AcelRx Pharmaceuticals Reports on ARX-04 Market and Landscape Presented at Analyst & Investor Event

December 6, 2016

- Peak revenue opportunity for ARX-04 estimated to be $1.1 billion
- NDA for ARX-04 on track for submission by year-end

REDWOOD CITY, Calif., Dec. 6, 2016 /PRNewswire/ -- 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, held an Analyst & Investor Event on December 1, 2016 during which members of AcelRx management and key opinion leaders reviewed market expectations and commercial plans for ARX-04 (sufentanil sublingual tablet, 30 mcg) as well as the current landscape for opioid treatment in the emergency medicine setting. During this event, AcelRx provided an updated U.S. commercial peak sales expectation for ARX-04 of $1.1 billion. A replay of the event is available on the AcelRx website along with a copy of the AcelRx slide presentation.

Presentation Highlights

- Nathaniel Katz, MD; CEO of Analgesic Solutions, Adjunct Assistant Professor of Anesthesia at Tufts University School of Medicine
  - Provided insights into the regulatory view of opioid approvals
- David Leiman, MD; President of AIPM of Houston and Director of HD Research Corp
  - Reviewed results of the ARX-04 clinical program: two pivotal, randomized, placebo-controlled studies, SAP202 and SAP301 (bunionectomy and outpatient abdominal surgery); and, two open-label Phase 3 studies, SAP302 and SAP303 (emergency department and ambulatory surgery)
- Gina Ford; AcelRx Vice President, Commercial Strategy
  - Explained the basis of AcelRx's expectations for the emergency department market opportunity, in terms of patient numbers and unmet need
  - Provided guidance on AcelRx's anticipated pilot launch program

Emergency Department Panel

- John Holcomb, MD; Retired COL, US Army, Division of Acute Care Surgery, Chief Center for Translational Injury Research, University of Texas Health Science Center, Houston, TX
- David Leiman, MD; President of AIPM of Houston and Director of HD Research Corp
- James Miner, MD; Chief of Emergency Medicine, Hennepin County Medical Center, Minneapolis, MN
- Michael Ritter, MD Emergency Medicine Physician, St. Joseph Health Mission Hospital, Mission Viejo, CA
  - Offered informed views of the functions of an emergency department, and the decisions that physicians and nurses must make in order to prioritize patient care and outflow
  - Discussed relative importance of speed and cost considerations when selecting pain medications and route of administration

"The event provided an opportunity for AcelRx and several key opinion leaders to share their outlook for ARX-04," commented Howie Rosen, chief executive officer of AcelRx. "The underlying theme of overcrowding in emergency rooms combined with a non-invasive sublingual approach to the treatment of moderate-to-severe acute pain resonates with practicing physicians. We look forward to the submission of the NDA later this month and in working with the FDA on its review of ARX-04."

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 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.

AcelRx expects to submit a New Drug Application for ARX-04 with the U.S. Food and Drug Administration in December 2016 using the 505(b)(2) pathway. Under these guidelines, AcelRx expects its application to be subject to a ten-month review period.

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 moderate-to-severe 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 medically supervised settings; and Zalviso® (sufentanil sublingual tablet system), designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting. 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 as well as Norway, Iceland, and Liechtenstein 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, and Australia, while AcelRx retains all other world-wide rights.

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.; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities and market size 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' ARX-04 development program; the uncertain clinical development process; the success, cost and timing of all development activities and clinical trials; actual market size for AcelRx products; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx'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. 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.

Logo - http://photos.prnewswire.com/prnh/20130226/MM67303LOGO

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/acelrx-pharmaceuticals-reports-on-arx-04-market-and-landscape-presented-at-analyst--investor-event-300373146.html

SOURCE AcelRx Pharmaceuticals, Inc.

Timothy E. Morris, Chief Financial Officer, 650.216.3511, tmorris@acelrx.com; Brian Korb, The Trout Group LLC, 646.378.2923, bkorb@troutgroup.com