AcelRx Pharmaceuticals Reports Second Quarter 2021 Financial Results

August 16, 2021

$55.3 million of cash and short-term investments as of June 30, 2021
Q2 2021 DSUVIA sales of $0.4M, a 117% increase compared to Q1 2021
516 formulary approvals as of July 31, 2021

HAYWARD, Calif., Aug. 16, 2021 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today reported its second quarter 2021 financial results.

"We continued to gain solid sales momentum with DSUVIA® as the recent real-world data became more widely disseminated to healthcare providers, and elective surgery restrictions at ambulatory surgery centers and hospitals eased during the second quarter," said Vince Angotti, Chief Executive Officer of AcelRx. "Our continued commitment to supporting investigator-initiated trials to generate additional DSUVIA real-world data should further add to healthcare provider awareness of the advantages of DSUVIA. Finally, business development remains a key priority and completing the DZUVEO® agreement with an exceptional partner in Europe and expanding our portfolio in the U.S. with two complementary innovative product candidates should drive incremental value to AcelRx."

Second Quarter and Recent Highlights

- In July 2021, AcelRx entered into agreements with Laboratoire Aguettant (Aguettant) providing Aguettant with a license to commercialize DZUVEO in Europe, allowing AcelRx to receive up to approximately $55 million in combined up-front and sales-based milestone payments, and providing AcelRx with two innovative pre-filled syringe product candidates for the U.S. The expected market opportunity for these two product candidates exceeds $100 million, and AcelRx currently plans to file New Drug Applications for them within 12 months.
- In June 2021, the U.S. Army Medical Materiel Development Activity (USAMMDA) publicly communicated their support of DSUVIA for battlefield pain management. USAMMDA stated concerns with the standard intramuscular morphine autoinjectors and emphasized that another commonly used battlefield analgesic, oral transmucosal fentanyl citrate, is licensed only for use in chronic pain syndromes found in cancer patients and it is specifically labeled not to be used for acute pain management.
- In June 2021, AcelRx announced it had reached agreement with the U.S. Food and Drug Administration (FDA) with regards to finalizing corrective actions the company had taken or plans to take in response to the previously announced FDA warning letter, dated February 11, 2021, regarding certain DSUVIA promotional materials.
- In June 2021, AcelRx announced important findings from a podium presentation on DSUVIA during the *Best Papers of the Regional Societies* session at the California Society of Plastic Surgeons 71st Annual Meeting. Following long-duration procedures, which often included multiple cosmetic procedures combined (averaging approximately 3 hours), 89% of the patients were opioid-free in the PACU, recovery time averaged 1 hour and the only adverse event was 1 patient that had nausea. *See Additional Study Information section below.*
- In May 2021, AcelRx announced an investigator-initiated study to be conducted at Tampa General Hospital to evaluate the use of DSUVIA for patients with sickle cell disease presenting to the emergency department with painful vaso-occlusive crisis.
- In May 2021, AcelRx announced a poster presentation at the 46th Annual American Society of Regional Anesthesia (ASRA) Meeting reviewing the results of a study on the intraoperative administration of DSUVIA for the management of acute pain in an ambulatory surgery center. Among other results, the study showed orthopedic surgery patients in the DSUVIA group required 50% less opioids in the PACU (p=0.018), with significantly more of them opioid-free (36% vs 8%; p=0.037) compared to the control group. Furthermore, DSUVIA-treated patients had improved overall benefit of analgesia scores (OBAS) compared to the control group (p=0.006). *See Additional Study Information section below.*
- In May 2021, the fully automated packaging equipment was installed at our contract manufacturer in the U.S. with final site acceptance testing in the process of being finalized and first commercial batches on target for Q3 2022, subject to regulatory approvals.
- In May 2021, AcelRx announced an investigator-initiated study to be conducted at The CORE Institute Specialty Hospital in Phoenix, Arizona by the Musculoskeletal Orthopedic Research and Education (MORE) Foundation evaluating the perioperative use of DSUVIA for patients undergoing hip or knee replacement as a same-day surgical procedure.
- In April 2021, AcelRx announced an investigator-initiated study at Montefiore Medical Center evaluating the perioperative use of DSUVIA for same-day surgical procedures in patients on buprenorphine therapy for opioid-use disorder or for

chronic pain management.
- Through July 31, 2021, AcelRx has achieved 516 formulary approvals, and is on track to exceed its guidance of 615 approvals by year end 2021.

