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): August 15, 2016

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**001-35068**	**41-2193603**
(State of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

351 Galveston Drive
Redwood City, CA 94063
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(650) 216-3500**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

Dr. Pamela P. Palmer, co-founder and chief medical officer of AcelRx Pharmaceuticals, Inc., (the "Company" or "AcelRx") will present topline results from the single-arm, open-label Phase 3 SAP302 trial which assessed ARX-04 (sufentanil sublingual tablet, 30 mcg) in patients who presented to the emergency room with moderate-to-severe acute pain associated with trauma or injury, at the 2016 Military Health System Research Symposium on August 15, 2016, and will utilize a slide presentation. The slide presentation is furnished as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

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 August 15, 2016, the Company issued a press release entitled "AcelRx Pharmaceuticals' ARX-04 Phase 3 Trial met its Primary Endpoint, Reduced Pain Intensity in ER Patients with Moderate-to-Severe Acute Pain," a copy of which is attached as Exhibit 99.2 to this Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Slide presentation entitled, "Phase 3 Efficacy and Safety Results of Sufentanil Sublingual Tablet."
99.2	Press release dated August 15, 2016.

SIGNATURES

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

Date: August 15, 2016

ACELRX PHARMACEUTICALS, INC.

By: /s/ Jane Wright-Mitchell
Jane Wright-Mitchell
Chief Legal Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Slide presentation entitled, "Phase 3 Efficacy and Safety Results of Sufentanil Sublingual Tablet."
99.2	Press release dated August 15, 2016.

Exhibit 99.1

Phase 3 Efficacy and Safety Results of Sufentanil Sublingual Tablet

2016 MHSRS Plenary Session

Pamela Palmer, MD PhD

Chief Medical Officer, AcelRx Pharmaceuticals, Inc.

Treatment Considerations for Battlefield Acute Pain

U.S. Department of Defense aware of our development of small sublingual sufentanil tablets for post-operative pain

- Requested single-dose, easy to use applicator for field-based scenarios

Sublingual delivery of sufentanil offers potential for field-based analgesia

- Clinical data has shown greater pain intensity reduction in the first 4 hours compared to IV morphine[1]
- Sublingual tissue perfusion maintained during shock[2]
- Eliminate needle-stick injury and associated risk of infection

Issues with other current battlefield treatments

- IM morphine less effective during shock due to peripheral vasoconstriction[2]
- Oral transmucosal fentanyl lozenge can take over 30 minutes to dissolve[3]
- Ketamine can produce dissociative effects[4]

1. Melson TI, Boyer DL, Minkowitz HS, et al (2014) Sufentanil sublingual microtablet system versus intravenous patient-controlled analgesia with morphine for postoperative pain control: a randomized, controlled trial. *Pain Pract* 14:679–688
2. de Moya, M. A. *Shock*. In Merck manual online, professional version. Retrieved from http://goo.gl/I8Xpa
3. Actiq package insert, Dec 2011, Cephalon, Inc.
4. Curran HV, Morgan C (2000) Cognitive, dissociative and psychotogenic effects of ketamine in recreational users on the night of drug use and 3 days later. *Addiction* 95:575-590

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Profile of Desired Battlefield Analgesic

Excerpted from - Combat Anesthesia: The First 24 Hours (eds. Buckenmaier C and Mahoney PF, 2015)[1]

- Robust stability in the face of environmental challenges
- Straightforward method of delivery to increase potential caregivers
- Rapid onset with a rarity of adverse events
- Minimize altered mental status
- Large therapeutic index

1. Published by Office of the Surgeon General, United States Army, Falls Church, Virginia, p. 268

Why Sublingual Sufentanil?

