AcelRx Pharmaceuticals Provides Corporate Update and Reports Third Quarter and Nine Months 2016 Financial Results

November 1, 2016

REDWOOD CITY, Calif., Nov. 1, 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 and nine months ended September 30, 2016.

Corporate Highlights

ARX-04 Clinical and Commercial Update:

During the third quarter of 2016, AcelRx presented the results of SAP302, the single-arm, open-label Phase 3 trial of ARX-04 (sufentanil sublingual tablet, 30 mcg) in patients who presented to the emergency room with moderate-to-severe acute pain associated with trauma or injury, at the Military Health System Research Symposium. Overall, the 76 adults treated with ARX-04 in this study experienced a 35% decrease, an overall reduction of 2.9 from a baseline of 8.1, in mean pain intensity at 60 minutes. Adverse events reported in the study were typical of opioid therapy, the most common of which were nausea, somnolence (sleepiness) and vomiting.

Results were also announced in the third quarter from SAP303, an open-label Phase 3 trial of ARX-04 in 140 adults who underwent short-stay, in-hospital surgeries associated with moderate-to-severe acute pain. Patients in this study were at least 40 years old and included patients with baseline renal and/or hepatic impairment. In SAP303, treatment with ARX-04 was associated with improvements in pain intensity as early as 30 minutes after the start of dosing and a 49% reduction in mean pain intensity during the first 2 hours. The most commonly reported adverse events were nausea and headache. Notably, there were no differences in adverse events between patients with normal and impaired liver or renal function.

Howie Rosen, chief executive officer, commented, "With clinical development of ARX-04 completed, we have been focused on completing the New Drug Application, which we expect to submit before the end of the year. In anticipation of achieving this very significant milestone, we are finalizing our commercial strategy, which currently has AcelRx launching ARX-04 into the emergency medicine market with our own sales force."

Zalviso® U.S. and European Update:

In September, AcelRx also announced the initiation of IAP312, a Phase 3 trial of Zalviso (sufentanil sublingual tablet system) in approximately 315 hospitalized, post-operative patients who will use the Zalviso system to self-administer sufentanil sublingual tablets as needed for 24 to 72 hours to manage their moderate-to-severe acute pain. This study was designed with input from the U.S. Food and Drug Administration, and, in addition to safety and efficacy measures, will collect information on device usability, including any incidence of Zalviso's failure to dispense medication as well as the incidence of misplaced or dropped tablets.

In Europe, AcelRx's licensee, Grunenthal Group, continues its launch of Zalviso in additional hospitals and countries. Full commercial launch has begun in Germany, France and the UK; and a pilot launch program has commenced in Belgium, Italy, the Netherlands and Ireland. To date Zalviso has been used in 83 hospitals, in seven countries.

Third Quarter 2016 Financial Results
Net loss for the third quarter of 2016 was $11.4 million, or $0.25 basic and diluted net loss per share, compared to net income of $5.1 million, or $0.11 basic and diluted net income per share for the third quarter of 2015. The net income in the third quarter of 2015 was primarily due to revenue recognized from the milestone payment received under the Grunenthal agreement related to the approval of the Marketing Authorization Application in the EU. Common shares used in calculating net (loss) income per share were 45.3 million for basic and diluted earnings per share (EPS) in the third quarter of 2016, compared to 44.4 million for basic EPS and 45.0 million for diluted EPS in the third quarter of 2015.

During the third quarter of 2016, AcelRx recognized revenue of $1.6 million under the collaboration agreement with Grunenthal and $1.8 million related to work performed under the Department of Defense (DoD) contract for ARX-04. This compares to $13.9 million in revenue recognized under the collaboration agreement with Grunenthal and $1.5 million in revenue recognized related to the DoD contract during the third quarter of 2015. AcelRx anticipates royalty revenue from Grunenthal will continue to be modest in 2016 and into 2017 as they continue their pilot programs and commercial expansion in various countries.

Operating costs and expenses during the third quarter of 2016 included cost of goods sold of $2.6 million. Research and development expenses for the third quarter of 2016 were $4.6 million, as compared to $5.4 million for the third quarter of 2015. The $0.8 million decrease in research and development expenses was primarily due to a reduction in overhead costs, predominantly as a result of the allocation of certain personnel and related expenses to cost of goods sold.

General and administrative expenses were $4.1 million during the third quarter of 2016, as compared to $2.9 million for the third quarter of 2015. The $1.2 million increase in general and administrative expenses during the three months ended September 30, 2016, as compared to the three months ended September 30, 2015, was primarily due to ARX-04-related market research activities in preparation for the anticipated commercial launch of ARX-04.

Total other expenses increased from $1.3 million in the third quarter of 2015 to $3.5 million in the third quarter of 2016, primarily as a result of non-cash interest expense on the royalty monetization.

The royalty monetization resulted in a taxable gain of more than $60.0 million in the third quarter of 2015, the majority of which was offset with net operating loss carryforwards; however, AcelRx was subject to U.S. federal alternative minimum taxes in 2015, as reflected in its provision for income taxes in the third quarter of 2015.

Year-to-Date Financial Results
For the nine months ended September 30, 2016, AcelRx reported a net loss of $33.5 million, or $0.74 basic and diluted net loss per share, as compared to a net loss of $13.9 million, or $0.31 basic net loss per share and $0.37 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 the nine months ended September 30, 2016, as compared to 44.2 million for basic EPS and 44.4 million for diluted EPS in the nine months ended September 30, 2015.

AcelRx recognized revenue of $4.7 million under the collaboration agreement with Grunenthal and $6.2 million related to work performed under the DoD contract for ARX-04 in the nine months ended September 30, 2016. This compares to $14.5 million in revenue recognized under the collaboration agreement with Grunenthal and $3.0 million in revenue related to the DoD contract recognized in the nine months ended September 30, 2015.

