



AcelRx Pharmaceuticals Reports Fourth Quarter and Full Year 2013 Financial Results

March 3, 2014

REDWOOD CITY, Calif., March 3, 2014 /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 reported financial results for the three and twelve months ended December 31, 2013.

"AcelRx made strong progress in 2013 with the successful completion of the Zalviso™ (sufentanil sublingual NanoTab system) Phase 3 program, the filing and acceptance of the NDA for Zalviso, the execution of a commercial partnership agreement with Grunenthal for Zalviso that covers Europe and Australia, and agreement with FDA on a Phase 3 program for ARX-04, an investigational single-dose sublingual sufentanil NanoTab for moderate-to-severe acute pain," stated Richard King, president and CEO of AcelRx. "As we begin 2014, we are advancing our U.S. commercial capability and preparing for a potential Zalviso approval in third quarter of 2014. We are also readying Zalviso for MAA filing in Europe, and preparing to initiate a Phase 3 clinical program for ARX-04 in the second half of this year."

Fourth Quarter and Full Year 2013 Financial Results

Net income for the fourth quarter of 2013 was \$17.8 million, or \$0.41 per share, compared with a net loss of \$10.5 million, or \$0.41 per share for the fourth quarter of 2012. During the fourth quarter of 2013, AcelRx received a \$30.0 million upfront payment from Grunenthal GmbH associated with the Zalviso commercialization agreement in the EU and Australia, of which \$27.4 million was recognized as revenue in the quarter. Excluding the \$27.4 million of revenue recognized from the Grunenthal collaboration, and excluding a \$1.2 million one-time non-cash charge associated with the Hercules debt renegotiation and \$0.7 million non-cash expense resulting from the liability accounting related to warrants issued in connection with the PIPE financing completed in June 2012, the net loss for the fourth quarter of 2013 was \$7.7 million, or \$0.18 per share.

During the fourth quarters of 2013 and 2012, AcelRx recognized revenue of \$27.6 million and \$1.7 million, respectively. The fourth quarter of 2013 revenue includes \$27.4 million of revenue recognized from the \$30.0 million upfront payment from Grunenthal and \$0.2 million of reimbursement for work completed under a research grant from the U.S. Army Medical Research and Materiel Command (USAMRMC), for development of ARX-04. Fourth quarter of 2012 revenue consisted of \$1.7 million in reimbursement for work associated with the USAMRMC grant.

Research and development (R&D) expenses for the quarter ended December 31, 2013 totaled \$4.3 million, compared with \$7.8 million for the quarter ended December 31, 2012. The decrease in R&D expense reflects completion of the Phase 3 development for Zalviso by the third quarter of 2013.

Selling, general and administrative (SG&A) expenses were \$3.3 million for the fourth quarter of 2013, compared with \$1.9 million for the fourth quarter of 2012, due primarily to an increase in commercial activities related to Zalviso, including increased market research activities and the initial build of internal marketing capabilities. Fourth quarter 2013 SG&A expense of \$3.3 million includes \$1.0 million in marketing costs.

Other income and expense includes a \$0.7 million non-cash charge in the fourth quarter of 2013 resulting from the liability accounting related to warrants issued in connection with the PIPE financing completed in June 2012. The primary determinant of this charge was an increase in share price during the fourth quarter of 2013 and its resulting impact on the Black-Scholes valuation of these warrants. Additionally, in connection with the renegotiated debt with Hercules, AcelRx recorded in the fourth quarter a \$1.2 million non-cash charge for the extinguishment of the original Hercules loan that was paid off upon the signing of the new debt arrangement.

For the twelve months ended December 31, 2013, AcelRx reported a net loss of \$23.4 million, or \$0.59 per share, compared with a net loss of \$33.4 million, or \$1.51 per share for the same period in 2012. Excluding the \$27.4 million recognized from the Grunenthal upfront payment, the \$14.1 million in non-cash expense resulting from the liability accounting related to the warrants issued in connection with the PIPE financing completed in June 2012 and the \$1.2 million one-time, non-cash charge associated with our debt renegotiation, adjusted net loss for 2013 was \$35.5 million, or \$0.89 per share.

R&D expenses for 2013 totaled \$26.3 million, compared with \$24.9 million in 2012. The increase for 2013 over 2012 was primarily due to expenditures related to the Zalviso Phase 3 clinical trials that were at their highest levels in the first and second quarters of 2013. SG&A expenses were \$9.9 million for 2013, compared with \$7.2 million in 2012, due primarily to an increase in stock based compensation and commercial activities related to Zalviso, including increased market research activities and the initial build of marketing capabilities.