Sufentanil first synthesized by Janssen in 1974[1]

First approved in US for IV delivery in 1984[1]

- Approved for induction of anesthesia
- Later approved for epidural delivery as an analgesic in combination with bupivacaine[1]

Sufentanil Physicochemical Properties

- Lipophilic: 1500 times more fat-soluble than morphine
- 20% non-ionized at physiological pH (fentanyl only 8%)
- Fat-soluble, non-ionized molecules = more rapid brain penetration than lipid-insoluble, charged molecules[2]

1. Stanley TH, Egan TD, Van Aken H. A tribute to Dr Paul AJ Janssen: entrepreneur extraordinaire, innovative scientist, and significant contributor to anesthesiology. Anesth. Analgesia. 2008;106(2):451–462
2. De Leon-Casasola et al. *Anesth Analg* 1996; 83:867-75.

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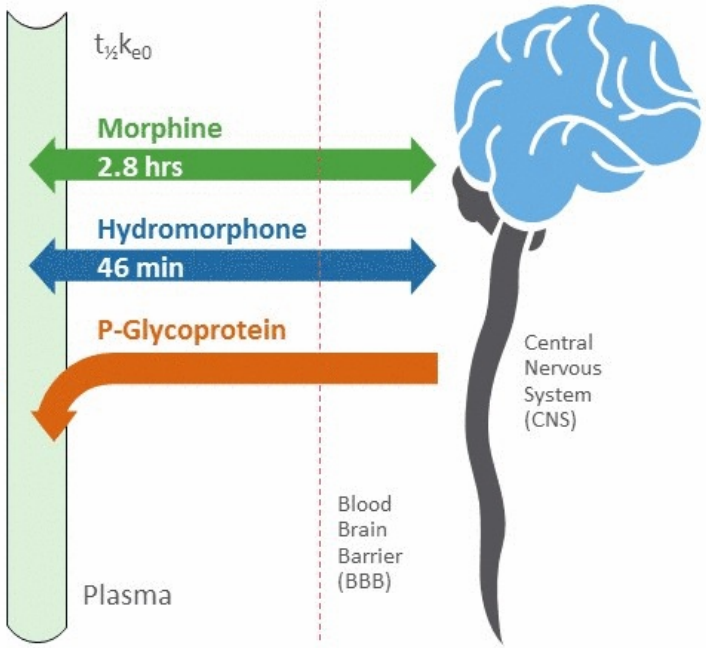
Sufentanil Penetrates CNS Due to Lipophilicity ($t_{½}k_{e0}$)

Commonly used IV opioids have delayed equilibration between plasma and CNS

- Morphine $t_{½}k_{e0}$ = 2.8 hours[1]
- Hydromorphone $t_{½}k_{e0}$ = 46 min[2]

Sufentanil rapidly penetrates the CNS due to its very lipophilic nature

- Sufentanil $t_{½}k_{e0}$ = 6 min[3]



1. Lotsch et al., *Anesthesiol* 95:1329-38, 2001
2. Shafer et al., *Geriatric Anesthesiology*. 2nd ed. New York, NY: Springer; Chapter 15:209–28, 2007
3. Scott et al., *Anesthesiol* 74:34-42, 1991

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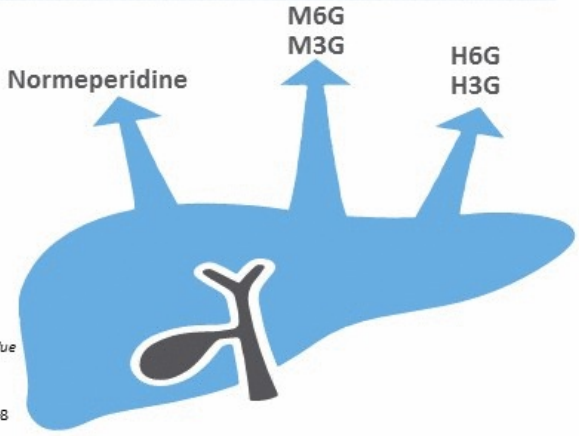
Sufentanil: High Therapeutic Index and No Active Metabolites

Opioid	Therapeutic index [lethal dose (LD_{50})/effective dose (ED_{50}) in animal studies]
Morphine	71[1]
Hydromorphone	232[2]
Fentanyl	277[1]
Sufentanil	26,716[1]

Other Opioid Active Metabolites[3-7]



