



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

May 08, 2017

- NDA for DSUVIA (sufentanil sublingual tablet, 30 mcg) and MAA for ARX-04 under review at respective agencies -

REDWOOD CITY, Calif., May 8, 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 months ended March 31, 2017.

Corporate Highlights

The U.S. Food and Drug Administration (FDA) notified the company in the first quarter that it has accepted the New Drug Application (NDA) under section 505(b)(2) for DSUVIA™ for the treatment of patients with moderate-to-severe acute pain in a medically supervised setting. Subsequently, AcelRx was notified that a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee would be convened.

The European Medicines Agency (EMA) notified AcelRx that the ARX-04 Marketing Authorisation Application (MAA) has advanced from the validation to scientific review phase. The MAA was filed in early March 2017 for the treatment of patients with moderate-to-severe acute pain in a medically supervised setting. The company expects an opinion from the Committee for Medicinal Products for Human Use (CHMP) to be rendered in the first half of 2018.

"The first quarter of 2017 held two significant regulatory milestones: the acceptance of the DSUVIA NDA by the US FDA and the initiation of scientific review of the ARX-04 MAA by the European regulatory authority," stated [Vincent J. Angotti](#), AcelRx's chief executive officer. "Over the next few months, the AcelRx team will be focused on our interactions with the FDA and EMA to support the potential approval and launch of DSUVIA in the US and ARX-04 in Europe."

Clinical Highlights

Medical education efforts continued in the first quarter of 2017, and were supported by the publication of complete findings from the DSUVIA Phase 3 SAP301 trial, which compared placebo to DSUVIA in patients who underwent ambulatory abdominal surgery. This publication may be found in the open-access journal, [Pain Practice](#), in an article titled "Sufentanil Sublingual Tablet 30 mcg for the Management of Pain Following Abdominal Surgery: A Randomized, Placebo-Controlled, Phase 3 Study."

SAP301 was a multi-center, double-blind, placebo-controlled study conducted in patients with moderate-to-severe acute pain following ambulatory abdominal surgery. In this study, patients who received DSUVIA experienced a greater reduction in pain from baseline over the study's 12-hour period (SPID 12) than did patients administered a placebo ($P < 0.001$). DSUVIA was generally well tolerated by patients in SAP301, with nausea and headache comprising the most commonly reported side effects.

Anticipated Upcoming 2017 Milestones:

- Top-line data results from the IAP312 clinical study in mid-2017.
- Joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee for DSUVIA this summer.
- FDA decision on the NDA for DSUVIA this fall.
- Resubmission of ZALVISO® NDA by year-end.

Mr. Angotti continued, "In addition to the regulatory progress made for DSUVIA/ARX-04, the company's IAP312 study of ZALVISO completed enrollment. We plan on making top-line results available in the coming months and preparing our resubmission of the ZALVISO NDA in the second half of the year."

First Quarter 2017 Financial Results

Net loss for the first quarter of 2017 was \$15.6 million, or \$0.34 basic and diluted net loss per share, compared to \$11.0 million, or \$0.24 basic net loss per share and \$0.25 diluted net loss per share for the first quarter of 2016. The net loss from operations in the first quarter of 2017 was \$12.1 million, compared to \$8.5 million for the first quarter last year.

During the first quarter of 2017, AcelRx recognized revenue of \$3.0 million under the collaboration agreement with Grunenthal, mainly due to product shipments, and \$0.1 million related to work performed under the Department of Defense (DoD) contract for DSUVIA. This compares to \$1.8 million in revenue recognized under the collaboration agreement with Grunenthal and \$1.2 million related to work performed under the DoD contract for DSUVIA during the three months ended March 31, 2016.

Operating costs and expenses during the first quarter of 2017 included cost of goods sold of \$4.1 million, as compared to \$3.6 million in the first quarter of 2016, in support of Grunenthal's developing launch of ZALVISO in the EU. Research and development expenses for the first quarter of 2017 were \$6.9 million, as compared to \$4.2 million for the first quarter of 2016. The \$2.7 million increase in research and development expenses was primarily due to an increase in spending related to the IAP312 clinical study, which was initiated in September 2016.

