AcelRx Pharmaceuticals Reports First Quarter 2012 Financial Results

May 8, 2012

REDWOOD CITY, Calif., May 8, 2012 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), ("AcelRx"), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain, today reported financial results for the first quarter ended March 31, 2012.

Net loss for the first quarter of 2012 was $7.1 million, or $0.36 per share, compared with a net loss of $3.2 million, or $0.30 per share, for the first quarter of 2011. Common shares used in calculating basic and diluted earnings per share were 19,607,483 for the first quarter of 2012 compared to 10,742,182 common shares for the first quarter of 2011.

During the first quarter of 2012, AcelRx recognized revenue of $329,000 resulting from reimbursement for work completed under a research grant from the US Army Medical Research and Material Command, or USAMRMC, for development of its ARX-04 product candidate, a Sufentanil NanoTab® for the treatment of moderate-to-severe acute pain.

Research and development expenses for the quarter ended March 31, 2012 totaled $4.8 million, compared with $1.9 million for the quarter ended March 31, 2011. The increase was primarily due to development expenses for ARX-01, the Sufentanil NanoTab PCA System, AcelRx's lead product candidate for the treatment of post-operative pain. During the first quarter, AcelRx prepared for and initiated the first of three planned Phase 3 clinical trials, a randomized, double-blind, placebo-controlled efficacy and safety trial in adults with post-operative pain, following open-abdominal surgery. In April 2012, AcelRx initiated the second ARX-01 Phase 3 study, a randomized, open-label, parallel-group comparison of the efficacy and safety of the Sufentanil NanoTab PCA System to the standard of care, IV PCA with morphine, in the treatment of acute post-operative pain in adults immediately following major abdominal or orthopedic surgery.

General and administrative expenses were $2.1 million for the quarter ended March 31, 2012, compared with $1.6 million for the quarter ended March 31, 2011. This increase resulted primarily from expenses associated with market research and patent prosecution efforts as well as personnel related expenses, including stock-based compensation, and expenses associated with being a public company.

As of March 31, 2012, AcelRx had cash, cash equivalents and investments of $27.6 million, compared to $35.8 million at December 31, 2011.

"With two of our three planned Phase 3 clinical studies actively enrolling, and with the initiation of the third Phase 3 clinical study planned for the third quarter of 2012, we are looking forward to seeing top-line data from all three Phase 3 clinical trials by late 2012 or early 2013," said Richard King, President and CEO of AcelRx. Mr. King added, "Based on our dialog with FDA, data from these studies should support an NDA filing, expected in the middle of 2013."

Development Update

- In March 2012, AcelRx initiated the first of three planned Phase 3 clinical trials, a double-blind, placebo-controlled efficacy and safety trial of adult patients with post-operative pain following open-abdominal surgery. We expect top-line data for this trial in the second half of 2012.
- In April 2012, AcelRx initiated a second Phase 3 clinical trial, an open-label active-comparator study comparing ARX-01 to the current standard of care, IV PCA with morphine, in patients with post-operative pain following open-abdominal surgery or major orthopedic surgery. We expect top-line data for this trial in the second half of 2012.
- In the third quarter of 2012, AcelRx plans to initiate our third planned Phase 3 clinical trial, a double-blind, placebo-controlled efficacy and safety study of patients with post-operative pain following hip and knee replacement surgeries, with top-line data expected in late 2012 or early 2013.

Financial Outlook

AcelRx anticipates that research and development expenses for the remainder of 2012 and into 2013 will increase significantly as AcelRx seeks to execute and complete the Phase 3 clinical development program of ARX-01. Development of ARX-04 through Phase 2 clinical work and Phase 3 preparatory work is fully funded by a grant from USAMRMC. The development of ARX-04 beyond Phase 2 and initial preparations for Phase 3 is dependent on identification of sources of additional funding. Additionally, AcelRx anticipates modest increases in general and administrative expenses due to costs associated with operating as a public company and expansion of its corporate infrastructure to support ongoing development of its product candidates.

AcelRx believes its current cash, cash equivalents and investments are sufficient to fund operations into the first quarter of 2013.

About AcelRx Pharmaceuticals, Inc.

Based in Redwood City, CA, AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX) 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. A fourth product candidate, ARX-04, is a sufentanil product for the treatment of moderate-to-severe acute pain, and AcelRx plans to initiate a Phase 2 study funded by a grant from USAMRMC, contingent on approval of the proposed clinical protocol for the study by USAMRMC.

Forward Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to AcelRx Pharmaceuticals' financial viability, anticipated increases in research and development and general and administrative expenses, the sufficiency of funds to support its clinical trials and operations, planned or anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, including the anticipated timing for clinical trials, progress towards initiation of the remaining Phase 3 study for ARX-01 and 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 Annual Report on Form 10-K for the year ended December 31, 2011 and the Quarterly Report on Form 10-Q for the three months ended March 31, 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.

SELECTED FINANCIAL DATA
(in thousands, except per share data)
(unaudited)

	Three Months Ended March 31,	
	2012	**2011**
Statement of Operations Data		
Research grant revenue	$ 329	$ -
Operating expenses:		
Research and development (1)	4,771	1,946
General and administrative (1)	2,104	1,589
Total operating expenses	6,875	3,535
Loss from operations	(6,546)	(3,535)
Interest expense	(594)	(1,359)
Interest income and Other income (expense), net	75	1,690
Net loss	$ (7,065)	$ (3,204)
Basic and diluted net loss per common share	$ (0.36)	$ (0.30)
Shares used in computing basic and diluted net loss per common share	19,607	10,742

(1) Includes the following noncash, stock-based compensation expense:

Research and development	$ 251	$ 120
General and administrative	291	203
Total non-cash, stock-based expense	$ 542	$ 323

	March 31, 2012	**December 31, 2011**
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 27,571	$ 35,785
Total assets	33,990	40,835
Total liabilities	22,959	23,367
Total stockholders' equity	11,031	17,468

SOURCE AcelRx Pharmaceuticals, Inc.

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