



AcelRx Pharmaceuticals Reports Third Quarter 2014 Financial Results

Nov 10, 2014

REDWOOD CITY, Calif., Nov. 10, 2014 /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 three and nine months ended September 30, 2014.

"In the third quarter, we held a meeting with the FDA to discuss the Zalviso CRL received in July. During the meeting we discussed the resubmission of the Zalviso NDA and the steps necessary for the resubmission," stated Richard King, president and CEO of AcelRx. "In advance of resubmitting our Zalviso NDA, we have agreed with the FDA to submit protocols for the bench testing and a Human Factors Study for their review and comment. We currently continue the preparation necessary to initiate bench testing and a Human Factors study to enable response to the CRL."

Subject to the timing of the FDA review and comment on the protocols, for the bench testing and the Human Factors Study, we are targeting resubmission of the Zalviso™ (sufentanil sublingual tablet system) NDA in the first quarter of 2015. However, depending on feedback from the FDA, including their review of the materials submitted, the timing of the filing of the NDA could be later than the first quarter of 2015. As is typical, the FDA has informed us that the adequacy of the Human Factors Study and resulting data will be subject to review when the NDA is resubmitted.

Third Quarter Financial Results

Net income for the third quarter of 2014 was \$671,000, or \$0.02 basic net income per share, and \$0.13 diluted net loss per share, compared to \$11.0 million net loss, or \$0.26 basic and diluted net loss per share, for the third quarter of 2013. Basic net income per share for the three months ended September 30, 2014 includes \$6.4 million in non-cash income related to the revaluation of PIPE warrants which were issued in connection with a PIPE financing completed in June 2012. This \$6.4 million was deducted from net income in order to arrive at the numerator for the calculation of diluted EPS and 0.8 million shares were added to the denominator (using the treasury stock method) to reflect the dilutive effect of the PIPE warrants. Common shares used in calculating earnings per share were 43.5 million for basic EPS and 44.3 million for diluted EPS for the third quarter of 2014, compared to 41.5 million for basic and diluted EPS for the third quarter of 2013.

Net income in the current quarter as compared to net loss in the prior year quarter was primarily due to an increase in revenue from the receipt and recognition of the milestone payment for the Marketing Authorization Application (MAA) submission under our collaboration agreement with Grunenthal and non-cash income from the revaluation of the PIPE warrants, partially offset by an increase in operating expenses.

During the third quarter of 2014, AcelRx recognized \$4.8 million of revenue, primarily due to the \$5 million milestone payment received related to the MAA submission, under the collaboration agreement with Grunenthal. During the third quarter of 2013, AcelRx recognized revenue of \$548,000 resulting from reimbursement for work completed under a research grant from the U.S. Army Medical Research and Materiel Command for development of ARX-04, a sufentanil tablet system product candidate for the treatment of moderate-to-severe acute pain in a range of ambulatory environments. Work under the research grant was completed in the fourth quarter of 2013.

Research and development expenses for the quarter ended September 30, 2014 were \$5.2 million, compared with \$6.5 million for the quarter ended September 30, 2013. The decrease was primarily due to lower expenses related to our Zalviso development program.

General and administrative expenses were \$4.7 million for the third quarter of 2014, compared with \$2.3 million for the third quarter of 2013. The increase was primarily due to market research and other pre-commercial activities in support of potential marketing approval of Zalviso.

As discussed above, other income and expense in the third quarter of 2014 includes \$6.4 million in non-cash income caused by a decrease in the value of the PIPE warrants. During the third quarter of 2013, the revaluation of the PIPE warrants resulted in \$2.4 million non-cash expense.

Year-to-Date Financial Results

For the nine months ended September 30, 2014, AcelRx reported a net loss of \$19.5 million, or \$0.45 basic net loss per share and \$0.63 diluted net loss per share, compared to \$41.2 million, or \$1.07 basic and diluted net loss per share for the same period in 2013. Basic net loss per share for the nine months ended September 30, 2014 includes \$8.2 million in non-cash income related to the revaluation of PIPE warrants, which was deducted from net loss in order to arrive at the numerator for the calculation of diluted EPS and 1.0 million shares were added to the denominator (using the treasury stock method) to reflect the dilutive effect of the PIPE warrants. Basic net loss per share for the nine months ended September 30, 2013 includes \$13.4 million in non-cash expense related to the revaluation of PIPE warrants. Common shares used in calculating earnings per share were 43.3 million for basic EPS and 44.3 million for diluted EPS for the nine months ended September 30, 2014, compared to 38.6 million for basic and diluted EPS for the same period in 2013.

Research and development expenses for the nine months ended September 30, 2014 were \$17.2 million, compared to \$22.0 million for the nine months ended September 30, 2013. The decrease over the nine months ended September 30, 2014, was primarily due to a high level of activity associated with Phase 3 clinical studies of Zalviso in the first nine months of 2013 and the payment of the PDUFA fee for filing of the Zalviso New Drug Application (NDA). General and administrative expenses were \$13.6 million for the nine months of 2014, compared with \$6.6 million for the nine months ended September 30, 2013. The increase was primarily due to market research and other pre-commercial activities in preparation for the commercialization of Zalviso.

As of September 30, 2014, AcelRx had cash, cash equivalents and investments of \$85.6 million, compared to \$92.3 million at June 30, 2014 and \$103.7 million at December 31, 2013. The decrease in cash during the year was driven by cash used in operations, primarily offset by the \$10.0 million draw down of the second tranche of the loan and security agreement with Hercules, in June 2014.

