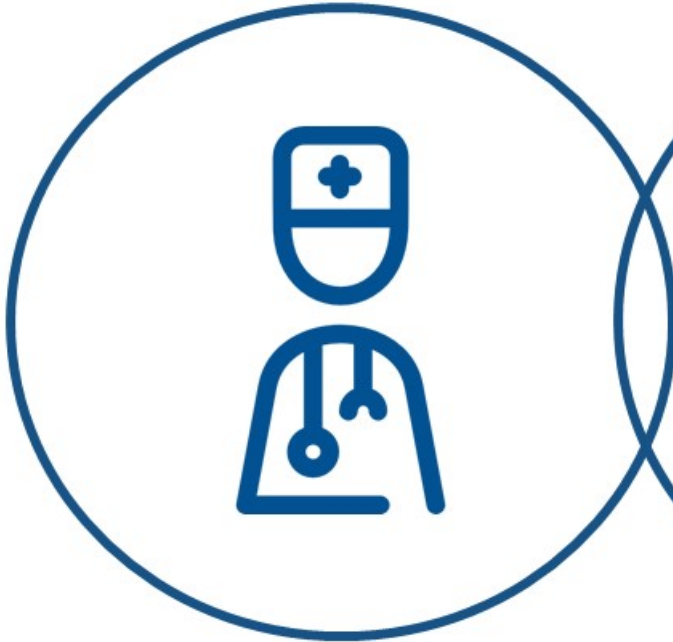


A clear unmet need in acute pain management



DSUVIA may address unmet clinical need and hospital efficiency

Clinical



Hospital Efficiency



Zalviso

Zalviso[®]: Sufentanil Sublingual 15 mcg in a Patient-Controlled Analgesia (PCA) System



reddot award
product design



Proposed Indication

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

Dosing

40 count - 15 mcg tablets / cartridge

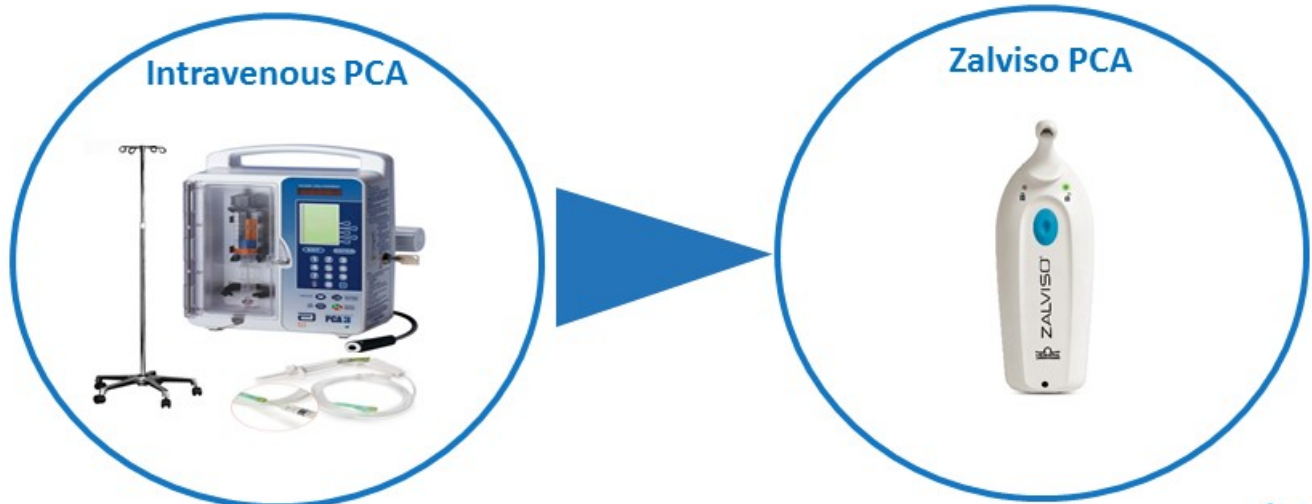
Development Status

- Clinical Study in life portion completed
- NDA resubmission planned for after DSUVIA Type A meeting
- Type II resubmission – 6 month review
- Launched in Europe April 2016 by our partner

Why PCA for inpatient (>24hrs) post-operative pain?

