AcelRx Pharmaceuticals Reports Fourth Quarter and Full-Year 2011 Financial Results

March 20, 2012

REDWOOD CITY, Calif., March 20, 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 fourth quarter and year ended December 31, 2011.

Net loss for the fourth quarter of 2011 was $6.4 million, or $0.33 per share, compared with a net loss of $3.5 million, or $5.23 per share, for the fourth quarter of 2010. Common shares used in calculating basic and diluted earnings per share were 19,568,000 for the fourth quarter of 2011 compared to 674,000 common shares for the fourth quarter of 2010.

During the fourth quarter of 2011, AcelRx recognized revenue of $624,000 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 December 31, 2011 totaled $4.7 million, compared with $1.9 million for the quarter ended December 31, 2010. 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, as AcelRx prepared for the initiation of Phase 3 clinical trials which began in early March 2012.

General and administrative expenses were $1.7 million for the quarter ended December 31, 2011, compared with $1.0 million for the quarter ended December 31, 2010. The increase resulted primarily from expenses associated with AcelRx's operation as a public company.

For the year ended December 31, 2011, AcelRx reported a net loss of $20.1 million, or $1.16 per share, compared with a net loss of $14.3 million, or $21.84 per share, for the same period in 2010. Common shares used in calculating basic and diluted earnings per share were 17,345,000 for the year ended December 31, 2011 compared to 657,000 common shares for the year ended December 31, 2010.

As of December 31, 2011, AcelRx had cash, cash equivalents and investments of $35.8 million, compared to $32.0 million at September 30, 2011 and $3.7 million at December 31, 2010. In February 2011, AcelRx completed its initial public offering, resulting in net proceeds to AcelRx of $34.9 million. In June 2011, AcelRx entered into a $20.0 million secured loan agreement with Hercules Technology Growth Capital, or Hercules. Upon execution of the agreement, AcelRx received $10.0 million in the first tranche of the loan and, in December 2011, AcelRx drew down the second $10.0 million tranche of the loan.

"During the last quarter of 2011 and into the first quarter of 2012, AcelRx completed system verification testing, software validation testing and reprocessing validation testing of our ARX-01 device, in addition to filing a new IND for our ARX-04 product candidate. In early March 2012, AcelRx accomplished a major milestone with the initiation of our first Phase 3 efficacy and safety study for ARX-01 for the treatment of post-operative pain following open abdominal surgery. Shortly, we will be initiating the second Phase 3 study, an active comparator study comparing ARX-01 to the standard of care. These studies, along with the third and final Phase 3 study to support an NDA for ARX-01 due to start in the second half of this year, will set up a very exciting 2012 with data from all three studies expected by early 2013," said Richard King, President and CEO of AcelRx.

Development Update

- In early March 2012, AcelRx initiated the first of three planned ARX-01 Phase 3 studies. This study is a randomized, double-blind, placebo-controlled efficacy and safety trial in adults following open abdominal surgery. Approximately 150 adults, randomized 2:1 to active or placebo treatment groups, will be treated for post-operative pain for 48 - 72 hours after randomization.
- A second Phase 3 study is planned as an open-label, active-comparator study comparing ARX-01 to the current standard of care, intravenous patient-controlled analgesia, with morphine. The primary endpoint for this study will assess a measure of efficacy, Global Patient Satisfaction over the 48-hour study period, and will compare ratings of "Good" and "Excellent" for Global Patient Satisfaction between the two groups in a non-inferiority comparison.
- The third and final planned Phase 3 clinical study is a randomized, double-blind, placebo-controlled efficacy and safety study comparing ARX-01 to placebo for post-operative pain control following major joint replacement surgery.

Financial Outlook

AcelRx anticipates that research and development expenses will increase significantly over the next several quarters as AcelRx seeks to complete Phase 3 clinical development of ARX-01. The development of ARX-04 beyond Phase 2 and initial preparations for Phase 3 are dependent on the identification of sources of additional funding from the USAMRMC or the identification of a partner to support these efforts. 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 providing 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 that is expected to enter Phase 2 clinical development in the second quarter of 2012 under a grant from the 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 two Phase 3 studies 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, when it becomes available. 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 December 31,		Twelve Months Ended December 31,	
	2011	**2010**	**2011**	**2010**
Statement of Operations Data				
Research grant revenue	$ 624	$ -	$ 1,072	$ -
Operating expenses:				
Research and development (1)	4,702	1,884	13,624	8,193
General and administrative (1)	1,715	955	6,800	3,993
Total operating expenses	6,417	2,839	20,424	12,186
Loss from operations	(5,793)	(2,839)	(19,352)	(12,186)
Interest expense	(417)	(742)	(2,309)	(1,397)
Interest income and Other income (expense), net	(163)	56	1,560	(761)
Net loss	$ (6,373)	$ (3,525)	$ (20,101)	$ (14,344)
Basic and diluted net loss per common share	$ (0.33)	$ (5.23)	$ (1.16)	$ (21.84)
Shares used in computing basic and diluted net loss per common share	19,568	674	17,345	657

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

Research and development	$ 207	$ 170	$ 785	$ 810
General and administrative	280	146	1,048	614
Total non-cash, stock-based expense	$ 487	$ 316	$ 1,833	$ 1,424

Selected Balance Sheet Data

	December 31, 2011	December 31, 2010
Cash, cash equivalents and investments	$ 35,785	$ 3,682
Total assets	40,835	6,830
Total liabilities	23,367	16,781
Total stockholders' equity (deficit)	17,468	(9,951)

SOURCE AcelRx Pharmaceuticals, Inc.

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