1. Mather, *Clin Exp Pharmacol Physiol* 1995; 22:833.
2. Kumar, *Eur J Pharmacol* 2008; 597:39 (ED50) and *Purdue Pharma MSDS*, 2009 (LD50)
3. Clark et al., *J Emerg Med 1995*;13:797–802
4. Smith et al., *Clin J Pain 2011*;27:824–38
5. Smith et al., *Clin Exp Pharmacol Physiol 2000*;27:524–8
6. Wright et al., *Life Sci 2001*;69:409–20
7. Smith, H. *Mayo Clin Proc 2009;84(7):613-614*

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Sufentanil Pharmacokinetics

- **Sublingual delivery of sufentanil blunts C_{max} and extends plasma half-time compared to IV administration[1]**

ARX-04 30 mcg	IV	Sublingual
Bioavailability, %, mean	100	53
C_{max} pg/mL, mean	1074	63
$CST_{½}$ h, median	0.1	2.3

CST½ = context-sensitive half-time (time from C_{max} to 50% of C_{max})

1. SAP101, data on file, AcelRx

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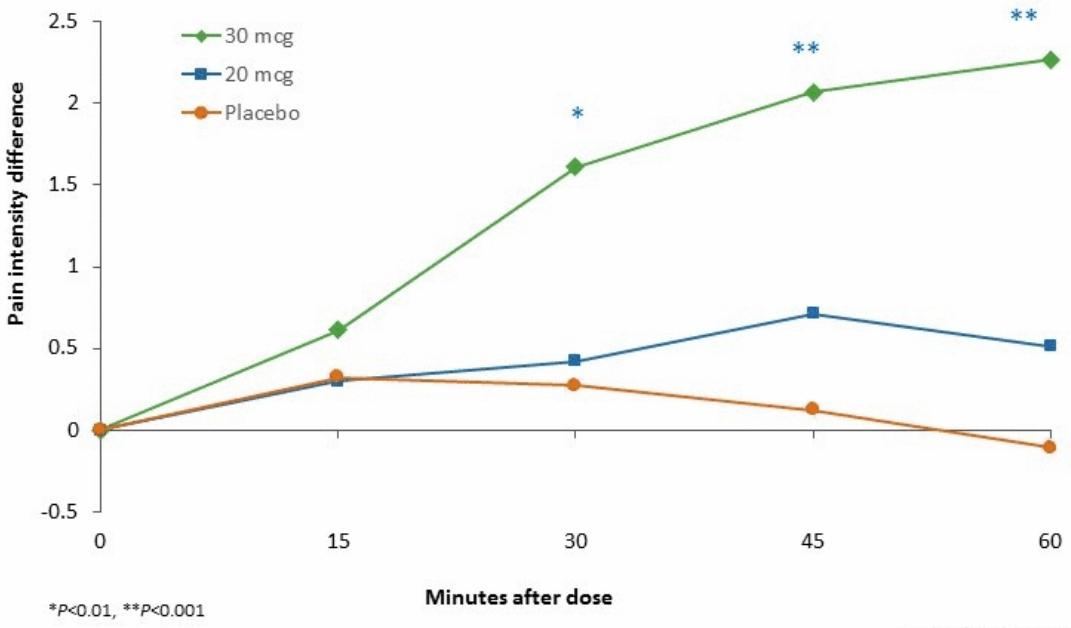
SAP202
ARX-04 Dose-Finding Study

- **Postoperative bunionectomy patients**
- **ARX-04 30 mcg dose demonstrated superiority over placebo within 30 minutes**



