



AcelRx Pharmaceuticals Reports Fourth Quarter and Year End 2016 Financial Results

Mar 02, 2017

- DSUVIA NDA Accepted and PDUFA Date Set for October 12, 2017 -

REDWOOD CITY, Calif., March 2, 2017 /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 pain, today provided a business update and reported financial results for the fourth quarter and full year ended December 31, 2016.

Corporate and Clinical Highlights

During the fourth quarter of 2016, AcelRx submitted a New Drug Application (NDA) under section 505(b)(2) with the U.S. Food and Drug Administration (FDA) for DSUVIA™ (sufentanil sublingual tablet, 30 mcg) for the treatment of patients experiencing moderate-to-severe acute pain in a medically supervised setting. Recently, this application was accepted for filing, and a Prescription Drug User Fee Act (PDUFA) goal date of October 12, 2017 was assigned.

During the fourth quarter, AcelRx updated its expectations of DSUVIA's market potential, and presented these findings at an analyst and investor event in December. Should DSUVIA be approved in the U.S. and then subsequently in Europe, the company's expectations, based on commissioned research, are for an estimated \$1.1 billion in peak sales in the U.S. and €700 million in Europe.

"We have taken meaningful steps towards meeting our goal of DSUVIA approval in the U.S., and we continue to make additional commercial preparations for a potential DSUVIA launch," commented Howie Rosen, chief executive officer. Mr. Rosen continued, "A key aspect of our preparations, as we announced a few weeks ago, is having appointed Vincent J. Angotti to be chief executive officer starting March 6th. Vince has over 25 years of successful commercial experience, most recently at Xenoport, where he managed the relaunch of Horizant as COO, and as CEO led their acquisition by Arbor Pharmaceuticals. I look forward to working with Vince and the AcelRx team in my continuing role on the Board of Directors."

In the fourth quarter of 2016, AcelRx also made a number of presentations of DSUVIA results from the Phase 3 clinical program. These included the first presentation of complete results from the Phase 3 SAP303 study, which was conducted in 140 patients aged ≥40 years who had undergone short-stay, in-patient or out-patient surgery. These results, which were presented at the Annual Pain Medicine Meeting of the American Society of Regional Anesthesia and Pain Medicine (ASRA), showed that patients administered DSUVIA experienced a 49% reduction ($p < 0.001$) in mean pain intensity from baseline during the first 2 hours, and maintained that reduction for the duration of the 12-hour study period. The most common study drug-related adverse events in the study population were nausea (27%) and dizziness (4%).

Corporate Milestones for DSUVIA and ARX-04 in the Upcoming Year:

- Submit the European Regulatory Application. AcelRx expects to submit a Marketing Authorization Application (MAA) under the Centralized Procedure for ARX-04 with the European Medicines Agency (EMA) in the first half of 2017.
- Plan for Potential U.S. Approval and Commercialization. In anticipation of the potential for NDA approval by the PDUFA date, AcelRx continues its preparation for commercialization of DSUVIA.

Fourth Quarter 2016 Financial Results

Net loss for the fourth quarter of 2016 was \$9.7 million, or \$0.21 basic and diluted net loss per share, compared to a net loss of \$10.5 million, or \$0.24 basic and diluted net loss per share for the fourth quarter of 2015. The decrease in net loss in the fourth quarter 2016, as compared to the fourth quarter 2015, was primarily due to an increase in revenue partially offset by increased operating costs and expenses.

During the fourth quarter of 2016, AcelRx recognized revenue of \$1.8 million under the collaboration agreement with Grunenthal and \$4.6 million related to work performed under the DoD contract for DSUVIA. This compares to \$0.3 million in revenue recognized under the collaboration agreement with Grunenthal and \$1.4 million in revenue recognized related to the DoD contract during the fourth quarter of 2015.

