AcelRx Pharmaceuticals Reports Third Quarter 2013 Financial Results

Nov 05, 2013

REDWOOD CITY, Calif., Nov. 5, 2013 /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 nine months ended September 30, 2013.

"With the submission of our NDA at the end of September for Zalviso™, AcelRx has commenced activities related to an anticipated U.S. commercial launch," stated Richard King, president and CEO of AcelRx. "We also continue to actively participate in key medical meetings worldwide to increase awareness of the results from our completed Zalviso Phase 3 clinical trials among a broad audience of medical professionals involved in pain treatment. Having appointed our Chief Commercial Officer last quarter, we are working diligently to prepare Zalviso to be well positioned for launch in the US market, subject to regulatory approval."

Third Quarter and Nine Months Financial Results

Net loss for the third quarter of 2013 was $11.0 million, or $0.26 per share, compared with a net loss of $8.6 million, or $0.38 per share for the third quarter of 2012. The adjusted net loss for the third quarter of 2013 was $8.6 million, or $0.21 per share and excludes a $2.4 million non-cash expense resulting from the liability accounting related to warrants issued in connection with the PIPE financing completed in June 2012. There was no such expense recorded in the third quarter of 2012.

During the third quarters of 2013 and 2012, AcelRx recognized revenue of $0.5 million and $0.2 million, respectively, as reimbursement for work completed under a research grant from the U.S. Army Medical Research and Materiel Command, or USAMRMC, for development of ARX-04, a sufentanil NanoTab product candidate for the treatment of moderate-to-severe acute pain in a range of military and ambulatory environments.

Research and development, or R&D, expenses for the quarter ended September 30, 2013 totaled $6.5 million, compared with $6.9 million for the quarter ended September 30, 2012. R&D expense for the third quarter of 2013 included a fee of approximately $1.95 million for submission of the NDA for Zalviso. Excluding the NDA submission fee, the third quarter R&D expenses reflect lower clinical costs when compared to second quarter 2013 as a result of the completion of the Phase 3 development program for Zalviso in the second quarter of 2013.

General and administrative expenses were $2.3 million for the third quarter of 2013, compared with $1.4 million for the third quarter of 2012, due primarily to an increase in Zalviso commercial preparation activities.

Other income and expense includes a $2.4 million non-cash charge in the third quarter of 2013 resulting from the liability accounting related to the 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 third quarter of 2013 and its resulting impact on the Black-Scholes valuation of these warrants.

For the nine months ended September 30, 2013, AcelRx reported a net loss of $41.2 million, or $1.07 per share, compared with a net loss of $22.8 million, or $1.09 per share for the same period in 2012. Adjusted net loss for the nine months ended September 30, 2013 was $27.8 million, or $0.72 per share. Adjusted net loss excludes the $13.4 million non-cash expense resulting from the liability accounting related to the warrants issued in connection with the PIPE financing completed in June 2012.

R&D expenses for the nine months ended September 30, 2013 totaled $22.0 million, compared with $17.1 million for the nine months ended September 30, 2012. The increase was primarily due to expenses associated with the Phase 3 clinical studies of Zalviso and the NDA filing fee. General and administrative expenses were $6.6 million for the nine months of 2013, compared with $5.3 million for the nine months ended September 30, 2012 due primarily to an increase in stock based compensation and commercial preparation activities.

As of September 30, 2013, AcelRx had cash, cash equivalents and investments of $76.0 million, compared to $59.8 million at December 31, 2012 and $36.8 million at June 30, 2013. In July 2013, AcelRx raised $47.9 million in net proceeds through the issuance of 4.37 million shares of common stock in an underwritten public offering. Net cash used in the third quarter of 2013, excluding the offering proceeds, was $8.7 million.

Review of Recent Accomplishments and Corporate Update

- On September 27, 2013, AcelRx submitted an NDA to the FDA for Zalviso for the management of moderate-to-severe acute pain in adult patients in the hospital setting. The NDA submission is based primarily on data from a Phase 3 registration program that included two double-blind, randomized, placebo-controlled clinical trials, one in patients following open abdominal surgery and the other in patients following hip or knee replacement surgery. An additional open label active comparator trial was conducted in patients following major abdominal or orthopedic surgery that compared Zalviso to intravenous patient controlled analgesia, or IV PCA, with morphine.
- In July 2013, AcelRx completed an underwritten public offering of 4,370,000 shares of common stock, including 570,000 shares which were issued pursuant to the exercise of the underwriters' option to purchase additional shares, at a price of $11.65 per share. The total net proceeds of this offering were $47.9 million after deducting underwriting discounts and commissions and other expenses payable by AcelRx. AcelRx intends to use the net proceeds from this offering to fund potential regulatory approval of Zalviso both in the U.S. and Europe, the continuing preparation for and the potential commercial launch of Zalviso in the U.S., and for working capital and other general corporate purposes.
- In September 2013, David H. Chung joined AcelRx as chief commercial officer with responsibility for establishing, developing and leading the company's commercial operations. Mr. Chung has over 20 years of hospital-focused, global medical device and pharmaceutical marketing experience, most recently as chief commercial officer at Conceptus, Inc.
- The expanding patent portfolio for AcelRx now totals 9 issued U.S. patents and 19 issued patents worldwide. These issued patents cover AcelRx's sufentanil NanoTab, medication delivery devices and platform technology, and are expected to

provide coverage through 2027 – 2031.