*P<0.01, **P<0.001

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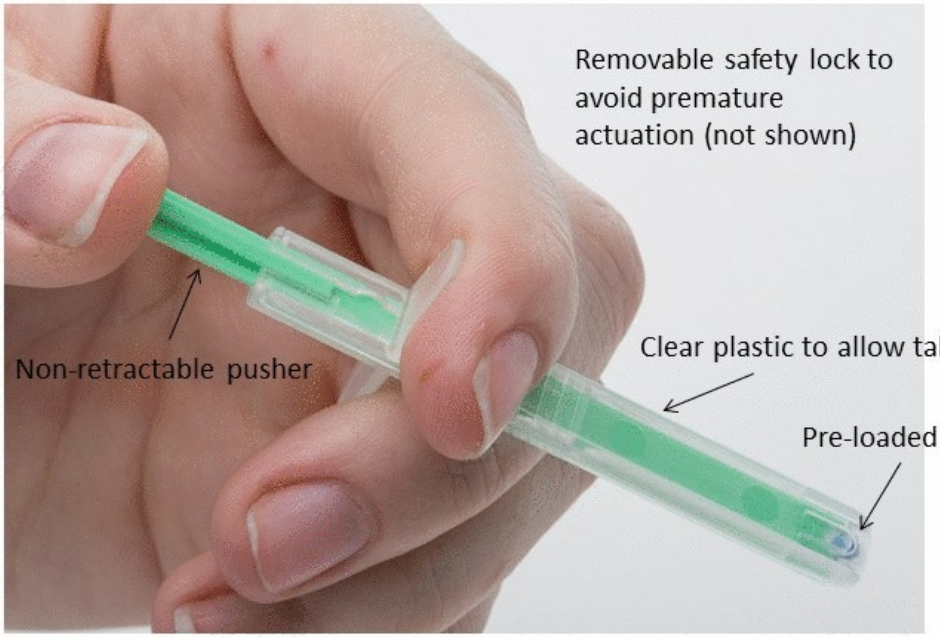
1. Singla NK, et al. A dose-finding study of sufentanil sublingual microtablets for the management of postoperative bunionectomy pain. *J. Trauma. Acute. Care. Surg.* 2014;77(3 Suppl 2):S198–S203

ARX-04 Single-Dose Applicator

- **Designed in collaboration with DoD (light-weight, extreme-environment tested, easily handled with gloves)[1]**



1. Data on file, AcelRx (2015-2016)

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SAP302: Emergency Dept. Trauma Pain

Study Design

Inclusion/Exclusion

Inclusion:

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

Exclusion:

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

Study Details

Multicenter, Single-Arm, Open-Label Study

ARX-04 30 mcg

Two Cohorts:

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

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SAP302
Outcome Measures

Study sites

- Hennepin County Medical Center, Minneapolis, MN (James Miner, MD)
- Memorial Hermann-Memorial City Medical Center, Houston, TX (Harold Minkowitz, MD)
- Baylor College of Medicine, Ben Taub General Hospital, Houston, TX (Zubaid Rafique, MD)

Primary Endpoint	Key Secondary Efficacy Endpoints	Safety Endpoints
▪ Sum of the pain intensity difference to baseline over the first hour of treatment (SPID1)	▪ PID assessments ▪ Patient and Healthcare Global Assessment ▪ Use of rescue medication ▪ Drop-outs due to inadequate analgesia	▪ Adverse Events ▪ Vital Signs ▪ Six-item Cognitive Screener ▪ Concomitant Medications

SAP302: Demographics (n=76)

Category		Category	
Sex, male, %	61	BMI, %	
Age, years, mean	42	< 30kg/m^2	61
Race, %		≥ 30kg/m^2	39
Caucasian	59	ASA Classification, %	
African American	34	1	61
Native American	7	2	33
Ethnicity, %		3	7
Hispanic/Latino	16	**Baseline Pain**	**8.1/10**