Operating costs and expenses during the fourth quarter of 2016 included cost of goods sold of \$3.2 million, as compared to \$1.8 million for the fourth quarter 2015. Research and development expenses for the fourth quarter of 2016 were \$6.3 million, as compared to \$3.5 million for the fourth quarter of 2015. The \$2.8 million increase in R&D expenses was primarily due to increased DSUVIA-related expenses, including the filing fee for the DSUVIA NDA. General and administrative expenses were \$4.1 million during the fourth quarter of 2016, as compared to \$4.0 million for the fourth quarter of 2015.

Total other expense decreased from \$3.0 million in the fourth quarter of 2015 to \$2.5 million in the fourth quarter of 2016, primarily due to the change in the fair value of our warrants, or PIPE warrants, issued in connection with the private placement of our common stock, which was completed in June 2012.

Full-Year 2016 Financial Results

For the year-ended December 31, 2016, AcelRx reported a net loss of \$43.2 million, or \$0.95 basic and diluted net loss per share, as compared to a net loss of \$24.4 million, or \$0.55 basic net loss per share and \$0.60 diluted net loss per share for the same period in 2015. Common shares used in calculating earnings per share were 45.3 million for basic and diluted net loss in 2016, as compared to 44.3 million for basic EPS and 44.5 million for diluted EPS in 2015.

AcelRx recognized revenue of \$6.4 million under the collaboration agreement with Grunenthal and \$10.9 million related to work performed under the DoD contract for DSUVIA in 2016. This compares to \$14.9 million in revenue recognized under the collaboration agreement with Grunenthal and \$4.4 million in revenue related to the DoD contract recognized in 2015. AcelRx began shipments of commercial product to Grunenthal in the second quarter of 2016. In 2015, upon approval of the MAA for ZALVISO, the Company recognized revenue related to a milestone payment received from Grunenthal under the collaboration agreement.

Operating costs and expenses during 2016 included cost of goods sold of \$12.3 million, as compared to \$1.8 million during the year ended December 31, 2015. Research and development, and general and administrative expenses during the year were \$21.4 million and \$15.6 million, respectively. These compare to \$22.5 million in research and development expenses and \$14.2 million in general and administrative expenses last year. The \$1.1

million decrease in R&D expenses was primarily attributable to a \$3.1 million reduction in overhead costs, predominantly as a result of the allocation of certain research and development personnel and related expenses to cost of goods sold, a \$0.9 million decrease in ZALVISO-related expenses due to the completion of certain development activities as AcetRx finalized the development path forward with the FDA, partially offset by an incremental increase of \$2.9 million in DSUVIA-related spending as the DSUVIA development program reached completion and the NDA was prepared and submitted to the FDA. The \$1.4 million increase in general and administrative expenses in 2016 was primarily due to \$2.4 million in increased DSUVIA-related market research activities, and \$0.3 million in ZALVISO-related market research activities, offset by decreases of \$0.6 million in professional services and legal expenses, \$0.5 million in stock-based compensation expense, and a net decrease of \$0.2 million in other general and administrative-related expenses.

Total other expense was \$11.2 million during 2016, as compared to \$3.7 million during 2015. The difference was primarily a result of the non-cash interest expense related to the monetization of the expected royalty stream, or Royalty Monetization, from the sales of ZALVISO in the EU by Grunenthal to PDL BioPharma, Inc.

The Royalty Monetization resulted in a taxable gain of more than \$60.0 million in the year ended December 31, 2015, the majority of which was offset with net operating loss carryforwards; however, AcetRx was subject to U.S. federal alternative minimum taxes in 2015, as reflected in its provision for income taxes in 2015.

As of December 31, 2016, AcetRx had cash, cash equivalents and investments of \$80.3 million, compared to \$113.5 million at December 31, 2015. The decrease was primarily attributable to cash used in operating activities.

Conference Call

AcetRx will conduct a conference call and webcast today, March 2, 2017 at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) to discuss these financial results and business 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.acetrx.com. A webcast replay will be available on the AcetRx website for 90 days following the call by visiting the Investors section of the company's website at www.acetrx.com.

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. An NDA for DSUVIA (sufentanil sublingual tablet, 30mcg) with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised settings, was accepted for filing by the FDA with a Prescription Drug User Fee Act (PDUFA) goal date of October 12, 2017.

