AcelRx Pharmaceuticals to Acquire Lowell Therapeutics and Reports Third Quarter 2021 Financial Results

November 15, 2021

AcelRx to expand its pipeline with Niyad™, Lowell's investigational product that has received Breakthrough Designation status from the FDA

Lowell provides AcelRx diversification into new therapeutic areas within medically supervised settings

AcelRx had $48.7 million of cash and short-term investments as of September 30, 2021

DSUVIA® achieved 646 formulary approvals as of October 31, 2021, exceeding the year-end goal of 615 approvals

AcelRx reports $1.9M total revenues in Q3 2021

HAYWARD, Calif., Nov. 15, 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 announced the execution of a definitive merger agreement to acquire Lowell Therapeutics, Inc. (Lowell), a privately held company, and reported its third quarter 2021 financial results.

Lowell, Niyad and LTX-608 Overview

Lowell is a privately held company developing Niyad, a regional anticoagulant for the dialysis circuit during continuous renal replacement therapy for acute kidney injury patients in the hospital. Niyad is being studied under an investigational device exemption, or IDE, and has received Breakthrough Device Designation status from the FDA. While not approved for commercial use in the U.S., the active drug component of Niyad, nafamostat, has been approved in Japan and South Korea as a regional anticoagulant for the dialysis circuit, disseminated intravascular coagulation, and acute pancreatitis. Niyad is a lyophilized formulation of nafamostat, a broad-spectrum, synthetic serine protease inhibitor, with anticoagulant, anti-inflammatory, and potential anti-viral activities. The second intended indication for Niyad is as a regional anticoagulant for the dialysis circuit for chronic kidney disease patients undergoing intermittent hemodialysis in dialysis centers. LTX-608 is Lowell's proprietary nafamostat formulation for direct IV infusion being developed for the treatment of acute respiratory distress syndrome (ARDS) and disseminated intravascular coagulation (DIC).

The Transaction

The agreement to acquire Lowell in a transaction valued at approximately $32.5 million plus net cash acquired and certain other adjustments, includes approximately $26.0 million of contingent consideration payable in cash or stock at AcelRx's option, upon the achievement of regulatory and sales-based milestones. The merger consideration payable upon the closing is payable in shares of AcelRx common stock, or at the option of certain Lowell stockholders, in cash acquired from Lowell of up to $3.5 million to such stockholders. An amount of shares of AcelRx common stock valued at approximately $6.5 million is expected to be issued to Lowell securityholders at the closing. If those certain stockholders do not elect to receive cash, the amount of shares of common stock issued by AcelRx will be greater. The transaction was unanimously approved by the AcelRx and Lowell Boards of Directors and is expected to close in the fourth quarter of 2021, subject to certain closing conditions, including Lowell stockholder approval. Certain of Lowell's stockholders, representing a majority of the outstanding shares of capital stock of Lowell, have signed agreements to vote in favor of the transaction, subject to certain conditions.

"We continue to execute on our strategy to consolidate commercial-ready and late-stage development assets in medically supervised settings. To that end, we recently in-licensed two innovative pre-filled syringe products for FDA submission in 2022. The acquisition of Lowell will provide us with a late-stage asset that has received Breakthrough Device Designation status from the FDA and has the potential to fulfill an unmet need for regional anticoagulation of the dialysis circuit, an indication for which there are currently no FDA-approved products," said Vince Angotti, Chief Executive Officer of AcelRx. "This acquisition will further diversify AcelRx's portfolio as this broad-spectrum, synthetic serine protease inhibitor may have a number of other potential indications suited to medically supervised settings. This pipeline expansion momentum comes at a time when DSUVIA is gaining solid traction for use in the plastic surgery and cosmetic procedure specialties, with these specialties driving strong growth as evidenced by October being our highest commercial order month since launch. We expect these two specialties to be the foundation for further DSUVIA growth," continued Angotti.

Third 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 in 2022.
- In August 2021, Azza Halim, MD and Hisham Seify, MD, PhD, FACS presented data on the administration of sufentanil sublingual tablet 30 mcg (SST) and its effect on reducing post-operative recovery time and opioid use in the outpatient plastic surgery setting in patients undergoing "awake" procedures not under general anesthesia during the Miami Cosmetic Surgery (MCS) conference. The authors were presented with an MCS 2021 Maverick Program Award in which the

recipients' "progressive, innovative ideas have been recognized for the lasting impact they will have on medical aesthetics." Dr. Seify is a paid consultant for AcelRx but was not compensated for this study. Dr. Halim is not a paid consultant for AcelRx.
- Through October 31, 2021, AcelRx has achieved 646 formulary approvals, exceeding year-end guidance of 615 approvals.

