ACELYRIN

ACELYRIN, INC. Reports Third Quarter 2023 Financial Results and Recent Highlights

November 7, 2023

Portfolio of programs continues to advance with data from both the global Phase 2b/3 trial for izokibep in PsA and proof-of-concept for lonigutamab as a subcutaneous treatment for thyroid eye disease expected in first quarter 2024

Additional PsA Phase 2 long-term data on clinical measures of disease resolution and quality of life to be presented at 2023 Annual Meeting of the American College of Rheumatology

Cash, cash equivalents and short-term marketable securities totaled $788.4 million on September 30, 2023, providing runway through multiple key milestones across all three clinical programs

Company to host conference call and webcast at 4:30 p.m. ET today

LOS ANGELES, Nov. 07, 2023 (GLOBE NEWSWIRE) -- ACELYRIN, INC. (Nasdaq: SLRN), a late-stage clinical biopharma company focused on accelerating the development and delivery of transformative medicines in immunology, today reported financial results for the third quarter ended September 30, 2023 and highlighted additional corporate updates and milestones.

"We remain focused on building a leading I&I company and continuing to advance programs across multiple autoimmune and inflammatory diseases with the goal to deliver transformative medicines for patients," said Shao-Lee Lin, MD, PhD, founder and CEO of ACELYRIN. "We look forward to our Phase 2b/3 results in psoriatic arthritis for izokibep and proof of concept in thyroid eye disease for lonigutamab as our next important clinical milestones, expected by the end of the first quarter 2024. Both programs are examples of the 'diamonds in the rough' we seek to build our portfolio – programs where, based on molecule characteristics, our collective experience and expertise, and the evolving scientific and medical understanding, we can establish a development plan that tests our hypotheses around clinically meaningful differentiation for patients, with emphasis on determining potential for disease resolution."

Recent Highlights and Upcoming Milestones

Our lead program, izokibep, is a small protein therapeutic designed to inhibit IL-17A with high potency and small molecular size, approximately 1/10th the size of a monoclonal antibody. Previously presented clinical trial data supports the hypothesis that these unique characteristics of izokibep may provide clinically meaningful and differentiated benefits for patients, including resolution of key manifestations of disease leading to improved quality of life.

We previously shared results from a Phase 2, placebo-controlled trial of izokibep in PsA, which demonstrated differentiated, dose-ordered responses as early as one month into treatment and increasing over time, including an ACR50 response of 50% at Week 12 or 44% placebo-adjusted for the 80mg Q2W dose.

Long-term 46-week results from the same trial showed continued improvement and deepening of responses including >75% achievement of ACR50, >50% achievement of ACR70, >70% achievement of PASI100, >80% resolution of enthesitis as measured by the Leeds Enthesitis Index (LEI), and >50% achievement of Minimal Disease Activity (MDA), an important composite measure of overall disease impact. These clinical responses further increased Quality of Life (QoL) for patients, with the majority of patients showing important improvements in disease burden as measured by the PsAID, a validated psoriatic arthritis-specific patient reported outcome measure.

Drs. Peter Taylor and Philip Mease will present these and additional data on clinical measures of disease resolution and QoL in a poster and oral podium presentation, respectively, at the 2023 Annual Meeting of the American College of Rheumatology on Monday, November 13, 2023 at 4:15pm PT.

Internal modeling from the Phase 2 PsA data predicted the potential to increase response over time, as has been demonstrated with the 46-week data. The modeling further predicts the potential for increased response with higher doses over the 80mg Q2W utilized in the Phase 2 trial. To that end, the ongoing Phase 2b/3 trial in PsA is evaluating both 160mg QW and Q2W to continue to maximize potential responses for patients.

This trial completed enrollment in the second quarter of 2023. Top-line data is expected in the first quarter of 2024.

We believe in izokibep's potential in hidradenitis suppurativa, with ~25% of patients achieving HiSCR100 responses within 12 weeks, which means they rapidly achieved resolution of all abscesses and nodules without new draining tunnels. As we previously shared, discussions with the FDA will help inform next steps to advance our registrational program. We expect to have an update by the end of this year or early next year.

Recent safety updates across the landscape for molecules that target IL-17 more broadly than IL-17A continue to indicate increased infection risk, accentuate elevated suicidal ideation risk, and note the potential need for routine liver monitoring. We continue to be pleased with the safety profile of izokibep, which is consistent with the long established well-tolerated safety profile of the class of medicines that selectively target IL-17A.

In Thyroid Eye Disease (TED), we are conducting an ongoing Phase 1/2 trial of lonigutamab delivered subcutaneously in TED patients. We anticipate initial proof of concept data including proptosis response and clinical activity score by the end of first quarter 2024.

Leadership Updates

We continue to scale our capabilities and capacity to support the breadth of our clinical portfolio with multiple late-stage development programs.

Shephard (Shep) Mpofu, MD, MRCP, FRCP joined as Senior Vice President of Development with responsibility for Clinical Development and Translational Sciences. Dr. Mpofu most recently served as Chief Medical Officer of Novartis' Gene Therapy franchise and was previously the Global Lead for secukinumab, which he advanced from early development through to approvals across multiple indications including Psoriasis, Psoriatic Arthritis, Axial Spondyloarthritis and Hidradenitis Suppurativa.

