



AcelRx Reports Third Quarter 2023 Financial Results and Provides Corporate Update

Nov 08, 2023

Niyad™ Investigational Device Exemption (IDE) approval by the FDA achieved in third quarter

Company plans to begin its Niyad registrational study this quarter with topline data expected mid-2024

Cash and investments of \$13.4 million as of September 30, 2023

Financing closed in July led by new healthcare investors providing up to \$26.3 million, of which \$10 million was made immediately available

Key Opinion Leader panel discussion on Niyad planned for December 6th

Webcast and conference call to be held today at 4:30 p.m. ET

SAN MATEO, Calif., Nov. 8, 2023 /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 third quarter 2023 financial results and provided a corporate update.

"We continue to advance our lead product candidate Niyad™, that has FDA Breakthrough Device designation, by prioritizing our resources to achieve regulatory and development milestones on this asset," said Vince Angotti, Chief Executive Officer of AcelRx. "Importantly, at the close of the third quarter, we received IDE approval from the FDA to proceed with the Niyad NEPHRO CRRT Study. NEPHRO stands for Nafamostat Efficacy in Phase 3 Registrational Continuous Renal Replacement Therapy Study. The NEPHRO study is set to start this quarter with top-line data expected by mid-2024 and submission of an application for Premarket Approval, or PMA, planned in the second half of next year. Niyad would be the first-ever U.S. approved regional anticoagulant for use in a dialysis circuit."

"In addition, we have a Key Opinion Leader panel discussion that we will host on December 6th featuring nephrology and critical care experts where we plan to discuss the results from our market research, as well as the NEPHRO Study," continued Angotti.

The NEPHRO Study, which recently received central Institutional Review Board (IRB) approval, is designed as a prospective, double-blinded trial to be conducted at up to 10 U.S. hospital intensive care units. The study will enroll and evaluate 166 adult patients undergoing renal replacement therapy, who cannot tolerate heparin or are at risk for bleeding. The primary endpoint of the study is mean post-filter activated clotting time using Niyad versus placebo over the first 24 hours. Key secondary endpoints include filter lifespan, number of filter changes over 72 hours, number of transfusions over 72 hours and dialysis efficacy (based on urea concentration) over the first 24 hours.

2023 Third Quarter and Recent Corporate Highlights

- In October, AcelRx announced the approval of an Investigational Device Exemption (IDE) submission to the United States Food and Drug Administration (FDA) allowing the Company to advance Niyad into a registrational study. This study will evaluate the safety and efficacy of Niyad to support a PMA application expected to be submitted to the FDA in the second half of 2024.
- In July, AcelRx announced a private placement of common stock, pre-funded warrants and common warrants for aggregate gross proceeds to the Company of \$10 million, before deducting the placement agent's fees and other offering expenses payable by the Company, with an additional potential \$16.3 million upon the exercise of common warrants, which include an acceleration feature should the Company achieve certain performance milestones. This financing provides up to \$26.3 million in gross proceeds upon the exercise of milestone-affected warrants. The private placement was priced "at-the-market" under the rules and regulations of The Nasdaq Stock Market LLC. The private placement was led by new investors including Nantahala Capital Management and closed on July 21, 2023.

Third Quarter 2023 Financial Information

- The cash and cash equivalents balance was \$13.4 million as of September 30, 2023. The senior debt with Oxford was fully repaid in the second quarter of 2023.
- Revenues of \$0.1 million for the third quarter primarily represent the royalty revenue earned on the sales of DSUVIA by Alora, principally driven by sales to the Department of Defense. Revenues in the prior period are included within the net loss from discontinued operations line item of the Statement of Operations.
- Combined R&D and SG&A expenses for the third quarter of 2023 totaled \$3.4 million compared to \$4.5 million for the third quarter of 2022. Excluding non-cash stock-based compensation expense, these amounts were \$3.0 million for the third quarter of 2023, compared to \$3.9 million for the third quarter of 2022. The decrease in combined R&D and SG&A expenses in the third quarter of 2023 was primarily due to a reduction in headcount partially offset by an increase in Niyad-related research and development costs.
- The divestment of DSUVIA represents a discontinued operation; accordingly, all historical operating results for the business are reflected within discontinued operations. For the three months ended September 30, 2023, the Company recognized net loss from continuing operations of \$1.4 million. For the three months ended September 30, 2022, the Company recognized a net loss from continuing operations of \$4.6 million.
- Net loss attributable to common shareholders for the third quarter of 2023 was \$1.4 million, or \$0.08 per basic and diluted share, compared to a net loss of \$6.9 million, or \$0.94 per basic and diluted share, for the third quarter of 2022.

Conference Call and Webcast Information

AcelRx will host a live webcast and conference call today, Wednesday, November 8, 2023 at 4:30 p.m. Eastern Standard Time/1:30 p.m. Pacific Standard Time to discuss the results and provide an update on the Company's business.

The webcast can be accessed [here](#) or by visiting the Investors section of the Company's website at www.aceRx.com and clicking on the webcast link within Investors/News & Events/Upcoming Events section. The webcast will include a slide presentation and a replay will be available on the AcelRx website for 90 days following the event.

Investors who wish to participate in the conference call may do so by dialing 1-866-361-2335 for domestic callers, 1-855-669-9657 for Canadian callers, or 1-412-902-4204 (toll applies) for international callers. The conference ID is 10182244.