Financial Information

- Cash, cash equivalents and short-term investments balance of $48.7 million as of September 30, 2021;
- Third quarter 2021 net revenues were $1.9 million, including $1.7 million related to the $2.9 million upfront payment received from Aguettant;
- Combined R&D and SG&A expenses for the third quarter of 2021 totaled $10.1 million compared to $8.6 million for the third quarter of 2020. Excluding non-cash depreciation and stock-based compensation expense, these amounts were $8.6 million for the third quarter of 2021 compared to $7.3 million for the third quarter of 2020. The increase in the third quarter of 2021 as compared to the third quarter of 2020 was mainly driven by higher SG&A costs supporting business development activities.
- For the third quarter of 2021, net loss was $8.4 million, or $0.07 per basic and diluted share, compared to $8.9 million, or $0.10 per basic and diluted share, for the third quarter of 2020.

Webcast and Conference Call Information
As previously announced, AcelRx will host a live webcast Monday, November 15, 2021 at 8:00 a.m. Eastern Time (5:00 a.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 non-cash depreciation and 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.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the expected benefits and timing of the proposed acquisition of Lowell, and the acquisition being consummated, expected areas of growth for DSUVIA, the expected market opportunity for

product candidates of each company, and plans to file NDAs and the timing of such filings. 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, which are predictions, projections and other statements about future events that are based on current expectations and assumptions. 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: (i) the risk that the proposed acquisition may not be completed in a timely manner or at all, which may adversely affect AcelRx's business and the price of AcelRx's common stock; (ii) the failure to satisfy the conditions to the consummation of the proposed acquisition, or any effects relating to the waiver of certain conditions; (iii) the occurrence of any event, change or other circumstance that could give rise to the termination of the definitive agreement to acquire Lowell or could change the expected benefits thereof; (iv) the effect of the announcement or pendency of the proposed acquisition on the companies' respective business relationships, operating results and business generally; (v) risks that the proposed acquisition disrupts the current plans and operations of the companies; (vi) risks relating to diverting AcelRx management's attention from ongoing business operations; (vii) the ability of AcelRx to implement its plans, forecasts and other expectations with respect Lowell's business following the completion of the proposed acquisition and realize additional opportunities for growth and innovation; (viii) the ability to achieve the expected benefits from the proposed acquisition; (ix) the impacts of any breaches of representations and warranties contained in the merger agreement and whether adequate remedies exist therefor, (x) the risk that Lowell changes its recommendation of the transaction or terminates the merger agreement in connection with an unsolicited superior offer, and (xi) unexpected variations in market growth and demand for AcelRx's and Lowell's products and technologies. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described under the caption "Risk Factors" and elsewhere 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) and any subsequent public filings. 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 new information, 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 September 30		Nine Months Ended September 30	
	2021	**2020**	**2021**	**2020**
Statement of Comprehensive Loss Data				
Revenue:				
Product sales	$ 160	$ 1,287	$ 1,003	$ 1,864
Contract and other collaboration	1,702	81	1,813	2,814
Total revenue	1,862	1,368	2,816	4,678
Operating costs and expenses:				
Cost of goods sold (1)	439	1,851	2,519	4,732
Research and development (1)	1,416	956	3,109	3,181
Selling, general and administrative (1)	8,640	7,598	24,978	28,484
Total operating costs and expenses	10,495	10,405	30,606	36,397
Loss from operations	(8,633)	(9,037)	(27,790)	(31,719)
Other income (expense):				
Interest expense	(538)	(824)	(1,824)	(2,551)
Interest income and other income (expense), net	32	106	92	311
Non-cash interest income on liability related to sale of future royalties	764	825	2,345	2,502
Total other income (expense)	258	107	613	262
Provision for income taxes	-	-	(5)	(4)
Net loss	$ (8,375)	$ (8,930)	$ (27,182)	$ (31,461)
Basic and diluted net loss per common share	$ (0.07)	$ (0.10)	$ (0.23)	$ (0.38)
Shares used in computing basic and diluted net loss per common share	119,224	87,913	117,222	82,896

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

Cost of goods sold	$ 73	$ 128	$ 220	$ 411
Research and development	389	188	769	572
Selling, general and administrative	1,048	1,062	3,288	3,191
Total	$ 1,510	$ 1,378	$ 4,277	$ 4,174

	September 30, 2021	December 31, 2020
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 48,699	$ 42,886
Total assets	72,263	66,295
Total liabilities	115,284	122,045
Total stockholders' deficit	(43,021)	(55,750)

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2021	2020	2021	2020
Operating expenses (GAAP):				
Research and development	$ 1,416	$ 956	$ 3,109	$ 3,181
Selling, general and administrative	8,640	7,598	24,978	28,484
Total operating expenses	10,056	8,554	28,087	31,665
Less depreciation and stock-based compensation expense	1,437	1,250	4,057	3,763
Operating expenses (non-GAAP)	$ 8,619	$ 7,304	$ 24,030	$ 27,902

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