Financial Outlook

We have revised our financial guidance for the year, as follows:

- Research and development expenses are expected to be in the range of \$25 to \$27 million for the year.

- General and administrative expenses, including pre-commercialization expenses, are expected to be in the range of \$18 to \$20 million for the year.
- Total operating expenses for 2014 are anticipated to be in the range of \$43 to \$47 million.
- Estimated cash, cash equivalents and investment balances at December 31, 2014 of at least \$68 million.

Conference Call

AcelRx will conduct a conference call and webcast today, November 10, 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 1-866-361-2335 for domestic callers, 1-855-669-9657 for Canadian callers, or 1-412-902-4204 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.acelrx.com and selecting the Webcast link for the Q3 2014 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.acelrx.com.

About Zalviso™

Zalviso is an investigational pre-programmed, non-invasive system to allow hospital patients with moderate-to-severe acute pain to self-dose with sublingual sufentanil tablets to manage their pain. Zalviso consists of sufentanil tablets delivered by the Zalviso System, a needle-free, handheld, patient-administered, pain management system (together, "Zalviso"). Zalviso is designed to help address certain problems associated with post-operative intravenous patient-controlled analgesia, by offering:

- A high therapeutic index opioid: Zalviso uses sufentanil, an opioid that has a high therapeutic index. The therapeutic index is the ratio of the effective dose versus the lethal or toxic dose. In animal studies, the therapeutic index for sufentanil was approximately 100 times larger than fentanyl and 300 times larger than morphine.
- A non-invasive route of delivery: Zalviso utilizes a sufentanil tablet which allows for a sublingual (under the tongue) route of delivery. Sufentanil is highly lipophilic which provides for rapid absorption in the fatty cells (or mucosal tissue) found under the tongue and for rapid transit across the blood-brain barrier to bind the mu-opioid receptors in the brain. The sublingual delivery used by Zalviso provides rapid onset of analgesia. The sublingual delivery system also eliminates the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections. In addition, because patients do not require direct connection to an IV PCA infusion pump through IV tubing, Zalviso allows for ease of patient mobility.
- A pre-programmed PCA solution: Zalviso allows patients to self-dose sufentanil sublingual tablets via a pre-programmed, secure system designed to eliminate the risk of programming errors.

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 improve the management of moderate-to-severe acute pain in adult patients in the hospital setting by utilizing a high therapeutic index opioid, through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. 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 and on July 25th, received a Complete Response Letter from the FDA. 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. 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.acelrx.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 proceeds under the Grunenthal agreement, the process and timing of anticipated future development of AcelRx's product candidates, including Zalviso, the NDA submission and the CRL, the recent meeting held with the FDA to discuss the CRL, AcelRx's plans to address the issues raised in the CRL, and anticipated resubmission of the Zalviso NDA to the FDA, including the scope of the resubmission and the timing of the resubmission and FDA review time, the impact, if any, of the FDA's review of the amendments to the Zalviso NDA that were not previously reviewed, planned initiation of the Phase 3 clinical trial for ARX-04, and the therapeutic and commercial potential of AcelRx Pharmaceuticals' product candidates, including Zalviso. 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: AcelRx Pharmaceuticals' ability to receive regulatory approval for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso, in the United States and Europe; AcelRx's ability to build an effective commercial organization; its ability to receive any milestones or royalty payments under the Grunenthal 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 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 Pharmaceuticals' U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on August 11, 2014. 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 September 30,		Nine Months Ended September 30,	
2014	2013	2014	2013

Statement of Comprehensive Loss Data

Revenue:

Collaboration agreement	\$	4,825	\$	-	\$	4,991	\$	-
Research grant		-		548		-		1,895
Total revenue		4,825		548		4,991		1,895

Operating expenses:

Research and development ⁽¹⁾		5,244		6,548		17,239		21,974
General and administrative ⁽¹⁾		4,650		2,310		13,622		6,571
Total operating expenses		9,894		8,858		30,861		28,545
Loss from operations		(5,069)		(8,310)		(25,870)		(26,650)

Interest expense		(816)		(348)		(1,818)		(1,205)
Interest income and other income (expense), net ⁽²⁾		6,556		(2,328)		8,153		(13,340)
Net income (loss)	\$	671	\$	(10,986)	\$	(19,535)	\$	(41,195)

Basic net income (loss) per common share	\$	0.02	\$	(0.26)	\$	(0.45)	\$	(1.07)
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Diluted net income (loss) per common share	\$	(0.13)	\$	(0.26)	\$	(0.63)	\$	(1.07)
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Shares used in computing basic net income (loss) per common share		43,469		41,462		43,332		38,635
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Shares used in computing diluted net income (loss) per common share		44,263		41,462		44,288		38,635
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(1) Includes the following non-cash, stock-based compensation expense:

Research and development	\$	568	\$	427	\$	1,607	\$	1,193
General and administrative		631		449		1,461		1,242
Total	\$	1,199	\$	876	\$	3,068	\$	2,435

(2) Interest income and other income (expense) includes \$6.4 million and \$8.2 million in non-cash income for the three and nine months ended September 30, 2014, respectively, and \$2.4 million and \$13.4 million in non-cash charges during the three and nine months ended September 30, 2013, respectively, related to revaluation of the PIPE warrants issued in connection with a private placement equity financing, completed in June 2012.

September 30, 2014 December 31, 2013**Selected Balance Sheet Data**

Cash, cash equivalents and investments	\$	85,570	\$	103,663
Total assets		96,442		110,031
Total liabilities		37,365		36,872
Total stockholders' equity		59,077		73,159



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SOURCE AcelRx Pharmaceuticals, Inc.

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