



AcelRx Pharmaceuticals Reports Third Quarter 2017 Financial Results

Nov 09, 2017

- \$67.9 million of cash and cash equivalents at September 30, 2017

- Type A FDA meeting requested and Briefing Book submitted to FDA regarding DSUVIA complete response letter (CRL)

REDWOOD CITY, Calif., Nov. 9, 2017 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company today reported third quarter 2017 financial results.

"In response to the DSUVIA CRL, we are pleased to have compiled and submitted the Briefing Book and request for a Type A meeting with the FDA. Our goal is to have this meeting scheduled before the end of the year to provide clarity on our path towards DSUVIA NDA resubmission," stated Vince Angotti, AcelRx's chief executive officer. "DSUVIA remains our core asset as we believe the recommendations in the CRL are manageable. In addition, we successfully completed the ZALVISO Phase 3 study requested by the FDA, and remain focused on providing physicians and patients with non-invasive pain management options for moderate-to-severe acute pain within medically supervised settings. We also reduced our cash spending during the quarter, and plan to continue our prudent cash management in the coming quarters to maintain our solid liquidity position."

Recent Highlights

- Reported successful outcome of ZALVISO Phase 3 IAP312 study on device functionality, achieving the study objective with 2.2% of patients experiencing a device error, which was statistically less than the 5% limit specified in the study objective.
- On track for the resubmission of the NDA for ZALVISO by the end of the year with the intention to resubmit after the DSUVIA Type A meeting.
- Received a CRL in October 2017 from the FDA regarding its NDA for DSUVIA. A Type A meeting request was submitted to the FDA to discuss the topics covered in the CRL and to confirm plans to move towards resubmission of the DSUVIA NDA.

Third Quarter 2017 Financial Information

- September 30, 2017 cash balance of \$67.9 million.
- Revenue of \$1.5 million, consisting of \$1.2 million related to the collaboration with Grunenthal, and \$0.3 million related to work performed under the Department of Defense (DoD) contract for DSUVIA. The \$1.9 million decline from the third quarter of 2016 is mainly attributed to lower invoicing under our DoD contract due to less DSUVIA development work in the quarter.
- Cost of goods sold of \$2.0 million related to commercial production of ZALVISO in support of Grunenthal's European launch, as compared to \$2.6 million during the third quarter of 2016.
- R&D and G&A expenses totaled \$8.3 million, and excluding stock-based compensation was \$7.4 million, declining \$0.4 million compared to the third quarter of 2016. The decrease was mainly due to the completion of the Phase 3 DSUVIA trials in 2016, and lower ZALVISO-related development costs offset by an increase in DSUVIA-related pre-commercialization expenses.
- Net loss for the third quarter of 2017 was \$13.0 million, or \$0.28 basic and diluted net loss per share, compared to \$11.4 million, or \$0.25 basic and diluted net loss per share for the third quarter of 2016. The net loss from operations in the third quarter of 2017 was \$8.9 million, compared to \$8.0 million during the third quarter last year.

Year-to-Date Financial Information

- For the nine months ended September 30, 2017, revenue of \$7.2 million, consisting of \$6.4 million under the collaboration agreement with Grunenthal, and \$0.8 million related to work performed under the Department of Defense contract for DSUVIA. This compares to revenue related to those two agreements of \$4.7 million and \$6.2 million, respectively, for the nine months ended September 30, 2016. Higher ZALVISO product sales to Grunenthal were offset by the timing of DSUVIA development work reimbursed under our contract with the DoD.
- Cost of goods sold of \$9.7 million related to the production of ZALVISO for Grunenthal's European launch, as compared to \$9.2 million in the comparable period last year.
- R&D and G&A expenses totaled \$28.4 million, and excluding stock-based compensation was \$25.4 million, in the nine months ended September 30, 2017, compared to \$26.6 million, and excluding stock-based compensation was \$23.4 million, during the nine months ended September 30, 2016. The increase was primarily due to the IAP312 clinical trial for ZALVISO and DSUVIA-related pre-commercialization expenses.
- Net loss of \$41.6 million, or \$0.91 basic and diluted net loss per share, compared to \$33.5 million, or \$0.74 basic and diluted net loss per share for the same period in 2016.