About Nafamostat

Nafamostat is a broad spectrum, synthetic serine protease inhibitor with anticoagulant, anti-inflammatory and potential anti-viral activities. Niyad™ is a lyophilized formulation of nafamostat and is currently being studied under an investigational device exemption, or IDE, as an anticoagulant for the extracorporeal circuit, and has received Breakthrough Device Designation Status from the FDA. LTX-608 is a proprietary nafamostat formulation for direct IV infusion that will be investigated and developed as a potential anti-viral for the treatment of COVID, acute respiratory distress syndrome (ARDS), disseminated intravascular coagulation (DIC) and acute pancreatitis.

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 lead product candidate, Niyad™ is a lyophilized formulation of nafamostat and is currently being studied under an investigational device exemption, or IDE, as an anticoagulant for the extracorporeal circuit, and has received Breakthrough Device Designation Status from the FDA. AcelRx is also developing two pre-filled syringes in-licensed from its partner Aguetant: Fedsyra™, a pre-filled ephedrine syringe, and PFS-02, a pre-filled phenylephrine syringe. This release is intended for investors only. For additional information about AcelRx, please visit www.aceRx.com.

Forward-looking statements

This press release contains forward-looking statements based upon AcelRx's current expectations. 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 "potential," "believe," "expect," "expects," "expected," "anticipate," "may," "will," "enable," "should," "seek," "approximately," "intends," "intended," "plans," "planned," "planning," "estimates," "benefits," 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) risks relating to AcelRx's product development activities and ongoing commercial business operations; (ii) risks related to the ability of AcelRx and its business partners to implement development plans, launch plans, forecasts and other business expectations; (iii) risks related to unexpected variations in market growth and demand for AcelRx's commercial and developmental products and technologies; (iv) risks related to AcelRx's liquidity and our ability to maintain capital resources sufficient to conduct the clinical studies required for our developmental products; (v) risks related to AcelRx's ability to retain its listing on the Nasdaq exchange; (vi) risks related to the ability of AcelRx to successfully design and conduct safe, effective and timely clinical studies for our developmental products; and (vii) risks relating to AcelRx's ability to fund, seek and obtain regulatory approvals for our developmental product candidates. 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.aceRx.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	
	2023	2022
Statement of Comprehensive Income (Loss) Data		
Royalty revenue	\$ 117	\$ -
Operating costs and expenses:		
Research and development ⁽¹⁾	1,178	799
Selling, general and administrative ⁽¹⁾	2,248	3,724
Impairment of property and equipment	-	-
Total operating costs and expenses	3,426	4,523
Loss from operations	(3,309)	(4,523)
Other income (expense):		
Interest expense	-	(245)
Interest income and other income (expense), net	1,893	140
Non-cash interest income on liability related to sale of future royalties	-	-
Gain on extinguishment of liability related to sale of future royalties	-	-
Total other income (expense)	1,893	(105)

Net income (loss) before income taxes	(1,416)	(4,628)
Provision for income taxes	(2)	(11)
Net income (loss) from continuing operations	(1,418)	(4,639)
Net income (loss) from discontinued operations	61	(2,111)
Net income (loss)	(1,357)	(6,750)
Deemed dividends related to Series A Redeemable Convertible Preferred Stock	-	(186)
Income allocated to participating securities	-	-
Net income (loss) attributable to Common Shareholders, basic	\$ (1,357)	\$ (6,936)
Net income (loss) attributable to Common Shareholders, diluted	\$ (1,357)	\$ (6,936)

Net income (loss) per share attributable to stockholders:

Basic earnings (loss) per share

Income (loss) from continuing operations	\$ (0.08)	\$ (0.65)
Income (loss) from discontinued operations	\$ 0.00	\$ (0.29)
Net income (loss)	\$ (0.08)	\$ (0.94)

Diluted earnings (loss) per share

Income (loss) from continuing operations	\$ (0.08)	\$ (0.65)
Income (loss) from discontinued operations	\$ 0.00	\$ (0.29)
Net income (loss)	\$ (0.08)	\$ (0.94)

Shares used in computing net income (loss) per share of common stock, basic 16,758 7,377

Shares used in computing net income (loss) per share of common stock, diluted 16,758 7,377

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

Research and development	\$ 210	\$ 139
Selling, general and administrative	168	519
Discontinued operations	-	43
Total	\$ 378	\$ 701

Selected Balance Sheet Data
(in thousands)

	<u>September 30, 2023</u>	<u>December 31, 2022⁽¹⁾</u>
	(Unaudited)	
Cash, cash equivalents, restricted cash and investments	\$ 13,389	\$ 20,770
Total assets	23,261	47,487
Total liabilities	4,954	25,673
Total stockholders' equity	18,307	21,814

(1) Derived from the audited financial statements as of that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

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

	Three Months Ended	
	September 30	
	<u>2023</u>	<u>2022</u>
Operating expenses (GAAP):		
Research and development	\$ 1,178	\$ 799
General and administrative	2,248	3,724
Total operating expenses	3,426	4,523
Less stock-based compensation expense	378	658
Operating expenses (non-GAAP)	\$ 3,048	\$ 3,865



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SOURCE AcelRx Pharmaceuticals, Inc.

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