AcelRx Pharmaceuticals Provides Corporate Update and Reports First Quarter 2016 Financial Results

May 2, 2016

REDWOOD CITY, Calif., May 2, 2016 /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 three months ended March 31, 2016.

Corporate Highlights

- *ARX-04 Emergency Room and Postoperative Studies:* AcelRx initiated two Phase 3 studies in the first quarter of 2016. The first, an extension to the SAP302 study, is targeted to enroll up to an additional 60 patients who present to the Emergency Room (ER) with moderate-to-severe acute pain associated with trauma or injury. Patients in this extension phase may receive multiple doses of ARX-04 hourly as needed for pain, for up to 4 doses. The second, SAP303, is targeted to enroll approximately 100 patients 40 years of age and older who have moderate-to-severe acute pain following a surgical procedure. In SAP303, patients may receive ARX-04 hourly as needed for pain for up to 12 hours. Both trials are open-label and are anticipated to be completed by the third quarter of this year.
- *Zalviso launch in Europe:* In April 2016, AcelRx's partner, Grunenthal Group completed the first commercial sale of the Zalviso system. Grunenthal is expected to deploy the Zalviso system initially in a limited number of hospitals in Germany under a pilot program, whereby the hospital will use Zalviso in a small number of post-operative patients. The pilot program, which is expected to last approximately two months at each institution, will be made available to additional hospitals in Germany over the next several months. Pending success with the pilot program, Grunenthal expects to make the product widely available in Germany.
- *ARX-04 and Zalviso Clinical Data Presentations and Publications:* In the first quarter, clinical results for ARX-04 and Zalviso were presented and published as follows:
  - ARX-04 SAP301 Phase 3 results were presented at the Annual European Congress of Ambulatory Surgery and the 38th Annual John A. Boswick, M.D. Burn and Wound Care Symposium.
  - ARX-04 SAP302 Phase 3 interim efficacy and safety results of the ongoing single-arm, open-label study for the treatment of adult patients who present in the emergency room with moderate-to-severe acute pain associated with trauma or injury were reported by AcelRx.
  - Zalviso Phase 3 results were published in a review article entitled "Evolution of Patient-Controlled Analgesia: From Intravenous to Sublingual Treatment" in the peer-reviewed journal, *Hospital Pharmacy*. This article provides insights into patient-controlled analgesia (PCA) systems, the choice of opioid, risks, and costs associated with PCA usage in U.S. hospitals.
- *Department of Defense ARX-04 Contract:* AcelRx amended the contract with the Department of Defense for ARX-04 to include certain amounts for reimbursement for the SAP302 and SAP303 studies under the existing agreement.

"We made significant progress on ARX-04 in the first quarter with the initiation of what we expect to be the last two clinical studies before the anticipated NDA submission in the fourth quarter," commented Howie Rosen, chief executive officer of AcelRx. "We produced and delivered commercial product to Grunenthal in advance of their first Zalviso sale in Germany. In the United States, we made the decision to use Zalviso systems from our commercial vendors in the upcoming IAP312 study which we will initiate when production and testing of the supplies are complete. While our timelines for Zalviso have been modified, we anticipate that this decision will ultimately make the launch of Zalviso in the U.S. smoother."

First Quarter 2016 Financial Results

Net loss for the first quarter of 2016 was $11.0 million, or $0.24 basic net loss per share and $0.25 diluted net loss per share, compared to $10.0 million, or $0.23 basic net loss per share and $0.27 diluted net loss per share for the first quarter of 2015. The net loss from operations in the first quarter of 2016 was $8.5 million, compared to $11.4 million for the first quarter last year. The net loss in the first quarter of 2016 included $2.2 million in non-cash interest expense on the liability related to the sale of future royalties to PDL, whereas net loss in the first quarter of 2015 included non-cash income of $2.2 million due to the change in the valuation of outstanding PIPE warrants.

During the first quarter of 2016, AcelRx recognized revenue of $1.8 million under the collaboration agreement with Grunenthal and $1.2 million related to work performed under the DoD contract for ARX-04. This compares to $181,000 of previously deferred revenue that was recognized in the first quarter of 2015 under the collaboration agreement with Grunenthal.

