



AcelRx Pharmaceuticals Reports Second Quarter 2017 Financial Results and Provides Corporate Update

August 1, 2017

REDWOOD CITY, Calif., Aug. 1, 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 moderate-to-severe acute pain, today provided a business update and reported financial results for the three and six months ended June 30, 2017.

Clinical Highlights

In the second quarter of 2017, AcelRx presented efficacy and integrated safety results from the DSUVIA™ (sufentanil sublingual tablet, 30 mcg) clinical program during the Annual Regional Anesthesiology and Acute Pain Medicine Meeting. DSUVIA is AcelRx's lead investigational candidate for the treatment of patients with moderate-to-severe acute pain in a medically supervised setting. A New Drug Application (NDA) is currently under review at the U.S. Food and Drug Administration and a Marketing Authorisation Application (MAA) for ARX-04 (known as DSUVIA in the U.S.) is being evaluated by the European Medicines Agency.

ZALVISO® (sufentanil sublingual tablet system), the company's patient-controlled analgesia system, was selected for a Red Dot Award in the category of Product Design – Life Sciences and Medicine in the second quarter of 2017. The Red Dot Award is organized by the Design Zentrum Nordrhein Westfalen in Essen, Germany, and is one of the largest design competitions in the world. ZALVISO is currently marketed in the EU through the company's licensee, Grunenthal, for the treatment of moderate to severe post-operative pain management in a hospital setting.

Today AcelRx reported top-line results from IAP312, a Phase 3 study that treated 320 hospitalized, post-operative patients who used ZALVISO to self-administer 15 mcg sublingual sufentanil tablets as often as once every 20 minutes for 24-to-72 hours to manage their moderate-to-severe acute pain. Throughout the study, 2.2% of patients experienced a ZALVISO device error, which was statistically less than the 5% limit specified in the study objectives. In addition, results of this study supported earlier clinical findings, with favorable tolerability and a significant majority of "good" or "excellent" ratings provided by both patients and healthcare providers when assessing the method of pain control. AcelRx remains on track to resubmit the NDA for ZALVISO by the end of the year.

"We are making solid progress on our path to commercializing our two late-stage product candidates, DSUVIA and ZALVISO," stated [Vincent J. Angotti](#), AcelRx's chief executive officer. "We expect to receive a decision from the FDA on our marketing application for DSUVIA in the fourth quarter, and are on track to resubmit the NDA for ZALVISO to the FDA that same quarter. We also continue to manage our expenses and cash in line with our plan leading into these major company milestones."

Second Quarter 2017 Financial Results

Net loss for the second quarter of 2017 was \$13.1 million, or \$0.29 basic and diluted net loss per share, compared to \$11.1 million, or \$0.24 basic and diluted net loss per share for the second quarter of 2016. The net loss from operations in the second quarter of 2017 was \$9.9 million, compared to \$8.3 million during the second quarter last year.

During the second quarter of 2017, AcelRx recognized revenue of \$2.2 million under the collaboration agreement with Grunenthal, mainly due to ZALVISO product shipments, and \$0.5 million related to work performed under the Department of Defense (DoD) contract for DSUVIA. This compares to \$1.3 million and \$3.2 million in revenue recognized, respectively, from those two agreements in the second quarter of 2016.

Operating costs and expenses during the second quarter of 2017 included cost of goods sold of \$3.5 million related to commercial production of ZALVISO in support of Grunenthal's European launch, as compared to \$3.0 million during the three months ended June 30, 2016. Research and development expenses for the second quarter of 2017 and 2016 were \$4.9 million and \$6.3 million, respectively. The net decrease was due to the completion of the Phase 3 DSUVIA trials in June 2016, partially offset by an increase in R&D expenses in 2017 related to the IAP312 study for ZALVISO. General and administrative expenses for the second quarter of 2017 and 2016 were \$4.2 million and \$3.6 million, respectively, primarily due to increased pre-commercialization expenses in 2017. Total other expense for the second quarter of 2017 was \$3.1 million as compared to \$2.8 million in the second quarter of 2016, and consists mainly of non-cash interest expense on the liability related to the sale of future royalties.

Year-to-Date Financial Results

For the six months ended June 30, 2017, AcelRx reported a net loss of \$28.6 million, or \$0.63 basic and diluted net loss per share, compared to \$22.1 million, or \$0.49 basic and diluted net loss per share for the same period in 2016. The increased net loss in the first half of 2017 is primarily due to decreased DoD contract revenue, combined with increased costs of goods sold related to larger shipments of ZALVISO, and higher expenses related to the IAP312 study and pre-commercialization activities. In addition, total other expense increased in the six months ended June 30, 2017 primarily due to increased interest expense on the Hercules loan and other non-cash items, including interest expense on the liability related to the sale of future royalties.

During the six months ended June 30, 2017, AcelRx recognized revenue of \$5.2 million under the collaboration agreement with Grunenthal and \$0.6 million related to work performed under the DoD contract for ARX-04. This compares to \$3.1 million and \$4.4 million in revenue, respectively, related to these agreements in the six months ended June 30, 2016.

Operating costs and expenses during the six months ended June 30, 2017 included cost of goods sold of \$7.7 million, as compared to \$6.6 million in the comparable period last year. Research and development, and general and administrative expenses during the six months ended June 30, 2017 were \$11.8 million and \$8.3 million, respectively. These compare to \$10.5 million in research and development expenses and \$7.4 million in general and administrative expenses in the first half of last year.

Total other expense of \$6.6 million during the six months ended June 30, 2017 compares to \$5.2 million in other income during the six months ended June 30, 2016.

