



AcelRx Pharmaceuticals Provides Zalviso Regulatory Update and Reports First Quarter 2015 Financial Results

May 04, 2015

REDWOOD CITY, Calif., May 4, 2015 /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 provided a regulatory update on Zalviso and reported financial results for the three months ended March 31, 2015.

Zalviso Regulatory Update

On April 21, 2015, AcelRx submitted a request to the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP or the Division) of the Food and Drug Administration (FDA) for a Type B meeting. This past Friday the Division notified the Company that the request for a meeting was denied and restated the Division's view that a clinical study is required. We are consulting with our regulatory, legal and clinical advisors to determine our next steps. We will be considering all options to determine a pathway forward for Zalviso including the possibility of dispute resolution through one of the FDA prescribed pathways as well as conducting additional clinical or Human Factors studies.

"As part of the Type B meeting, we intended to share with the Division the results of the bench testing and the Human Factors studies they had requested as part of the CRL and Type A meeting, and further discuss their desire for additional clinical work. We continue to believe that an additional clinical study should not be required to demonstrate the safety and efficacy of the Zalviso System beyond what has already been established in the Phase 3 clinical studies, as well as the bench testing and Human Factors studies," stated Howie Rosen interim chief executive officer of AcelRx Pharmaceuticals. "We will provide a further update as to our next steps once we finalize our plan for moving forward towards gaining Zalviso approval in the U.S."

First Quarter Financial Results

Net loss for the first quarter of 2015 was \$10.0 million, or \$0.23 basic net loss per share, and \$0.27 diluted net loss per share, compared to a net loss of \$9.6 million, or \$0.22 basic and diluted net loss per share for the first quarter of 2014. The increase in the net loss and net loss per share was due primarily to higher headcount related expenses in the first quarter of 2015 as compared to the first quarter of 2014. The cost reduction plan implemented at the end of March 2015 reduced our workforce by approximately 36%. The associated termination and related costs are reflected as restructuring costs in the Statement of Comprehensive Loss. Common shares used in calculating earnings per share were 43.9 million for basic EPS and 44.4 million for diluted EPS for the first quarter of 2015, compared to 43.2 million for basic and diluted EPS for the first quarter of 2014.

For the quarter ended March 31, 2015, AcelRx recognized \$181,000 of previously deferred revenue under the collaboration agreement with Grunenthal, as compared to \$95,000 for the quarter ended March 31, 2014.

Research and development expenses for the quarter ended March 31, 2015 were \$6.3 million, compared with \$4.7 million for the quarter ended March 31, 2014. The increase was primarily due to increased medical affairs personnel, which positions were subsequently eliminated as part of the cost reduction plan, and the initiation of SAP-301, a pivotal Phase 3 clinical study for ARX-04, in the quarter ended March 31, 2015.

General and administrative expenses were \$4.5 million for the first quarter of 2015, compared with \$3.9 million for the first quarter of 2014. The increase was primarily due to increased commercial personnel in anticipation of potential FDA approval of Zalviso, which positions were subsequently eliminated as part of the cost reduction plan in the quarter ended March 31, 2015.

Other income and expense includes \$2.2 million in non-cash income and \$0.7 million in non-cash expense in the first quarter of 2015 and 2014, respectively, resulting from the liability accounting related to the warrants issued in connection with the PIPE financing completed in June 2012. These PIPE warrants are considered a liability for accounting purposes and they are remeasured at the end of each reporting period utilizing the Black-Scholes valuation model. As of March 31, 2015, there were approximately 0.5 million PIPE warrants outstanding.

As of March 31, 2015, AcelRx had cash, cash equivalents and investments of \$64.4 million, compared to \$75.4 million at December 31, 2014. The net decrease in cash, cash equivalents and investments was \$11.0 million in the first quarter of 2015.

ARX-04 Update

In March 2015, AcelRx reported dosing of the first patient in a pivotal Phase 3 study of ARX-04, SAP-301, a multi-center, double-blind, placebo-controlled study that will evaluate the efficacy and safety of ARX-04 and placebo for the treatment of moderate-to-severe acute pain following ambulatory abdominal surgery. ARX-04 is a non-invasive, single-use 30 mcg sufentanil sublingual tablet in a disposable, pre-filled, single-dose applicator (SDA).