In preparation for the launch of Zalviso in Europe by the company's licensee, Grunenthal Group, AcelRx shipped $1.4 million of commercial inventory. Shipped product consists of devices, drug product and accessories. As the first commercial sale happened in April 2016, AcelRx did not recognize any

royalty revenue in the first quarter of 2016. Beginning in the third quarter of 2016, AcelRx will receive quarterly royalty reports from Grunenthal for the prior quarter. As the royalty amounts are not currently reasonably estimable without royalty reports, AcelRx will recognize royalty revenue and non-cash royalty revenue quarterly in arrears beginning in the third quarter of 2016. In addition, AcelRx recognized $0.4 million in other revenue under the collaboration agreement with Grunenthal in the first quarter of 2016, primarily related to demonstration devices and research and development services.

As of March 31, 2016, AcelRx had current and non-current portions of the deferred revenue balance under the collaboration agreement with Grunenthal of $1.4 million and $2.4 million, respectively. Long term deferred revenue increased during the first quarter of 2016 from $0.6 million to $2.4 million. AcelRx anticipates that the long-term deferred revenue balance will peak at approximately $4.0 million, as AcelRx completes invoicing Grunenthal in connection with the collaboration agreement in 2016, and decline on a straight-line basis through 2029, as AcelRx recognizes manufacturing services revenue under the agreement.

Total cost of goods sold was $3.6 million for the three months ended March 31, 2016 related to commercial production of Zalviso in support of Grunenthal's European launch. Costs of goods sold includes internal indirect costs plus the actual cost to manufacture at AcelRx's contract manufacturers. Under the arrangement with Grunenthal, AcelRx will sell Zalviso to Grunenthal at a predetermined transfer price that approximates the direct cost of manufacture at AcelRx's contract manufacturers. AcelRx will not recover internal indirect costs as part of the transfer price.

Research and development, and general and administrative expenses for the first quarter of 2016 were $4.2 million and $3.8 million, respectively. These compare to $6.3 million in research and development expenses and $4.5 million in general and administrative expenses in the comparable quarter last year. The decrease in general and administrative expenses was primarily due to a reduction in personnel-related expenses, predominantly as a result of the cost reduction plan implemented in March 2015. The decrease in research and development expenses was primarily due to lower personnel-related expenses of $1.4 million due to the reclassification of production-related personnel expenses to cost of goods sold and a reduction in headcount due to the March 2015 cost reduction plan. In addition, Zalviso-related spending decreased by $0.7 million due to the slowing of development activities as AcelRx clarified the development path forward with the FDA.

Total other expenses of $2.5 million in the first quarter of 2016 compares to other net income of $1.4 million in the first quarter of 2015, primarily as a result of $2.2 million in non-cash interest expense on the liability related to the sale of future royalties.

As of March 31, 2016, AcelRx had cash, cash equivalents and investments of $107.2 million, compared to $113.5 million at December 31, 2015. The decrease was primarily attributable to cash used in operating activities.

Conference Call

AcelRx will conduct a conference call and webcast today, May 2, 2016, 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.acelrx.com. 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 pain. The Company's late-stage pipeline includes ARX-04 (sufentanil sublingual tablet, 30 mcg) designed for the treatment of moderate-to-severe acute pain in a medically supervised setting; and Zalviso™ (sufentanil sublingual tablet system) designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting.

ARX-04 delivers 30 mcg sufentanil, a high therapeutic index opioid, sublingually through a disposable, pre-filled, single-dose applicator. AcelRx has reported positive results from the pivotal Phase 3 SAP301 ambulatory surgery study, and has advanced ARX-04 into studies in emergency room patients (SAP302) and post-operative patients 40 years and older (SAP303). Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. In response to the New Drug Application (NDA) AcelRx submitted to the U.S. Food and Drug Administration (FDA) seeking approval for Zalviso, AcelRx received a Complete Response Letter (CRL) on July 25, 2014. The FDA has requested an additional clinical study (IAP312), which AcelRx is planning to initiate once production and testing of the supplies are complete, and clinical sites are ready, in order to support its NDA resubmission.