As of June 30, 2017, AcclRx had cash, cash equivalents and investments of \$62.1 million, compared to \$80.3 million at December 31, 2016. The decrease was primarily attributable to cash used in operating activities.

Conference Call

As previously announced, AcclRx will conduct an investment-community conference call on Tuesday, August 1, 2017 at 8:30 am Eastern Time (5:30 am Pacific Time) to discuss top-line results from the IAP312 study. IAP312 was a Phase 3 study in which hospitalized, post-operative patients self-administered 15 microgram sublingual sufentanil tablets using ZALVISO® (sufentanil sublingual tablet system) as often as once every 20 minutes to manage their moderate-to-severe acute pain. The company also plans to discuss its financial results for the three and six months ended June 30, 2017. Please note, this conference call and webcast will replace the previously announced financial results conference call that had been scheduled for August 2, 2017. A separate press release regarding the Phase 3 IAP312 study top-line results was issued today.

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.acclrx.com and clicking on the webcast link on the Investors home page. The webcast will be archived on the AcclRx website for 90 days following the call.

About AcclRx Pharmaceuticals, Inc.

AcclRx 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. A New Drug Application (NDA) for 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, was accepted for filing by the United States Food and Drug Administration (FDA) and has been given a PDUFA date of October 12, 2017. In the EU, the European Medicines Agency (EMA) has notified the company that the ARX-04 (sufentanil sublingual tablet, 30 mcg) Marketing Authorisation Application (MAA) has passed validation and that the scientific review of the MAA is underway.

The company's product candidate, ZALVISO® (sufentanil sublingual tablet system), is designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting. The company recently completed a Phase 3 clinical trial, IAP312, which included input from the FDA on the study protocol. This study was designed to evaluate the effectiveness of changes made to the functionality and usability of the ZALVISO device, to evaluate the incidence of inadvertent dosing, and to take into account comments from the FDA on the study protocol. AcclRx intends to resubmit the NDA for ZALVISO to the FDA by the end of the year. 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 United States. Grunenthal Group holds the rights for ZALVISO in Europe, where a commercialization across multiple countries is underway.

For additional information about AcclRx's clinical programs, please visit www.acclrx.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 AcclRx'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 European Medicines Agency (EMA) scientific review of the ARX-04 Marketing Authorisation Application (MAA); the DSUVIA and ARX-04 clinical trial results; AcclRx's pathway forward towards gaining approval of ZALVISO in the United States, including the planned resubmission and timing of the ZALVISO NDA to the FDA; and the therapeutic and commercial potential of AcclRx's product candidates, including potential market opportunities for DSUVIA, ARX-04 and ZALVISO. These forward-looking statements are based on AcclRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcclRx 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 AcclRx Pharmaceuticals' DSUVIA and ARX-04 development programs, including the FDA review of the DSUVIA NDA, the EMA review of the ARX-04 MAA, and the possibility that the FDA or EMA may dispute or interpret differently clinical results obtained from the DSUVIA or 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 AcclRx's estimates regarding expenses, capital requirements and the need for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcclRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on May 8, 2017. AcclRx 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		Six Months Ended	
	June 30		June 30	
	2017	2016	2017	2016
Statement of Comprehensive Loss Data				
Revenue:				
Collaboration agreement revenue	\$ 2,192	\$ 1,314	\$ 5,219	\$ 3,107
Contract and other revenue	467	3,217	549	4,449
Total revenue	2,659	4,531	5,768	7,556
Operating costs and expenses:				
Cost of goods sold ⁽¹⁾	3,543	2,976	7,668	6,575
Research and development ⁽¹⁾	4,901	6,280	11,820	10,451
General and administrative ⁽¹⁾	4,156	3,597	8,294	7,374
Total operating costs and expenses	12,600	12,853	27,782	24,400
Loss from operations	(9,941)	(8,322)	(22,014)	(16,844)
Other (expense) income:				
Interest expense	(903)	(687)	(1,677)	(1,367)
Interest income and other income (expense), net ⁽²⁾	396	241	250	660
Non-cash interest expense on liability related to sale of future royalties	(2,609)	(2,324)	(5,167)	(4,520)
Total other expense	(3,116)	(2,770)	(6,594)	(5,227)
Provision for income taxes	(2)	-	(2)	(2)
Net loss	\$ (13,059)	\$ (11,092)	\$(28,610)	\$(22,073)
Basic net loss per common share	\$ (0.29)	\$ (0.24)	\$ (0.63)	\$ (0.49)
Shares used in computing basic net loss per common share	45,379	45,312	45,364	45,300
Diluted net loss per common share	\$ (0.29)	\$ (0.24)	\$ (0.63)	\$ (0.49)

Shares used in computing diluted net loss per common share	45,379	45,312	45,364	45,300
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(1) Includes the following non-cash, stock-based compensation expense:

Cost of goods sold	\$ 79	\$ 77	\$ 163	\$ 148
Research and development	448	586	985	1,186
General and administrative	551	482	1,074	996
Total	\$ 1,078	\$ 1,145	\$ 2,222	\$ 2,330

(2) Interest income and other income (expense) includes \$0.3 million and \$0.2 million in non-cash income for the three months ended June 30, 2017 and 2016, respectively, and \$0.3 million and \$0.5 million in non-cash income for the six months ended June 30, 2017 and 2016, respectively, related to warrants issued in connection with a private placement equity financing, completed in June 2012.

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
Selected Balance Sheet Data		
Cash, cash equivalents and investments	\$ 62,148	\$ 80,310
Total assets	66,769	99,993
Total liabilities	109,814	105,330
Total stockholders' deficit	(31,624)	(5,337)



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