As of December 31, 2013, AcelRx had cash, cash equivalents and investments of \$103.7 million, compared to \$59.8 million at December 31, 2012. In July 2013, AcelRx raised approximately \$47.9 million in net proceeds through the issuance of 4.37 million shares of common stock in an underwritten public offering. In December 2013, AcelRx received an upfront licensing fee of \$30 million from Grunenthal GmbH under the terms of a collaboration agreement for Zalviso in Europe and Australia and an additional \$6.0 million, net of payments to Hercules, from the renegotiated debt agreement.

Review of Recent Accomplishments and Corporate Update

- The Zalviso New Drug Application (NDA) was accepted for filing by the FDA on November 26, 2013. The acceptance indicates the FDA has determined that the application is sufficiently complete to permit a substantive review and the FDA has subsequently confirmed a PDUFA action date of July 27, 2014. The NDA seeks approval of Zalviso for the management of moderate-to-severe acute pain in adult patients in the hospital setting.

- AcelRx and Grunenthal GmbH announced a commercial collaboration in December 2013 covering the territory of the European Union, certain other European countries and Australia for Zalviso for potential use in pain treatment within or dispensed by a hospital, hospice, nursing home or other medically supervised setting. Under the terms of the agreement, AcelRx received an upfront cash payment of \$30.0 million and is eligible to receive approximately \$220.0 million in potential additional milestone payments, based upon successful regulatory and product development efforts and net sales target achievements. Grunenthal will also make tiered royalty, supply and trademark fee payments in the mid-teens to the mid-twenties percent range on potential net sales of Zalviso in the Grunenthal territory.
- In December 2013, AcelRx completed an end of Phase 2 meeting with the FDA to seek the agency's feedback on future development plans for ARX-04. The FDA requested a 500 patient safety database, consisting of 100 patients exposed to multiple doses and 400 patients exposed to a single dose of ARX-04. The FDA confirmed that the Phase 2 bunionectomy trial could be considered as an adequate and well-controlled study. Consistent with FDA guidance at the meeting, AcelRx plans a single additional Phase 3 registration trial, to be conducted in a visceral, or soft tissue, model of pain, the primary endpoint for which will be Summed Pain Intensity Difference over 12 hours (SPID-12). AcelRx plans to begin this Phase 3 study during the second half of the 2014 and expects that top-line results should be available during the second half of 2015.
- In December 2013, AcelRx entered into a new amended and restated credit facility with Hercules Technology Growth Capital, Inc. that extended AcelRx's previous relationship with Hercules, which was established in June 2011. The new Hercules credit facility provides for up to \$40.0 million of new loans. Upon the closing of the new credit facility, AcelRx drew the initial tranche of \$15.0 million, \$9.0 million of which was used to pay the outstanding balance and fees of the prior Hercules credit facility.

Financial Outlook

AcelRx records as revenue the reimbursement received pursuant to the 2011 \$5.6 million USAMRMC grant. Recognition of revenue from this grant has resulted in recorded revenues of \$5.6 million through December 31, 2013 with no funding remaining on the USAMRMC grant.

AcelRx expects the first of the Grunenthal regulatory milestones to be triggered with the planned submission of the MAA in mid-2014, resulting in a \$5.0 million milestone payment anticipated in the third quarter of 2014.

AcelRx forecasts that quarterly R&D expenses through the end of 2014 will be relatively consistent across all quarters with total R&D expenses expected to be in the range of \$27 to \$29 million for the year.

Additionally, AcelRx anticipates general and administrative expenses, excluding sales and marketing costs, will increase gradually quarter over quarter in 2014 as the company builds infrastructure to support Zalviso's commercial activities. Consistent with planned commercial preparation, sales and marketing costs are expected to accelerate over the remaining quarters of 2014 as the company prepares for the possible approval and the planned commercial launch of Zalviso. In 2014, total SG&A costs in the \$21 to \$23 million range are anticipated, assuming FDA approval for Zalviso in the third quarter of 2014.

Total operating expenses for 2014 are anticipated to be in the range of \$48 to \$52 million.