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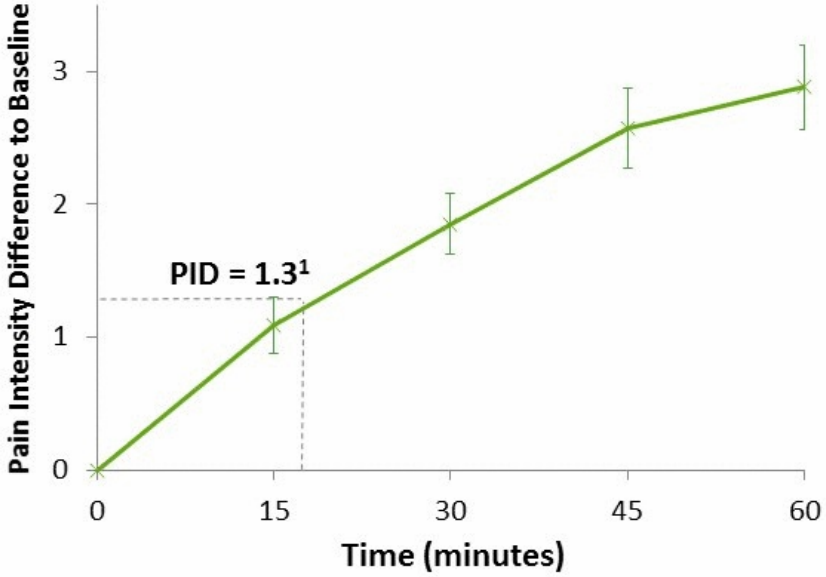
SAP302: Efficacy
Combined Cohorts (n=76)

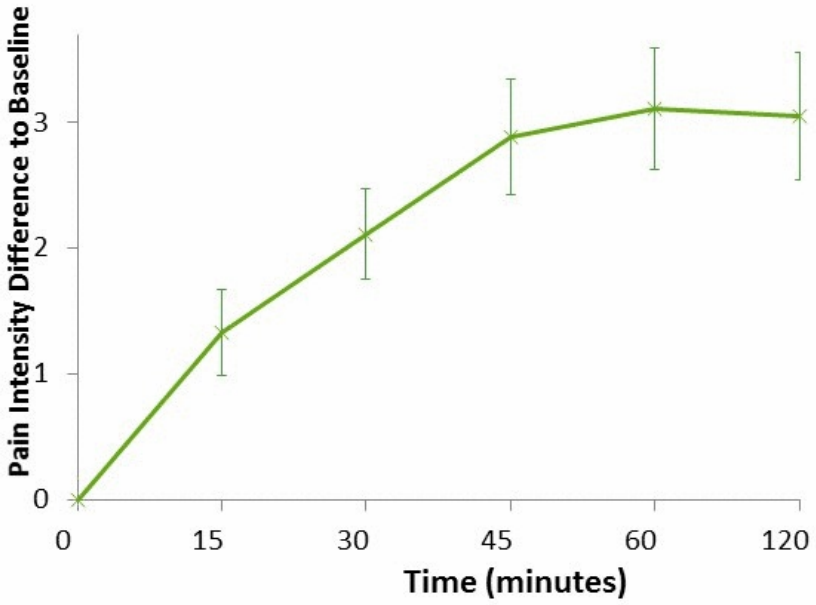
- **Over 35% drop in pain intensity by 60 minutes**
- **A clinically significant drop in pain intensity when administering 0-10 point numerical rating scale (NRS) to measure pain is 1.3[1]**



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

SAP302: Efficacy
Multiple-Dose Cohort (n=36)

- Re-dosing allowed hourly if needed
- 75% of patients did not require re-dosing



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SAP302: Efficacy
Use of Rescue

- **Low rate of rescue opioid usage**

Study Period	Patients Requiring Use of Rescue Opioid	
	Single-Dose Cohort (n = 40)	Multiple-Dose Cohort (n = 36)
Use in First Hour	7.5%	0%
Use after First Hour	NA	8.3%

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SAP302: Safety
Adverse Events (≥ 2% of patients)

- **Majority of patients experienced no side effects**

Adverse Event, n (%)	ARX-04 (30 mcg) n=76
No Adverse Event	**79%**
Nausea	9%
Somnolence	5%[1]
Vomiting	4%
Oxygen Desaturation	3%[2]

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)

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SAP302: Safety
Six-Item Screener (SIS) Cognitive Test

Sublingual sufentanil not associated with cognitive impairment

- DoD requested cognitive test before and 1 hour after dosing of sublingual sufentanil 30 mcg
- Impaired cognitive skills a concern with other field-based analgesics used in the military (e.g., ketamine)[1]
- A score of 4 or less has been validated as indicating cognitive impairment[2]
- Only 2 of 76 patients had a drop on the SIS at one hour compared to baseline (6 >> 5; 5 >> 4)

1. Green, et al., Clinical Practice Guideline for Emergency Department Ketamine Dissociative Sedation: 2011 Update. Ann Emerg Med. 2011;57:449-461.
2. Callahan et al., Six-Item Screener to Identify Cognitive Impairment Among Potential Subjects for Clinical Research. Med Care. 2002;40:771-781.