Financial Information

- Cash, cash equivalents and short-term investments balance of $55.3 million as of June 30, 2021;
- Second quarter 2021 net revenues were $0.4 million and first half 2021 net revenues were $1.0 million;
- Combined R&D and SG&A expenses for the second quarter of 2021 totaled $9.4 million compared to $8.4 million for the second quarter of 2020. Excluding stock-based compensation expense, these amounts were $8.3 million for the second quarter of 2021 compared to $7.3 million for the second quarter of 2020. R&D and SG&A expenses for the first half of 2021 totaled $18.0 million compared to $23.1 million in the first half of 2020. Excluding stock-based compensation expense, these figures were $15.8 million for the first half of 2021 compared to $20.9 million for the first half of 2020. The decrease in combined R&D and SG&A expenses in the first half 2021 was primarily due to reductions in personnel-related costs, including travel expense, and DSUVIA-related commercialization expenses.
- For the second quarter of 2021, net loss was $9.9 million, or $0.08 per basic and diluted share, compared to $6.6 million, or $0.08 per basic and diluted share, for the second quarter of 2020. Net loss for the first half of 2021 was $18.8 million, or $0.16 basic and diluted net loss per share, compared to $22.5 million, or $0.28 basic and diluted net loss per share, for the prior year period.

Webcast and Conference Call Information
As previously announced, AcelRx will host a live webcast Monday, August 16, 2021 at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time) to discuss these financial results and provide other corporate updates. The webcast is accessible by visiting the Investors page of AcelRx's website at www.acelrx.com and clicking on the webcast link. The webcast will be accompanied by a slide presentation. 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. A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investor page of AcelRx's website at www.acelrx.com.

About DSUVIA (sufentanil sublingual tablet), 30 mcg
DSUVIA®, known as DZUVEO® in Europe, is indicated for use in adults in certified medically supervised healthcare settings, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic, and for which alternative treatments are inadequate. DSUVIA was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with intravenous (IV) administration. DSUVIA is a single-strength solid dosage form administered sublingually via a single-dose applicator (SDA) by healthcare professionals. Sufentanil is an opioid analgesic previously only marketed for IV and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile when delivered sublingually avoids the high peak plasma levels and short duration of action observed with IV administration. The European Commission approved DZUVEO for marketing in Europe and AcelRx has entered into a licensing agreement with Laboratoire Aguettant to commercialize DZUVEO in Europe.

This release is intended for investors only. For more information, including important safety information and black box warning for DSUVIA, please visit www.DSUVIA.com.

About AcelRx Pharmaceuticals, Inc.
AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. AcelRx's proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles. AcelRx has one approved product in the U.S., DSUVIA® (sufentanil sublingual tablet, 30 mcg), known as DZUVEO® in Europe, indicated for the management of acute pain severe enough to require an opioid analgesic for adult patients in certified medically supervised healthcare settings, and one product candidate, Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg), an investigational product in the U.S., is being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings. AcelRx has obtained the rights to file New Drug Applications (NDAs) and, subject to U.S. Food and Drug Administration (FDA) approval, commercialize in the U.S. two of Laboratoire Aguettant's innovative, EU-approved, pre-filled syringe products – ready-to-use ephedrine and phenylephrine. DZUVEO and Zalviso are both approved products in Europe.

For additional information about AcelRx, please visit www.acelrx.com.

Non-GAAP Financial Measures
To supplement AcelRx's financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), AcelRx uses certain non-GAAP financial measures in this press release, in particular, excluding stock-based compensation expense from its operating expenses. AcelRx believes that these non-GAAP financial measures provide useful supplementary information to, and facilitate additional analysis by, investors and analysts. In particular, AcelRx believes that these non-GAAP financial measures, when considered together with AcelRx's financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare AcelRx's results from period to period and to its forward-looking guidance. In addition, these types of non-GAAP financial measures are regularly used by investors and analysts to model and track AcelRx's financial performance. AcelRx's management also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate AcelRx's business and to make operating decisions. Non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read in conjunction with AcelRx's consolidated financial statements prepared in accordance with GAAP. The non-GAAP financial measures in this press release and the accompanying tables have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

Additional Study Information
Podium Presentation. The presentation was presented by Hisham Seify, MD, PhD, FACS and reported on data collected from a total of 76 patients

during both short and long-duration general anesthesia plastic surgery cases as well as "awake" cosmetic procedures. Procedures were performed utilizing a single DSUVIA tablet in combination with general anesthesia. Patients undergoing short (< 1 hour) procedures required no opioids in the postanesthesia care unit (PACU) and had an average recovery time of 33 minutes with no adverse events reported. Dr. Seify also presented his protocol for using DSUVIA during "awake" surgery cases and reported that to date they had seen no adverse events or vital sign instability in these patients. The data presented at the meeting are from an investigator-initiated trial supported by AcelRx. Dr. Seify is a paid consultant for AcelRx.