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 the process and timing of anticipated future development of AcelRx's product candidates, ARX-04 (sufentanil sublingual tablet, 30 mcg) and Zalviso™ (sufentanil sublingual tablet system), including the anticipated timing of the completion of the Phase 3 SAP302 and SAP303 studies for ARX-04; ability to fund ARX-04 development from the contract with the Department of Defense; anticipated submission of the New Drug Application, or NDA, for ARX-04; AcelRx's pathway forward towards gaining approval of Zalviso in the U.S.; the anticipated timing, design and results of the IAP312 clinical trial for Zalviso; anticipated resubmission of the Zalviso NDA to the U.S. Food and Drug Administration, or FDA, including the scope of the resubmission and the timing of the resubmission, and FDA review time; the status of the Collaboration and License Agreement with Grunenthal or any other future potential collaborations, including potential milestones and royalty payments under the Grunenthal agreement; and the therapeutic and commercial potential of AcelRx's product candidates, including ARX-04 and Zalviso. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx 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 AcelRx Pharmaceuticals' ability to complete Phase 3 clinical development of ARX-04 and support ARX-04 development under the contract with the Department of Defense; AcelRx's ability to successfully execute the pathway towards a resubmission of the Zalviso NDA to the FDA, including the initiation and completion of the IAP312 clinical study for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including ARX-04 in the United States and Europe, and Zalviso in the United States; AcelRx's ability to receive any milestones or royalty payments under the Grunenthal agreement and the timing thereof; ability to manufacture and supply sufficient quantities of Zalviso to Grunenthal on a timely basis; the uncertain clinical development process, including adverse events; the risk that planned clinical trials may not begin on time, have an effective clinical design, enroll a sufficient number of patients, or be initiated or completed on schedule, if at all; the success, cost and

timing of all development activities and clinical trials, including the Phase 3 ARX-04 SAP302 and SAP303 trials, and the additional clinical trial for Zalviso, IAP312; the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 SAP301 study of ARX-04; the market potential for AcelRx's product candidates; the accuracy of AcelRx's estimates regarding expenses, capital requirements and the need 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 Annual Report on Form 10-K filed with the SEC on March 7, 2016. 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 March 31	
	2016	**2015**
Statement of Comprehensive Loss Data		
Collaboration agreement revenue	$ 1,793	$ 181
Contract and other revenue	1,232	-
Total revenue	3,025	181
Operating costs and expenses:		
Cost of goods sold (1)	3,599	-
Research and development (1)	4,171	6,306
General and administrative (1)	3,777	4,521
Restructuring costs	-	754
Total operating expenses	11,547	11,581
Loss from operations	(8,522)	(11,400)
Other (expense) income:		
Interest expense	(680)	(806)
Interest income and other income(2)	419	2,180
Non-cash interest expense on liability related to sale of future royalties to PDL	(2,196)	-
Total other (expense) income	(2,457)	1,374
Provision for income taxes	(2)	-
Net loss	$ (10,981)	$ (10,026)
Basic net loss per common share	$ (0.24)	$ (0.23)
Shares used in computing basic net loss per common share	45,287	43,873
Diluted net loss per common share	$ (0.25)	$ (0.27)
Shares used in computing diluted net loss per common share	45,297	44,427

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

Cost of goods sold	$ 71	$ -
Research and development	600	702
General and administrative	514	836
Total	$ 1,185	$ 1,538

(2) Interest income and other income (expense) includes $0.3 million and $2.2 million in non-cash income for the three months ended March 31, 2016 and 2015, respectively, related to warrants issued in connection with a private placement equity financing, completed in June 2012.

	March 31, 2016	**December 31, 2015**
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 107,157	$ 113,464
Total assets	121,225	127,785
Total liabilities	97,782	94,672
Total stockholders' equity	23,443	33,113

Logo - http://photos.prnewswire.com/prnh/20130226/MM67303LOGO

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/acelrx-pharmaceuticals-provides-corporate-update-and-reports-first-quarter-2016-financial-results-300261078.html

SOURCE AcelRx Pharmaceuticals, Inc.

Timothy E. Morris, Chief Financial Officer, 650.216.3511, tmorris@acelrx.com; or Brian Korb, The Trout Group LLC, 646.378.2923, bkorb@troutgroup.com