Conference Call

As previously announced, AcelRx will conduct an investment-community conference call on Thursday, November 9, 2017 at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time) to discuss these financial results. Investors who wish to participate in the conference call may do so by dialing (866) 361-2335 for domestic callers, (855) 669-9657 for Canadian callers or (412) 902-4204 for international callers. Those interested in listening to a webcast of the conference call live via the Internet may do so by visiting the Investors page of the company's website at www.acelrx.com and clicking on the webcast link on the Investors home page. The webcast will be archived on the AcelRx website for 90 days following the call.

About AcetRx Pharmaceuticals, Inc.

AcetRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain. AcetRx's proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles. The company has two product candidates including DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as ARX-04 outside the United States, with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised settings, and ZALVISO® (sufentanil sublingual tablet system, SST system, 15 microgram) being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings.

For additional information about AcetRx's clinical programs, please visit www.acetrx.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 AcetRx's product candidates, DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as ARX-04 outside the United States, and ZALVISO® (sufentanil sublingual tablet system), including U.S. Food and Drug Administration, or FDA, review of the New Drug Application, or NDA, for DSUVIA; evaluation of the CRL and AcetRx's plans for resubmission of the NDA for DSUVIA with the FDA; the timing of the planned resubmission of the ZALVISO NDA; and the Company's ability to continue its cash management plan and maintain a solid liquidity position. These forward-looking statements are based on AcetRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcetRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements, and as a result of these risks and uncertainties, which include, without limitation, risks related to AcetRx Pharmaceuticals' DSUVIA and ARX-04 development programs, including EMA review of the ARX-04 MAA, and the possibility that EMA may dispute or interpret differently clinical results obtained from the ARX-04 Phase 2 and 3 studies; the possibility that the FDA may dispute or interpret differently the results of the ZALVISO development program, including the results from the IAP312 clinical trial; the resubmission of the ZALVISO NDA to the FDA; any delays or inability to obtain and maintain regulatory approval of its product candidates, including DSUVIA in the United States, ARX-04 in Europe and ZALVISO in the United States; the uncertain clinical development process, including adverse events; the success, cost and timing of all development activities and clinical trials; the accuracy of AcetRx's estimates regarding expenses, capital requirements and the need for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcetRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on August 2, 2017. AcetRx 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	
	2017	2016	2017	2016
Statement of Comprehensive Loss Data				
Revenue:				
Collaboration agreement revenue	\$ 1,225	\$ 1,562	\$ 6,444	\$ 4,669
Contract and other revenue	262	1,804	811	6,253
Total revenue	1,487	3,366	7,255	10,922
Operating costs and expenses:				
Cost of goods sold ⁽¹⁾	2,029	2,579	9,697	9,154
Research and development ⁽¹⁾	3,913	4,617	15,733	15,068
General and administrative ⁽¹⁾	4,406	4,145	12,700	11,519
Total operating costs and expenses	10,348	11,341	38,130	35,741
Loss from operations	(8,861)	(7,975)	(30,875)	(24,819)
Other (expense) income:				
Interest expense	(919)	(702)	(2,596)	(2,069)
Interest income and other income (expense), net ⁽²⁾	(465)	(360)	(215)	300
Non-cash interest expense on liability related to sale of future royalties	(2,768)	(2,401)	(7,935)	(6,921)
Total other expense	(4,152)	(3,463)	(10,746)	(8,690)
Benefit (provision) for income taxes	-	36	(2)	34
Net loss	\$(13,013)	\$(11,402)	\$(41,623)	\$(33,475)
Basic and diluted net loss per common share	\$ (0.28)	\$ (0.25)	\$ (0.91)	\$ (0.74)
Shares used in computing basic and diluted net loss per common share	46,365	45,319	45,701	45,306

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

Cost of goods sold	\$ 80	\$ 77	\$ 243	\$ 225
Research and development	458	560	1,442	1,746
General and administrative	480	441	1,555	1,437
Total	\$ 1,018	\$ 1,078	\$ 3,240	\$ 3,408

(2) Interest income and other income (expense) includes \$0.6 million and \$0.4 million in non-cash charges for the three months ended September 30, 2017 and 2016, respectively, and \$0.4 million in non-cash charges and \$0.1 million in non-cash income for the nine months ended September 30, 2017 and 2016, respectively, related to warrants issued in connection with a private placement equity financing, completed in June 2012.

	September 30, 2017	December 31, 2016
Selected Balance Sheet Data		
Cash and cash equivalents	\$ 67,936	\$ 80,310
Total assets	82,743	99,993
Total liabilities	113,052	105,330
Total stockholders' deficit	(30,309)	(5,337)



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