Poster Presentation. The primary objective of this study was to determine if DSUVIA given prior to emergence from anesthesia was efficacious in reducing initial post anesthesia care unit (PACU) pain scores compared to a control group which received no intervention. Secondary outcomes included opioid use and percentage of patients opioid free in PACU, and time until ready to discharge. The study was a prospective, randomized, controlled trial conducted at an ambulatory surgery center with patients aged 18-80 undergoing orthopedic surgery under general anesthesia. A total of 50 patients were included in the final analysis. There were no significant differences in baseline characteristics or duration of surgery between the two groups. The pain score on arrival to PACU was not significantly different between either group. However, patients in the DSUVIA group required 50% less opioids in the PACU (p=0.018), with significantly more of them opioid-free (36% vs 8%; p=0.037). Furthermore, DSUVIA-treated patients had improved overall benefit of analgesia scores (OBAS) compared to the control group (p=0.006). OBAS is a validated 7-item tool that assesses pain intensity, adverse effects and patients' satisfaction with analgesia. Limitations of the study include that the DSUVIA was not compared to an active comparator, in that it did not allow for preemptive opioid analgesia in the control group. Also, as the data collection ended at discharge, the authors were unable to assess any additional analgesic benefit of DSUVIA beyond the immediate postoperative period. One of the investigators of the study is a paid consultant for AcelRx but was not compensated for this study.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the effects of the COVID-19 pandemic and its anticipated impacts on AcelRx's business, the expected incremental value driven by business development efforts to AcelRx, the expected support for, and continuation of, investigator-initiated studies, the scope and benefits of investigator-initiated studies, the expected market opportunity for product candidates, plans to file NDAs and the timing of such filings, the expectation that the FDA will issue a close-out letter once corrective actions are satisfactorily completed by AcelRx, the availability of commercial batches from the fully automated packaging equipment and the timing thereof, and being on track to exceed its guidance of 615 approvals by year end 2021. These and any other forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "plans," "estimates," or the negative of these words or other comparable terminology. The discussion of financial trends, strategy, plans or intentions may also include forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied by such statements, including the uncertainties inherent in the initiation, execution and completion of investigator-initiated studies. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described in AcelRx's annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the Securities and Exchange Commission (SEC). You are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date such statements were first made. To the degree financial information is included in this press release, it is in summary form only and must be considered in the context of the full details provided in AcelRx's most recent annual, quarterly or current report as filed or furnished with the SEC. AcelRx's SEC reports are available at www.acelrx.com under the "Investors" tab. Except to the extent required by law, AcelRx undertakes no obligation to publicly release the result of any revisions to these forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

SELECTED FINANCIAL DATA
(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30				Six Months Ended June 30			
	2021	2020	$ Δ	% Δ	2021	2020	$ Δ	% Δ
Product sales	$ 392	$ 303	$ 89	29%	$ 843	$ 577	$ 266	
Contract and other collaboration	51	2,621	(2,570)	-98%	111	2,733	(2,622)	-96%
Total revenue	443	2,924	(2,481)	-85%	954	3,310	(2,356)	-71%
Operating costs and expenses:								
Cost of goods sold	1,040	1,370	330	24%	2,080	2,881	801	28%
Research and development	724	813	89	11%	1,693	2,225	532	24%
General and administrative	8,694	7,575	(1,119)	-15%	16,338	20,886	4,548	22%
Total operating costs and expenses	10,458	9,758	(700)	-7%	20,111	25,992	5,881	23%
Loss from operations	(10,015)	(6,834)	(3,181)	-47%	(19,157)	(22,682)	3,525	16%
Other income (expense):								
Interest expense	(614)	(872)	258	30%	(1,286)	(1,727)	441	26%
Interest income and other income (expense), net	(16)	270	(286)	-106%	60	205	(145)	-71%
Non-cash interest income on liability related to sale of future royalties	799	834	(35)	-4%	1,581	1,677	(96)	-6%
Total other income (expense)	169	232	(63)	-27%	355	155	200	129%
Provision for income taxes	(5)	(4)	(1)	25%	(5)	(4)	(1)	25%
Net loss	$ (9,851)	$ (6,606)	$ (3,245)	49%	$ (18,807)	$ (22,531)	$ 3,724	-17%
Basic and diluted net loss per common share	$ (0.08)	$ (0.08)			$ (0.16)	$ (0.28)		

Shares used in computing basic and diluted net loss per common share	119,120	80,662	116,204	80,360

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

Cost of goods sold	$ 21	$ 27	$ 43	$ 73
Research and development	200	184	381	384
Selling, general and administrative	951	879	1,837	1,779
Total	$ 1,172	$ 1,090	$ 2,261	$ 2,236

	June 30, 2021	December 31, 2020
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 55,325	$ 42,886
Total assets	79,586	66,295
Total liabilities	115,575	122,045
Total stockholders' deficit	(35,989)	(55,750)

Reconciliation of Non-GAAP Financial Measures
(Operating Expenses less associated stock-based compensation expense)

	Three Months Ended June 30		Six Months Ended June 30	
	2021	2020	2021	2020
Operating expenses (GAAP):				
Research and development	$ 724	$ 813	$ 1,693	$ 2,225
Selling, general and administrative	8,694	7,575	16,338	20,886
Total operating expenses	9,418	8,388	18,031	23,111
Less associated stock-based compensation expense	1,151	1,063	2,218	2,163
Operating expenses (non-GAAP)	$ 8,267	$ 7,325	$ 15,813	$ 20,948

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