AcelRx Pharmaceuticals Names Howard B. Rosen as Chief Executive Officer and Provides Update on Clinical Development Activities and Corporate Priorities for 2016

March 29, 2016

Conference call update at 4:30pm ET today

REDWOOD CITY, Calif., March 29, 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, announced today the appointment of Howard B. Rosen as the Chief Executive Officer of AcelRx, effective April 1, 2016. Mr. Rosen has served as the interim CEO for AcelRx since April 1, 2015. Mr. Rosen is an experienced and technically trained executive with over 25 years of success growing start-up and mid-size biopharmaceutical companies. Mr. Rosen previously held senior-level general management positions and functional roles in strategy, marketing, finance, business development, and research and development at Gilead Sciences, Inc. and ALZA Corporation. More recently he was interim CEO of Pearl Therapeutics which was subsequently acquired by Astra Zeneca for up to $1.15 billion in 2013. Mr. Rosen has served on the Board of Directors of AcelRx since 2008 and currently serves on the Board of Directors of Alcobra, Ltd. and two private biopharmaceutical companies.

"Howie has done a tremendous job over the past year helping the Company review and revise its priorities and in ensuring quality and timely execution of organizational goals. The Board determined that Howie is the best person to lead the Company in completing the NDA submissions for ARX-04 and Zalviso ™, and preparing the Company for the potential approval and commercialization of these important products," commented Adrian Adams, Chairman of the Board of Directors of AcelRx.

"I appreciate the support of the employees, the Board of Directors and our shareholders during the past year as interim CEO. We have successfully transitioned ARX-04 into late-stage development, defined the regulatory pathway for ARX-04 and Zalviso in the U.S., seen the approval for Zalviso in Europe and strengthened our balance sheet," commented Mr. Rosen.

In addition, AcelRx has revised its pipeline priorities for 2016 and has selected ARX-04, (30 mcg of sufentanil sublingual tablet), as its primary focus for clinical development and commercialization. AcelRx has also decided to postpone the start of the Zalviso Phase 3 trial (IAP312) originally planned for the first quarter of 2016 as we determined that our Zalviso commercial supplies provided the performance quality we expect to provide with our NDA resubmission and with an anticipated U.S. commercial launch. The Company considered recent testing comparing Zalviso clinical and commercial supplies and determined that commercial supplies may better optimize system functionalities for the conduct of IAP312. This testing focused on the healthcare professional initiation of the system during set-up and would not be expected to affect patient safety or dosing. The use of commercial supplies may also reduce review time for any potential post-approval changes with supply manufacturers and software updates.

"Now that we have received the necessary approvals from the Department of Defense and have initiated the two remaining Phase 3 studies for ARX-04, we have reviewed our resource needs and will focus our clinical, regulatory and commercial teams primarily on ARX-04," stated Howie Rosen, CEO. Also, we were going to make the switch to commercial Zalviso supplies post-approval but by doing it now, we anticipate it will ultimately make the launch of Zalviso in the U.S. smoother." Mr. Rosen affirmed, "Zalviso remains an important product for AcelRx and we look forward to updating the market on its progress toward NDA resubmission."

The Company confirms its corporate objective that, assuming successful completion of the ongoing ARX-04 Phase 3 studies (SAP302 and SAP303) by the third quarter of 2016, the Company anticipates submitting the NDA for ARX-04 in the fourth quarter of 2016.

Conference Call

AcelRx will conduct a conference call today, March 29, at 4:30 p.m. Eastern time (1:30 p.m. Pacific time). To listen to the conference call, dial in approximately ten minutes before the scheduled call 1-866-361-2335 for domestic callers, 1-855-669-9657 for Canadian callers, or 1-412-902-4204 for international callers.

A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investors section of the company's website at www.acelrx.com.

About AcelRx

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 advanced ARX-04 into studies in emergency room patients (SAP302) and post-operative patients 40 years and older (SAP303). 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, including ARX-04 and Zalviso; anticipated results and timing of the completion of the SAP302 and SAP303 studies for ARX-04; timing for submission of NDA for ARX-04; timing for initiation and completion along with anticipated results of IAP312 for Zalviso; timing and success of Grunenthal's planned Zalviso launch in Europe; AcelRx's planned pathway forward towards gaining approval of Zalviso in the United States; and anticipated resubmission of the Zalviso NDA to the FDA, including the scope and timing of resubmission, and the anticipated launch of Zalviso in the United States. These forward-looking statements are based on AcelRx's current expectations and inherently involve significant risks and uncertainties. AcelRx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: any delays or inability to obtain and maintain regulatory approval of its product candidates, including ARX-04 and Zalviso; its ability to successfully design, timely enroll and complete the additional clinical study requested by the FDA to support resubmission of the Zalviso NDA; its ability to timely resubmit the Zalviso NDA to the FDA and to receive regulatory approval for Zalviso; the fact that the FDA may dispute or interpret differently positive clinical results obtained to date from the pivotal Phase 3 SAP301 ambulatory surgery study of ARX-04; its ability to complete Phase 3 clinical development of ARX-04 and submit the NDA for ARX-04 to the FDA; the success, cost and timing of all product development activities and clinical trials, including the SAP302 and SAP303 ARX-04 trials and the IAP312 Zalviso trial; its reliance on Grunenthal to successfully launch Zalviso in Europe; 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-K filed with the SEC on March 7, 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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SOURCE AcelRx Pharmaceuticals, Inc.

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