AcelRx believes its current cash, cash equivalents, investments and cash available under credit facilities are sufficient to fund operations at least through 2015, excluding any potential proceeds from Grunenthal milestones.

Conference Call

AcelRx will conduct a conference call and webcast today, March 3, 2014 at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) to discuss its financial results and program updates. To listen to the conference call, dial in approximately ten minutes before the scheduled call to (877) 870-4263 for domestic callers, (855) 669-9657 for Canadian callers, or (412) 317-0790 for international callers. Those interested in listening to the conference call live via the Internet may do so by visiting the Investors section of the company's website at www.acelex.com and selecting the webcast link for the Q4 2013 earnings conference call. 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.acelex.com.

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, Zalviso™, 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 complexity of infusion pumps. AcelRx has announced positive results from each of the three completed Phase 3 clinical trials for Zalviso, and has submitted an NDA to the FDA seeking approval for Zalviso in the treatment of moderate-to-severe acute pain in adult patients in the hospital setting. AcelRx plans to initiate a Phase 3 clinical trial for ARX-04, a product candidate for the treatment of moderate-to-severe acute pain in a medically supervised setting, during the second half of 2014. The company has two additional pain treatment product candidates, ARX-02 and ARX-03, which have completed Phase 2 clinical development. For additional information about AcelRx's clinical programs, please visit www.acelex.com.

Forward Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to future financial results, including 2014 financial guidance and cash forecast, potential milestones and royalty payments under the Gruenthal agreement, the process and timing of anticipated future development of AcelRx's product candidates, including the timing of potential approval for Zalviso, therapeutic and commercial potential of Zalviso and the anticipated timing, therapeutic and commercial potential of other AcelRx product candidates, including the timing of the Phase 3 trial for ARX-04. 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: AcelRx's ability to receive regulatory approval for Zalviso, that fact that FDA may dispute or interpret differently clinical results obtained to date; any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso, in the United States and Europe; its ability to attract funding partners or collaborators with development, regulatory and commercialization expertise; its ability to receive any milestones or royalty payments under the Gruenthal agreement; its ability to obtain sufficient financing to commercialize Zalviso and proceed with clinical development of ARX-04; the success, cost and timing of all product development activities and clinical trials, including the planned Phase 3 ARX-04 trial; the uncertain clinical development process, including the risk that clinical trials, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all; the market potential for its product candidates; the accuracy of AcelRx's estimates regarding expenses, capital requirements and needs for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on November 5, 2013. 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.

SELECTED FINANCIAL DATA

(in thousands, except per share data)
(unaudited)

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2013	2012	2013	2012
Statement of Operations Data				
Revenue:				
Collaboration agreement	\$ 27,370	\$ -	\$ 27,370	\$ -
Research grant	237	1,675	2,132	2,394
Total revenue	27,607	1,675	29,502	2,394
Operating expenses:				
Research and development ⁽¹⁾	4,318	7,795	26,292	24,908
General and administrative ⁽¹⁾	3,306	1,909	9,877	7,199
Total operating expenses	7,624	9,704	36,169	32,107
Loss from operations	19,983	(8,029)	(6,667)	(29,713)
Interest expense	(313)	(518)	(1,518)	(2,283)
Other income (expense), net ⁽²⁾	(1,901)	(1,975)	(15,241)	(1,367)
Net income (loss)	\$ 17,769	\$ (10,522)	\$ (23,426)	\$ (33,363)
Basic net income (loss) per common share	\$ 0.41	\$ (0.41)	\$ (0.59)	\$ (1.51)
Shares used in computing basic net income (loss) per common share	43,044	25,588	39,747	22,125

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

Research and development	\$ 464	\$ 236	\$ 1,657	\$ 998
General and administrative	580	281	1,822	1,152
Total	\$ 1,044	\$ 517	\$ 3,479	\$ 2,150

(2) Other income and expense includes a \$0.7 million and \$14.1 million non-cash charge for the three and twelve months ended December 31, 2013, respectively, related to warrants issued in connection with a private placement equity financing, completed in June 2012.

December 31, 2013 December 31, 2012

Selected Balance Sheet Data

Cash, cash equivalents and investments	\$ 103,663	\$ 59,763
Total assets	110,031	64,520
Total liabilities	36,872	30,673
Total stockholders' equity	73,159	33,847

AceIRx

Pharmaceuticals, Inc.

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Jim Welch, Chief Financial Officer, 650.216.3511, jwelch@acelrx.com