The Company's follow on product candidate, ZALVISO[®] (sufentanil sublingual tablet system), designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting, is currently enrolling patients in a Phase 3 clinical trial, IAP312. ZALVISO delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. ZALVISO is approved in the EU and is investigational and in late-stage development in the U.S. Grunenthal Group holds the rights for ZALVISO in Europe, where a commercial launch has begun.

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; the potential approval of the DSUVIA NDA by the FDA; the DSUVIA and ARX-04 clinical trial results; AcetRx's pathway forward towards gaining approval of ZALVISO in the U.S., including successful completion of the IAP312 clinical study for ZALVISO; the therapeutic and commercial potential of AcetRx's product candidates, including potential market opportunities for DSUVIA, ARX-04 and ZALVISO and anticipated cash balance at year-end 2017. 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 the FDA review of the DSUVIA NDA and the possibility that the FDA may dispute or interpret differently clinical results obtained from the DSUVIA Phase 3 studies; the ZALVISO development program, including successful completion of IAP312 and 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; the success, cost and timing of all development activities and clinical trials; 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 November 2, 2016. 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 December 31		Twelve Months Ended December 31	
	2016	2015	2016	2015
Statement of Comprehensive Loss Data				
Collaboration agreement revenue	\$ 1,771	\$ 327	\$ 6,440	\$ 14,857
Contract and other revenue	4,664	1,403	10,917	4,406
Total revenue	6,435	1,730	17,357	19,263
Operating costs and expenses:				
Cost of goods sold ⁽¹⁾	3,161	1,770	12,315	1,770

Research and development ⁽¹⁾	6,334	3,479	21,402	22,488
General and administrative ⁽¹⁾	4,078	4,017	15,597	14,203
Restructuring costs	-	-	-	756
Total operating costs and expenses	13,573	9,266	49,314	39,217
Loss from operations	(7,138)	(7,536)	(31,957)	(19,954)
Other (expense) income:				
Interest expense	(701)	(681)	(2,770)	(2,977)
Interest income and other income ⁽²⁾	618	(195)	918	1,720
Non-cash interest expense on liability related to sale of future royalties to PDL	(2,461)	(2,146)	(9,382)	(2,428)
Total other expense	(2,544)	(3,022)	(11,234)	(3,685)
Benefit (provision) for income taxes	-	12	34	(760)
Net loss	\$ (9,682)	\$ (10,546)	\$ (43,157)	\$ (24,399)
Basic net loss per common share	\$ (0.21)	\$ (0.24)	\$ (0.95)	\$ (0.55)
Shares used in computing basic net loss per common share	45,334	44,568	45,313	44,300
Diluted net loss per common share	\$ (0.21)	\$ (0.24)	\$ (0.95)	\$ (0.60)
Shares used in computing diluted net loss per common share	45,334	44,568	45,313	44,468

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

Cost of goods sold	\$ 77	\$ 67	\$ 302	\$ 67
Research and development	562	620	2,308	2,587
General and administrative	432	503	1,869	2,356
Total	\$ 1,071	\$ 1,190	\$ 4,479	\$ 5,010

(2) Interest income and other income (expense) includes \$0.5 million in non-cash income for the three months ended December 31, 2016 and \$0.6 million in non-cash income for the twelve months ended December 31, 2016, as compared to \$0.3 million in non-cash charges for the three months ended December 31, 2015 and \$2.1 million in non-cash income for the twelve months ended December 31, 2015, respectively, related to warrants issued in connection with a private placement equity financing, completed in June 2012.

December 31, 2016 December 31, 2015

Selected Balance Sheet Data

Cash, cash equivalents and investments	\$ 80,310	\$ 113,464
Total assets	99,993	127,785
Total liabilities	105,330	94,672
Total stockholders' (deficit) equity	(5,337)	33,113



To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/accelrx-pharmaceuticals-reports-fourth-quarter-and-year-end-2016-financial-results-300417286.html>

SOURCE AcclRx Pharmaceuticals, Inc.

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