AcelRx Pharmaceuticals Receives Fourth and Fifth U.S. Patents for Small-Volume Oral Transmucosal Dosage Forms

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Two more U.S. patents expand intellectual property protection for AcelRx's pipeline of sufentanil NanoTab® pain products

REDWOOD CITY, Calif., Aug. 29, 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 the U.S. Patent and Trademark Office (USPTO) has recently issued AcelRx Patent Number 8,252,328 entitled "Bioadhesive Drug Formulations for Oral Transmucosal Delivery," and Patent Number 8,252,329 also entitled "Bioadhesive Drug Formulations for Oral Transmucosal Delivery." The '328 and '329 patents each make claims to a bioadhesive tablet for oral transmucosal administration of sufentanil. These newly issued patents will provide intellectual property protection for sufentanil NanoTab based products until at least January 5, 2027. AcelRx currently has more than 70 pending patent applications worldwide and continues to file additional new patent applications to further strengthen its market exclusivity.

"We have made significant progress this year in establishing our intellectual property portfolio, with five issued US patents now underpinning our novel NanoTab technology," said Richard King, AcelRx's President and CEO. "We look forward to building on this success through emphasis on the device aspects of our technology platforms as we seek multiple avenues of protection for our proprietary pipeline of product candidates."

The 8,252,328 patent is a composition of matter patent which provides protection in the United States for each of AcelRx's four development programs. The '328 patent covers AcelRx's proprietary NanoTab technology for delivering sufentanil with claims to a substantially homogenous bioadhesive tablet, comprising from about 2.5 to about 100 micrograms of sufentanil and a volume of from about 3 to about 15 microliters, which adheres throughout the period of drug delivery, generates a minimal saliva response and delivers a majority of the drug through the oral mucosa.

The 8,252,329 patent also covers the composition of sufentanil NanoTabs with claims to a bioadhesive tablet for sublingual administration to a subject, comprising from about 2.5 micrograms to about 100 micrograms of sufentanil, a volume of about 0.1 microliters to about 50 microliters, wherein the bioadhesive material is present at between 2% and 30% by weight, and the tablet generates a minimal saliva response and minimal swallowed drug and delivers at least 55% of the sufentanil through the oral transmucosal route. AcelRx exclusively owns both of these patents.

AcelRx also holds three other U.S. patents which claim both methods and compositions directed to sufentanil containing NanoTabs. Collectively these patents will provide intellectual property protection for sufentanil NanoTab based products in the United States through late 2030. European patent protection is provided by Patent Number EP2114383B1, which covers small-volume NanoTab dosage forms for transmucosal administration containing the opioid sufentanil. This European patent also covers elements of AcelRx's dispensing technology and provides patent protection of specific pharmacokinetic parameters derived from sublingual administration using the NanoTab technology.

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 AcelRx Pharmaceuticals' patent portfolio, including the useful life of its U.S. patents and the European patent, the continued expansion of its patent protection, market exclusivity, its ability to protect its proprietary technology, the scope of patent protection, and issued and planned or anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, including the execution of the Phase 3 clinical studies for ARX-01, the initiation of Phase 2 clinical trial for ARX-04, and the therapeutic 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 success of its patent prosecution strategy; its ability to protect its proprietary technology, including the risks that pending patent applications may not result in issued patents; 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; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx Pharmaceuticals' U.S. Securities and Exchange Commission filings, 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.

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