PCA has been shown to be more effective in treating inpatient post-operative pain than intermittent IM or IV injections¹

- Increased control over pain relief
- Provide higher patient satisfaction
- Lower pre-operative anxiety and post-operative depressive symptoms
- Other advantages include not having to receive injections, not having to wait for pain relief, and not having to summon nurses.



Zalviso IAP312 trial results achieved study objectives

2.2%

7 patients out of 320 experienced a device error (2.2%)

4 of 7 pts. experienced analgesic gap due to tablet not dispensed

Standard of care (IV PCA) device error ~ 12%¹

<0.1%

7 tablets discovered by HCP out of 7,293 dispensed (<0.1%)

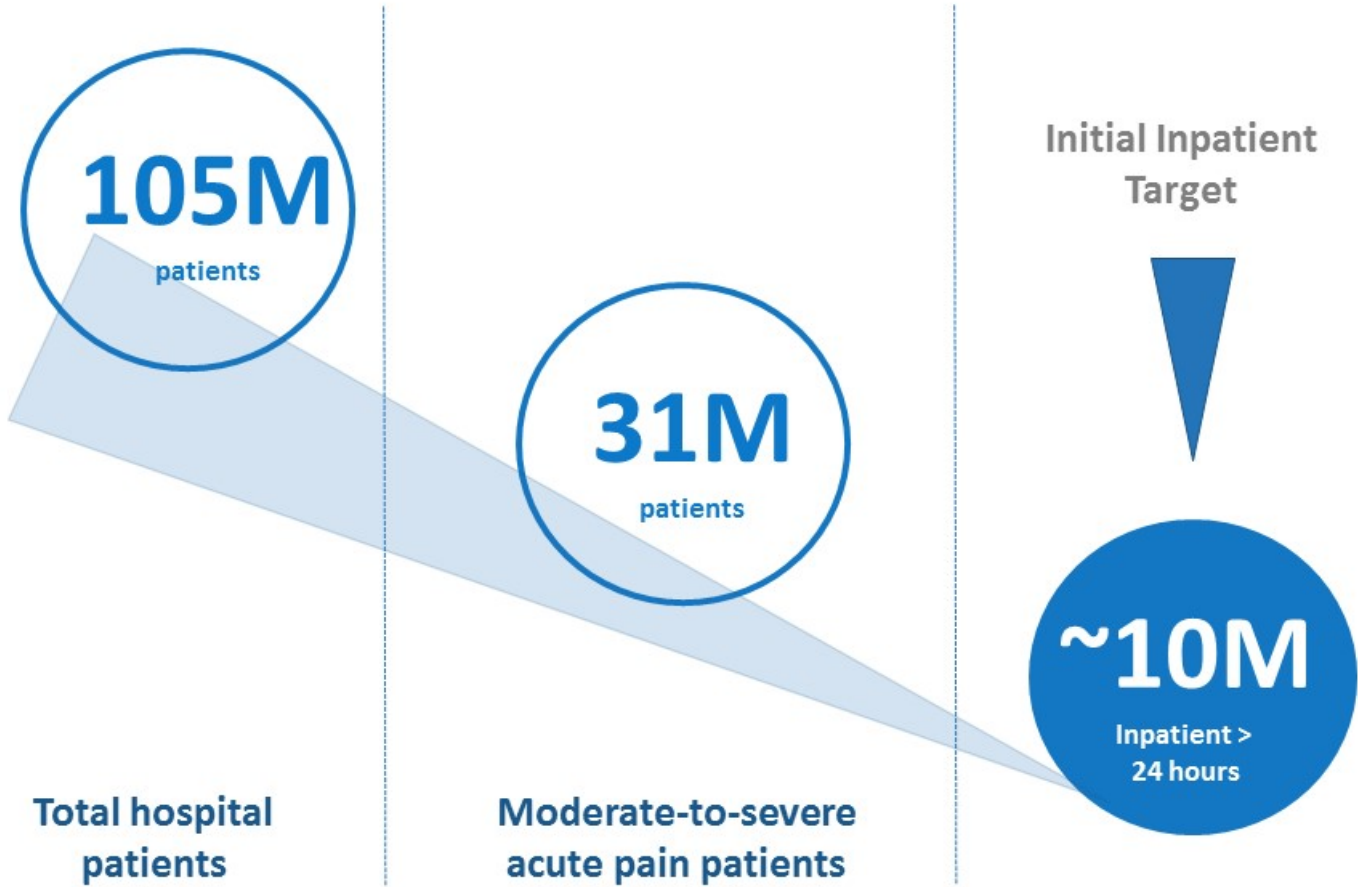
The 7 misplaced tablets occurred with 6 patients

