AcelRx Pharmaceuticals Hires Mike A. Royal, M.D. as Chief, Clinical Affairs

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REDWOOD CITY, Calif., Sept. 18, 2012 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain, today announced that Mike A. Royal, M.D., J.D., MBA, has joined the company as Chief, Clinical Affairs. Mike Royal has board certifications in internal medicine, pain medicine, and anesthesiology with sub-specializations in pain management and addiction medicine, along with extensive research, clinical and corporate work experience. For the past six years, Dr. Royal has worked at Cadence Pharmaceuticals, Inc. most recently as VP, Clinical Development and Medical Affairs, where he was responsible for activities such as the design, oversight, and completion of the OFIRMEV® (acetaminophen) injection clinical development program and new drug application, and medical support for pre-launch and launch activities, which resulted in the rapid acceptance of OFIRMEV onto hospital formularies.

"I am thrilled to welcome Mike to our executive leadership team," said Richard King, AcelRx's president and CEO. "I believe Mike's broad experience and proven track record will be exceptionally helpful to AcelRx as we approach late-stage clinical development and commercialization of our lead product, the Sufentanil NanoTab PCA System."

"I am particularly excited at the prospect of being involved in the development and commercialization of the novel sufentanil NanoTab PCA System, which has the potential to significantly improve pain management for post-operative patients," said Dr. Royal.

Dr. Royal will be responsible for managing the late-stage and post-approval clinical direction of AcelRx, as well as healthcare professional focused Medical Affairs on behalf of the company. This will include late-stage clinical trial design and management, data analysis, clinical publications and medical writing, product safety review and monitoring, and regulatory interactions. Prior to Cadence Pharmaceuticals, Dr. Royal's previous experience includes Solstice Neurosciences, where he served as Chief Medical Officer, Alpharma, where he served as VP, Strategic Brand Development and as VP, Global Medical Affairs, and Elan Pharmaceuticals, where he was Senior Medical Director. He currently serves on the clinical adjunct faculty at University of California San Diego, and was previously on faculty at the University of Pittsburgh Medical Center and as an attending anesthesiologist and pain physician, and director of the acute pain service. Dr. Royal earned a B.S. in chemistry from the Massachusetts Institute of Technology, M.D. from the University of Massachusetts Medical School, J.D. from the University of Maryland School of Law, and Global EMBA joint degree awarded from TRIUM (New York University Stern School, London School of Economics, and Haute Ecole Commerciale).

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 and breakthrough pain. AcelRx's lead product candidate, the ARX-01 Sufentanil NanoTab PCA System, which is currently in Phase 3 clinical development, is designed to solve the problems associated with post-operative intravenous patient-controlled analgesia which has been shown to cause harm to patients following surgery because of the side effects of morphine, the invasive IV route of delivery and the inherent potential for programming and delivery errors associated with the complexity of infusion pumps. AcelRx has two additional product candidates which have completed Phase 2 clinical development: ARX-02 for the treatment of cancer breakthrough pain, and ARX-03 for mild sedation, anxiety reduction and pain relief for patients undergoing painful procedures in a physician's office. AcelRx plans to initiate a Phase 2 study, pending protocol approval, for a fourth product candidate, ARX-04, a sufentanil formulation for the treatment of moderate-to-severe acute pain, funded through a grant from USAMRMC. 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 planned or anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, including the anticipated timing for the ARX-01 clinical trials, progress towards initiation of the Phase 2 study for ARX-04, and the therapeutic and commercial potential of AcelRx Pharmaceuticals' product candidates. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' 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: the success, cost and timing of AcelRx Pharmaceuticals' product development activities and clinical trials; the uncertain clinical development process, including the risk that planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be initiated or completed on schedule, if at all; any delays or inability to obtain, regulatory approval of its product candidates; its ability to obtain adequate clinical supplies of the drug and device components of its product candidates; its ability to attract funding partners or collaborators with development, regulatory and commercialization expertise; its ability to obtain sufficient financing to complete development and registration of its product candidates in the United States and Europe; its ability to obtain and maintain regulatory approvals of its product candidates; the market potential for its product candidates; the accuracy of AcelRx Pharmaceuticals' estimates regarding expenses, capital requirements and needs for financing; AcelRx Pharmaceuticals' ability to repay a portion of the principal under the loan and security agreement with Hercules with common stock; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx Pharmaceuticals' U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q for the three months ended June 30, 2012. AcelRx Pharmaceuticals 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.

SOURCE AcelRx Pharmaceuticals, Inc.

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