ARX-04: Positive Phase 3 Data in the Treatment of Moderate-to-Severe Acute Pain

- Single dose of ARX-04 30 mcg results in approximately a 3-point drop in pain intensity within 60 minutes, with clinically meaningful analgesia in < 20 minutes[1]
- ARX-04 is well-tolerated and did not show cognitive impairment in this clinical study
- ARX-04 is still investigational, but if approved, could provide an analgesic option for opioid-naïve patients
- Additional research is indicated to assess safety and efficacy in actual field-based environments

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

Thank you

Dr. Pamela Palmer

ppalmer@acelrx.com

Exhibit 99.2

AcelRx Pharmaceuticals' ARX-04 Phase 3 Trial met its Primary Endpoint, Reduced Pain Intensity in ER Patients with Moderate-to-Severe Acute Pain

- Topline SAP302 Results Presented at Military Health System Research Symposium -

REDWOOD CITY, Calif. – August 15, 2016 -- 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, reported topline results from the single-arm, open-label Phase 3 SAP302 trial (NCT02447848), which assessed ARX-04 (sufentanil sublingual tablet, 30 mcg) in patients who presented to the emergency room with moderate-to-severe acute pain associated with trauma or injury. Overall, the 76 adults treated with ARX-04 in this study experienced a mean pain intensity difference to baseline (PID) of 2.9 from a baseline of 8.1, or 35%, on a 0 – 10 numeric rating scale at 60 minutes.

SAP302 enrolled patients in two cohorts. The initial phase enrolled 40 adults who were administered a single dose of ARX-04; and an extension phase enrolled 36 adults who were eligible to receive up to four doses of ARX-04, given hourly as needed for pain. Interim results from the first cohort were reported in February 2016, and showed that patients treated with a single dose of ARX-04 experienced a mean pain intensity decrease from baseline of 2.7 at 60 minutes. Patients in the second cohort reported a mean pain intensity decrease from baseline of 3.1 on the 0 – 10 pain intensity scale at 60 minutes. Of these 36 patients, seven received a second dose of ARX-04, and two received a third dose. For 75% of patients in the second cohort, a single dose of ARX-04 was sufficient for pain relief and only 8% of patients received morphine in addition to ARX-04.

In addition, ARX-04 demonstrated a predicted onset of activity in patients enrolled in SAP302. Patients reported a mean pain intensity decrease of 1.1 compared to baseline 15 minutes following first administration of ARX-04, and a decrease of 1.9 after 30 minutes.

Overall ARX-04 was well tolerated in this study, with 79% of patients reporting no adverse events. The most common adverse events reported in the study occurred with single-digit rates - the most common being nausea (9%), somnolence (5%) and vomiting (4%). All these events were rated as mild with the exception of one event of moderate nausea. Drug-induced cognitive impairment was not seen with ARX-04 in this study, as assessed using the validated Six-Item Screener.

"The Department of Defense, which has provided us with development funding for ARX-04, suggested that we conduct a cognitive impairment assessment to determine if ARX-04 causes cognitive deficiencies, which is an understandable concern when treating wounded soldiers on the battlefield," explained Dr. Pamela Palmer, co-founder and chief medical officer of AcelRx Pharmaceuticals. "In addition to putting combat units in danger, drug-induced cognitive effects can impede diagnosis and treatment in a civilian emergency room. If borne out, ARX-04's onset of pain relief, sublingual dosage form and side effect profile could make it an attractive option for doctors considering opioid analgesic treatment in emergency rooms and field-based settings."