- In October, 2013, data from the Phase 3 clinical trial evaluating Zalviso in the treatment of post-operative pain in patients following either knee or hip replacement surgery compared to placebo, was presented at two major medical meetings. The presentations occurred during the European Federation of IASP Chapters Annual Congress in Florence, Italy and at the American Society of Anesthesiologists meeting in San Francisco. Results demonstrated that patients receiving Zalviso realized a significantly greater Summed Pain Intensity Difference to baseline for 48 hours (SPID-48), the FDA-requested primary endpoint, during the study period than placebo-treated patients (+76.1 vs. -11.5, $p<0.001$). Adverse events reported in the study were generally mild or moderate in nature and were similar in both placebo and treatment groups for the majority of adverse events. Additional posters presented at both of these meetings highlighted more detailed results from the Phase 3 placebo-controlled study conducted in abdominal surgery patients, the Phase 3 active-comparator study comparing Zalviso to IV PCA with morphine, and pharmacokinetic data from a study describing different routes of sufentanil delivery (IV vs. transmucosal vs. oral/swallowed).

Financial Outlook

AcelRx records as revenue the reimbursement received pursuant to the $5.6 million USAMRMC grant received in 2011. To date, revenue from this grant has been the only source of revenue recognized by AcelRx resulting in recorded revenues of $5.4 million through September 30, 2013. We expect the remaining $0.2 million to be recorded as revenue in the fourth quarter of 2013.

We anticipate that quarterly R&D expenses through the end of 2013 will continue to decline due to lower clinical development costs associated with the Zalviso and ARX-04 programs.

Additionally, we anticipate higher general and administrative expense in the fourth quarter of 2013 due to an increase in Zalviso U.S. commercial preparations and the expansion of its corporate infrastructure to support an emerging commercial organization.

Total operating expenses for 2013 are anticipated to be modestly higher than they were in 2012.

Other income and expense in future periods is expected to include non-cash charges that result from the liability accounting related to the warrants AcelRx issued in connection with the PIPE financing completed in the second quarter of 2012. The primary determinant of this charge is stock price change over each quarter and its impact on the Black-Scholes valuation of these warrants. For this reason, the impact in future periods is very difficult to predict and is not included in the company's guidance.

AcelRx believes its current cash, cash equivalents and investments including funding from the public equity offering in July 2013, are sufficient to fund operations at least through the end of 2014. We expect the use of cash will decrease during the fourth quarter of 2013 compared to the first three quarters of the year as expenditures, primarily R&D expenses, decline for clinical activity and final payments are made to contract research organizations.

Conference Call

AcelRx will conduct a conference call and webcast today, November 5, 2013 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.acelrx.com and selecting the webcast link for the Q3 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.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 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 to be used to treat moderate-to-severe acute pain in the hospital setting. AcelRx has also announced positive top-line results for a Phase 2 trial for ARX-04, a product candidate for the treatment of moderate-to-severe acute pain in a medically supervised setting, funded through a grant from the U.S. Army Medical Research and Materiel Command. 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 2013 financial guidance and cash forecast, use of proceeds from the recently completed financing, the process and timing of anticipated future development of AcelRx's product candidates, the potential acceptance by the FDA of the NDA for Zalviso and the timing thereof, therapeutic and commercial potential of Zalviso and the anticipated timing, therapeutic and commercial potential of other AcelRx product candidates. 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 submit an NDA and receive regulatory approval for Zalviso, that fact that FDA may not accept for filing the NDA for Zalviso or dispute or interpret differently positive 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 obtain sufficient financing to commercialize Zalviso; 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 today 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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Statement of Operations Data				
Research grant revenue	$ 548	$ 166	$ 1,895	$ 719
Operating expenses:				
Research and development [1]	6,548	6,948	21,974	17,113
General and administrative [1]	2,310	1,410	6,571	5,290
Total operating expenses	8,858	8,358	28,545	22,403
Loss from operations	(8,310)	(8,192)	(26,650)	(21,684)
Interest expense	(348)	(573)	(1,205)	(1,765)
Other income (expense), net[2]	(2,328)	183	(13,340)	608
Net loss	$ (10,986)	$ (8,582)	$(41,195)	$(22,841)
Basic and diluted net loss per common share	$ (0.26)	$ (0.38)	$ (1.07)	$ (1.09)
Shares used in computing basic and diluted net loss per common share	41,462	22,633	38,635	20,962

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

Research and development	$ 427	$ 258	$ 1,193	$ 762
General and administrative	449	304	1,242	871
Total	$ 876	$ 562	$ 2,435	$ 1,633

(2) Other income and expense includes a $2.4 million and $13.4 million non-cash charge for the three and nine months ended September 30, 2013, respectively, related to warrants issued in connection with a private placement equity financing, completed in June 2012.

	September 30, 2013	December 31, 2012
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 75,968	$ 59,763
Total assets	80,661	64,520
Total liabilities	27,456	30,673
Total stockholders' equity	53,205	33,847

(Logo: http://photos.prnewswire.com/prnh/20130226/MM67303LOGO)

SOURCE AcelRx Pharmaceuticals, Inc.

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