General and administrative expenses were \$4.1 million during the first quarter of 2017, as compared to \$3.8 million for the first quarter of 2016. The \$0.3 million increase in general and administrative expenses during the three months ended March 31, 2017, as compared to the three months ended March 31, 2016, was primarily due to DSUVIA-related market research activities.

Total other expenses increased to \$3.5 million in the first quarter of 2017 from \$2.5 million in the first quarter of 2016, primarily as a result of changes in

the fair value of the company's liabilities and an increase in non-cash interest expense on the royalty monetization.

As of March 31, 2017, AcetRx had cash, cash equivalents and investments of \$72.3 million, compared to \$80.3 million at December 31, 2016. The decrease was primarily attributable to cash used in operating activities.

Conference Call

AcetRx will conduct a conference call and webcast today at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) to discuss these financial results. 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 via the live and archived webcast may do so 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. 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, has been accepted for filing by the FDA in the United States. A joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee is anticipated to convene this summer. 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 follow on 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 has completed enrollment in a Phase 3 clinical trial, IAP312, for which it anticipates top-line data results in mid-2017. 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 and the anticipated joint advisory committee meeting; the potential approval of the DSUVIA NDA by the FDA; the European Medicines Agency, or EMA, scientific review of the ARX-04 Marketing Authorisation Application, or MAA; 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; and the therapeutic and commercial potential of AcetRx's product candidates, including potential market opportunities for DSUVIA, ARX-04 and ZALVISO. 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, the anticipated joint advisory committee meeting for DSUVIA, the EMA review of the ARX-04 MAA, including 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 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, including adverse events; the risk that planned clinical trials may not have an effective clinical design, enroll a sufficient number of patients, or be completed on schedule, if at all; the success and timing of all development activities and clinical trials, including the additional clinical trial for ZALVISO, IAP312; 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 Annual Report on Form 10-K filed with the SEC on March 3, 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

March 31

2017

2016

Statement of Comprehensive Loss Data

Revenue:

Collaboration agreement revenue	\$	3,027	\$	1,793
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Contract and other revenue	82	1,232
Total revenue	3,109	3,025
Operating costs and expenses:		
Cost of goods sold ⁽¹⁾	4,125	3,599
Research and development ⁽¹⁾	6,919	4,171
General and administrative ⁽¹⁾	4,138	3,777
Total operating costs and expenses	15,182	11,547
Loss from operations	(12,073)	(8,522)
Other (expense) income:		
Interest expense	(774)	(680)
Interest income and other income (expense), net ⁽²⁾	(146)	419
Non-cash interest expense on liability related to sale of future royalties	(2,558)	(2,196)
Total other expense	(3,478)	(2,457)
Provision for income taxes	-	(2)
Net loss	\$ (15,551)	\$ (10,981)
Basic net loss per common share	\$ (0.34)	\$ (0.24)
Shares used in computing basic net loss per common share	45,348	45,287
Diluted net loss per common share	\$ (0.34)	\$ (0.25)
Shares used in computing diluted net loss per common share	45,348	45,297

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

Cost of goods sold	\$ 84	\$ 71
Research and development	537	600
General and administrative	523	514
Total	\$ 1,144	\$ 1,185

(2) Interest income and other income (expense), net includes \$0.01 million in non-cash expense and \$0.3 million in non-cash income for the three months ended March 31, 2017 and 2016, respectively, related to warrants issued in connection with a private placement equity financing, completed in June 2012.

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
Selected Balance Sheet Data		
Cash, cash equivalents and investments	\$ 72,332	\$ 80,310
Total assets	88,444	99,993
Total liabilities	108,100	105,330
Total stockholders' deficit	(19,656)	(5,337)



To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/accelrx-pharmaceuticals-reports-first-quarter-2017-financial-results-and-provides-corporate-update-300453479.html>

SOURCE AcelRx Pharmaceuticals, Inc.

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