About MHSRS
The above results are being presented today at the 2016 Military Health System Research Symposium (MHSRS), the Department of Defense's premier scientific meeting. The MHSRS is being held at the Gaylord Palms Resort & Convention Center in Kissimmee, FL from August 15-18. It is a venue for communicating and discussing new scientific knowledge resulting from research and development aimed at optimizing care for members of the Uniformed Services in operational settings. It is the only military or civilian meeting that focuses specifically on the unique medical needs of the warfighter.

Clinical and Rehabilitative Medicine Research Program (CRMRP)
ARX-04 is funded in part by the Clinical and Rehabilitative Medicine Research Program (CRMRP) of the U.S. Army Medical Research and Materiel Command (USAMRMC) under contract No. W81XWH-15-C-0046. The CRMRP 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, AcelRx 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 ARX-04
ARX 04 is a non-invasive investigational product candidate consisting of 30 mcg sufentanil tablets delivered sublingually via a disposable, pre-filled, single-dose applicator (SDA). AcelRx is developing ARX 04 for the management of moderate-to-severe acute pain in a variety of medically supervised settings, including the emergency room, outpatient or ambulatory surgery, non-surgical patients experiencing pain in the hospital, and post-operative patients following short-stay surgery, who do not require more long-term patient-controlled analgesia (PCA).

The ARX-04 Phase 3 clinical program is comprised of three studies in patients with moderate-to-severe acute pain: SAP301, a double-blind, placebo-controlled trial in ambulatory abdominal surgery patients; SAP302, an open-label trial in adult emergency room patients; and SAP303, an open-label trial in postoperative patients. Results of SAP301, which were presented in 2015 at the American Society of Anesthesiologists annual meeting, may be viewed on the AcelRx website.

About AcelRx Pharmaceuticals, Inc.
AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain. The Company's late-stage pipeline includes ARX-04 (sufentanil sublingual tablet, 30 mcg) designed for the treatment of moderate-to-severe acute pain in a medically supervised setting; and Zalviso® (sufentanil sublingual tablet system) designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting.

ARX-04 delivers 30 mcg sufentanil, a high therapeutic index opioid, sublingually through a disposable, pre-filled, single-dose applicator. AcelRx has reported positive results from the pivotal Phase 3 SAP301 ambulatory surgery study, and has recently completed SAP302 (study in emergency room patients) and SAP303 (study in post-operative patients 40 years and older). Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. In response to the New Drug Application (NDA) AcelRx submitted to the U.S. Food and Drug Administration (FDA) seeking approval for Zalviso, AcelRx received a Complete Response Letter (CRL) on July 25, 2014. The FDA has requested an additional clinical study (IAP312), which AcelRx is planning to initiate once supply testing is complete in order to support its NDA resubmission.

For additional information about AcelRx's clinical programs, please visit www.acelrx.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 AcelRx's product candidates, ARX-04 (sufentanil sublingual tablet, 30 mcg) and Zalviso® (sufentanil sublingual tablet system), including the ARX-04 clinical trial results; anticipated submission of the New Drug Application, or NDA, for ARX-04 to the U.S. Food and Drug Administration, or FDA; AcelRx's pathway forward towards gaining approval of Zalviso in the U.S.; the anticipated timing, design and results of the IAP312 clinical trial for Zalviso; 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; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities for ARX-04 and Zalviso. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements, and as a result of these risks and uncertainties, which include, without limitation, risks related to AcelRx Pharmaceuticals' ability to successfully complete Phase 3 clinical development of ARX-04; AcelRx's ability to successfully execute the pathway towards a resubmission of the Zalviso NDA to the FDA, including the initiation and completion of the IAP312 clinical study for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including ARX-04 in the United States and Europe, and Zalviso in the United States; 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 Phase 3 ARX-04 SAP302 and SAP303 trials, and the additional clinical trial for Zalviso, IAP312; the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 studies of ARX-04 and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-Q filed with the SEC on July 29, 2016. AcelRx 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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