No repeat dropped tablets following re-training

Patient Global Assessment	%
PGA 24 hrs	86
PGA 48 hrs	89
PGA 72 hrs	100

HCP Global Assessment	%
HPGA 24 hrs	91
HPGA 48 hrs	95
HPGA 72 hrs	100

Zalviso inpatient acute pain opportunity in the US is estimated at ~10M adult patients annually



Zalviso is being commercialized in Europe with our partner, Grünenthal

ZALVISO®



Welcome to the ZALVISO® Resource Centre

A free, simple way to learn more about ZALVISO® and how to implement it in your clinical setting. Please proceed to the appropriate website

I AM A HEALTHCARE PROFESSIONAL

This site has been designed specifically for healthcare professionals who would like more in-depth information about ZALVISO®. By entering the HCP ZALVISO® Website, you are declaring and confirming that you are a healthcare professional.

I AM A PATIENT OR A MEMBER OF THE PUBLIC

This site has been designed specifically for patients and members of the public. It contains general educational information about ZALVISO®. By entering the Patients and Public ZALVISO® Website, you understand that this site is intended to provide educational information.

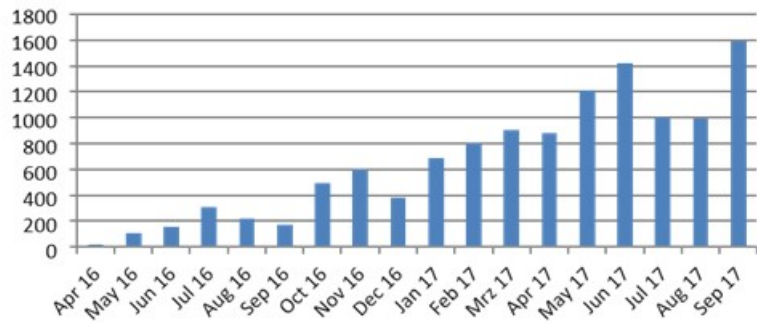
Grunenthal's EU Zalviso launch progressing well with a total estimated use by 16,000 patients through 2017

 (4230)	 (842)
 (2594)	 (318)
 (1157)	 (100)
 (779)	 (755*)
 (1074)	 (108)

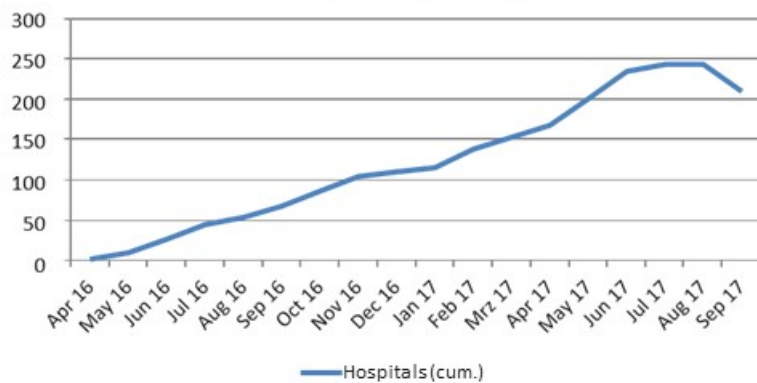
 (82)	 (20)
 (30)	 (8)
 (29)	 (1)
 (10)	 (8)
 (15)	 (7)

Status: 30 Sep 2017
* including Phase IIIb

Patients



Hospitals (cum.)



AcelRx investment highlights

- **DSUVIA NDA accepted for filing by FDA on February 10, 2017**
 - CRL received October 11, 2017 with Type A meeting set for the end of January 2018
 - CHMP opinion 1H 2018
 - US market opportunity is over 91M patients in multiple settings¹
- **ZALVISO resubmission planned after DSUVIA Type A meeting**
 - Successfully completed IAP312 study
 - Commercial launch in Europe – est 16,000 patients in over 200 hospitals by end of 2017
- **43 issued patents; 42 pending**
- **\$67.9 million cash as of September 30, 2017**
- **\$10-11 million quarterly cash burn pre-commercial**



For more information, visit:
www.aceIrx.com

AceIRx
Pharmaceuticals, Inc.