"During the first quarter of 2015 we implemented a plan to reduce operating costs and conserve capital," commented Howie Rosen. "For the remainder of 2015 we will focus our resources on moving Zalviso forward toward marketing approval in the U.S., continuing development of ARX-04 and supporting Grunenthal, our European partner for Zalviso."

Conference Call

AcelRx will conduct a conference call and webcast today, May 4, 2015 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 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 Q1 2015 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 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, 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 25, 2014, received a Complete Response Letter (CRL) from the FDA. In March 2015, AcelRx received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies AcelRx has performed to address dispensing issues raised in the CRL, an additional clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. AcelRx submitted a formal meeting request to the FDA and this request has been denied. AcelRx is currently evaluating its next steps with regards to the U.S. regulatory process for Zalviso. In March 2015, AcelRx initiated SAP-301, a pivotal Phase 3 study for ARX-04, a product candidate for the treatment of moderate-to-severe acute pain in a medically supervised setting. 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 the process and timing of anticipated future development of AcelRx's product candidates, including Zalviso and ARX-04; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the U.S., including meeting with outside advisors for consultation, potential additional clinical studies, additional Human Factors studies, additional data analyses, or the dispute resolution processes provided for by the FDA; AcelRx's belief that an additional clinical study should not be required to demonstrate the safety and efficacy of the Zalviso System beyond what has already been established in the Phase 3 clinical studies; 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; and the therapeutic and commercial potential of AcelRx Pharmaceuticals' product candidates, including Zalviso and ARX-04.

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 finalize the pathway towards timely resubmission of the Zalviso NDA to the FDA, including its ability to use dispute resolution processes provided for by the FDA; potential additional clinical trials, Human Factors studies, and/or additional data analyses necessary in order to resubmit the Zalviso NDA; AcelRx's 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; its ability to obtain sufficient financing to receive regulatory approval for and commercialize Zalviso and complete clinical development of ARX-04; the success, cost and timing of all product development activities and clinical trials, including the Phase 3 ARX-04 trial or trials; the market potential for its product candidates; the accuracy of AcelRx's estimates regarding expenses, capital requirements and needs for financing, as well as the charges and savings attributable to the reduction in force; 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 filed with the SEC on March 13, 2015. 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,	
	2015	2014
Statement of Comprehensive Loss Data		
Collaboration agreement revenue	\$ 181	\$ 95
Operating expenses:		
Research and development ⁽¹⁾	6,306	4,711
General and administrative ⁽¹⁾	4,521	3,925
Restructuring costs	754	-
Total operating expenses	11,581	8,636
Loss from operations	(11,400)	(8,541)
Interest expense	(806)	(472)
Interest income and other income (expense), net ⁽²⁾	2,180	(618)
Net loss	<u>\$ (10,026)</u>	<u>\$ (9,631)</u>
Basic net loss per common share	\$ (0.23)	\$ (0.22)
Shares used in computing basic net loss per common share	<u>43,873</u>	<u>43,190</u>
Diluted net loss per common share	\$ (0.27)	\$ (0.22)
Shares used in computing diluted net loss per common share	<u>44,427</u>	<u>43,190</u>

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

Research and development	\$ 702	\$ 479
General and administrative	836	496
Total	<u>\$ 1,538</u>	<u>\$ 975</u>

(2) Interest income and other income (expense) includes \$2.2 million in non-cash income and \$0.7 million in non-cash charges for the three months ended March 31, 2015 and 2014, respectively, related to warrants issued in connection with a private placement equity financing, completed in June 2012.

March 31, 2015**December 31, 2014**

Selected Balance Sheet Data

Cash, cash equivalents and investments \$	64,441	\$	75,350
Total assets	75,592		86,447
Total liabilities	34,507		39,791
Total stockholders' equity	41,085		46,656



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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/accelrx-pharmaceuticals-provides-zalviso-regulatory-update-and-reports-first-quarter-2015-financial-results-300076984.html>

SOURCE AcelRx Pharmaceuticals, Inc.

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