Operating costs and expenses during the nine months ended September 30, 2016 included cost of goods sold of $9.2 million. Research and development, and general and administrative expenses during the nine months ended September 30, 2016 were $15.1 million and $11.5 million, respectively. These compare to $19.0 million in research and development expenses and $10.2 million in general and administrative expenses in the first nine months of last year. The $3.9 million decrease in research and development expenses was primarily attributable to a reduction in overhead costs, predominantly as a result of allocation of certain research and development personnel and related expenses to cost of goods sold, while the increase in general and administrative expenses of $1.3 million was primarily due to ARX-04-related market research activities.

Total other expense was $8.7 million during the nine months ended September 30, 2016, as compared to $0.7 million during the nine months ended September 30, 2015. The difference was primarily a result of non-cash interest expense on the royalty monetization and the revaluation of the PIPE warrants issued in June 2012.

As of September 30, 2016, AcelRx had cash, cash equivalents and investments of $92.5 million, compared to $113.5 million at December 31, 2015. The decrease was primarily attributable to cash used in operating activities. AcelRx anticipates the cash balance will be approximately $75 million at the end of 2016.

On September 30, 2016, AcelRx amended the terms of the debt payable to Hercules Growth Technology. The amendment extends the interest only period by six months through April 1, 2017. Contingent upon FDA acceptance of the NDA for ARX-04 prior to April 1, 2017, Hercules has agreed to refinance the loan into a 36-month term note with an additional six month interest only period. In addition, subject to the achievement of certain milestones, AcelRx may be able extend the repayment period up to 48 months and extend the interest only period by up to a total of 18 months. Further, under certain conditions, AcelRx may be able to borrow an additional $10 million. In the short term, the additional interest only period will reduce cash used for financing activities over the next six months. In the long term, the potential to refinance the principal amount of $20.4 million and to obtain an additional $10 million will give AcelRx added flexibility to fund the anticipated launch of ARX-04.

Conference Call
AcelRx will conduct a conference call and webcast today, November 1, 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 moderate-to-severe 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 medically supervised settings; and Zalviso® (sufentanil sublingual tablet system), designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting. 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 as well as Norway, Iceland, and Liechtenstein and is investigational and in late-stage development in the U.S. Grunenthal Group holds the rights for Zalviso in Europe and Australia, while AcelRx retains all other world-wide rights.

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 ARX-04 clinical trial results; anticipated submission of the New Drug Application, or NDA, for ARX-04 to the U.S. Food and Drug Administration, or FDA; AcelRx's pathway forward towards gaining approval of Zalviso in the U.S.; anticipated resubmission of the Zalviso NDA to the FDA; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities for 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' ARX-04 development program, including anticipated submission of the ARX-04 NDA; the Zalviso development program, including completion of IAP312 and the resubmission of the Zalviso NDA; the uncertain clinical development process, including adverse events; the success, cost and timing of all development activities and clinical trials; the possibility that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 studies for ARX-04; 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; 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 Quarterly Report on Form 10-Q filed with the SEC on July 29, 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 September 30		Nine Months Ended September 30	
	2016	**2015**	**2016**	**2015**
Statement of Comprehensive Loss Data				
Collaboration agreement revenue	$ 1,562	$ 13,863	$ 4,669	$ 14,530
Contract and other revenue	1,804	1,565	6,253	3,003
Total revenue	3,366	15,428	10,922	17,533
Operating costs and expenses:				
Cost of goods sold [1]	2,579	-	9,154	-
Research and development [1]	4,617	5,393	15,068	19,009
General and administrative [1]	4,145	2,930	11,519	10,186
Restructuring costs	-	-	-	756
Total operating expenses	11,341	8,323	35,741	29,951
(Loss) income from operations	(7,975)	7,105	(24,819)	(12,418)
Other (expense) income:				
Interest expense	(702)	(713)	(2,069)	(2,296)
Interest income and other income[2]	(360)	(269)	300	1,915
Non-cash interest expense on liability related to sale of future royalties to PDL	(2,401)	(282)	(6,921)	(282)
Total other expense	(3,463)	(1,264)	(8,690)	(663)
Benefit (provision) for income taxes	36	(772)	34	(772)
Net (loss) income	$ (11,402)	$ 5,069	$(33,475)	$(13,853)
Basic net (loss) income per common share	$ (0.25)	$ 0.11	$ (0.74)	$ (0.31)
Shares used in computing basic net (loss) income per common share	45,319	44,407	45,306	44,210
Diluted net (loss) income per common share	$ (0.25)	$ 0.11	$ (0.74)	$ (0.37)
Shares used in computing diluted net (loss) income per common share	45,319	45,049	45,306	44,399

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

Cost of goods sold	$ 77	$ -	$ 225	$ -
Research and development	560	636	1,746	1,967
General and administrative	441	535	1,437	1,853
Total	$ 1,078	$ 1,171	$ 3,408	$ 3,820

(2) Interest income and other income (expense) includes $0.4 million in non-cash charges for the three months ended September 30, 2016 and $0.1 million in non-cash income for the nine months ended September 30, 2016, as compared to $0.3 million in non-cash income for the three months ended September 30, 2015 and $2.4 million in non-cash income for the nine months ended September 30, 2015, respectively, related to warrants issued in connection with a private placement equity financing, completed in June 2012.

	September 30, 2016	**December 31, 2015**
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 92,462	$ 113,464
Total assets	105,998	127,785
Total liabilities	102,726	94,672
Total stockholders' equity	3,272	33,113

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/acelrx-pharmaceuticals-provides-corporate-update-and-reports-third-quarter-and-nine-months-2016-financial-results-300355334.html

SOURCE AcelRx Pharmaceuticals, Inc.

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