Patricia Turney is joining as Chief Technical Operations Officer overseeing technical operations, CMC regulatory, corporate quality and facilities. Ms. Turney brings to ACELYRIN extensive expertise in process development, manufacturing, supply chain, and GxP operations. She most recently served as Senior Vice President, Operations at Arcutis Biotherapeutics, Inc. and prior to that held roles of increasing responsibility within Amgen.

Both Dr. Mpofu and Ms. Turney report directly to Dr. Lin and are members of the Company's Senior Leadership Team.

Upcoming Investor Conferences
Management will participate in a moderated fireside discussion at the following upcoming healthcare investment conferences:

- Jefferies London Healthcare Conference: November 16, 2023 from 9:00-9:25am GMT
- Piper Sandler Healthcare Conference: November 28, 2023 from 4:30-4:55pm ET
- Evercore ISI HealthCONx Conference: November 30, 2023 from 9:35-9:55am ET

Live webcasts of the fireside chats will be available via the "Events" section of the Company's website at www.acelyrin.com. A replay of the webcasts will be archived on the website for 30 days.

Third Quarter 2023 Financial Highlights

Cash Position: Cash, cash equivalents and short-term marketable securities totaled $788.4 million at September 30, 2023. The Company expects these to fund operations through key value-driving milestones across all three clinical programs.

R&D Expenses: Research and development expenses were $74.6 million for the third quarter as compared to $12.5 million for the same period in 2022. Comparing 2023 to 2022, the Company has undergone significant growth including expansion of the izokibep program across indications, and the addition of two programs in 2023, both of which are now advancing in clinical-stage development.

G&A Expenses: General and administrative expenses were $19.9 million for the third quarter as compared to $2.9 million for the same period in 2022. For the quarter ended September 30, 2023, these expenses include a stock-based compensation expense of $11.7 million. These increases in expenses were primarily a result of expanding our organizational capability to support the development of our broad portfolio of immunology product candidates.

Net Loss: Net loss totaled $83.9 million for the third quarter of 2023, or $0.87 per share, compared to $14.4 million or $8.17 per share for the third quarter of 2022. The total net loss for the current quarter includes stock-based compensation expense of $15.3 million.

Conference Call Information
ACELYRIN will host a conference call and webcast today, November 7, 2023, at 4:30 p.m. ET to review its third quarter 2023 financial results. A live webcast of the conference call can be accessed in the "Investors & Media" section of ACELYRIN's website at www.acelyrin.com. A recording of the webcast will be available and archived on the Company's website for 30 days.

About ACELYRIN, INC.
ACELYRIN, INC. (Nasdaq: SLRN) is a Los Angeles area-based late-stage clinical biopharma company – with additional operations in the San Francisco Bay area – focused on providing patients life-changing new treatment options by identifying, acquiring, and accelerating the development and commercialization of transformative medicines.

For more information about ACELYRIN, visit us at www.acelyrin.com or follow us on LinkedIn and X.

About Izokibep
Izokibep is a small protein therapeutic designed to inhibit IL-17A with high potency through tight binding affinity, the potential for robust tissue penetration due to its small molecular size, about one-tenth the size of a monoclonal antibody, and an albumin binding domain that extends half-life. Clinical trial data supports the hypothesis that these unique characteristics of izokibep may provide clinically meaningful and differentiated benefits for patients, including resolution of key manifestations of disease. Izokibep is being evaluated in multiple late-stage trials in moderate-to-severe hidradenitis suppurativa (HS), psoriatic arthritis (PsA), and uveitis, with plans to initiate an additional Phase 3 program in axial spondyloarthritis (AxSpA).

Forward Looking Statements
This press release contains forward-looking statements including, but not limited to, statements related to ACELYRIN's expectations regarding its cash runway and ability to fund several key milestones across multiple indications; the advancement of ACELYRIN's programs and ability to accelerate the development and delivery of transformative medicines; anticipated development activities including the planned initiation of a clinical program in AxSpA and the timing of clinical data; the therapeutic potential of ACELYRIN's product candidates including its ability to offer clinically meaningful, differentiated benefits for patients that may include resolution of key manifestations of disease and limit safety liability; market size and growth expectations; management participation in investor conferences; and other statements that are not historical fact. These forward-looking statements are based on ACELYRIN's current plans, objectives and projections, and are inherently subject to risks and uncertainties that may cause ACELYRIN's actual results to materially differ from those anticipated in such forward-looking statements. Such risks and uncertainties include, without limitation, those associated with the successful completion of development and regulatory activities with respect to ACELYRIN's product candidates; maintaining and defending intellectual property protection; delays or failures to secure adequate supply of its product candidates; ACELYRIN's failure to realize the expected benefits of its acquisition of additional programs; legal proceedings, government investigations or other actions; macroeconomic conditions; market volatility; and other risks and uncertainties affecting ACELYRIN including those described from time to time under the caption "Risk Factors" and elsewhere in ACELYRIN's current and future reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2023. Forward-looking statements contained in this press release are made as of this date, and ACELYRIN undertakes no duty to update such information except as required under applicable law.

ACELYRIN, Inc.
Preliminary Condensed Consolidated Statement of Operations and Comprehensive Loss

(in thousands)

	Three months ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 74,562	$ 12,509	$ 272,512	$ 38,222
General and administrative	19,861	2,887	44,440	8,145
Total operating expenses	94,423	15,396	316,952	46,367
Loss from operations	(94,423)	(15,396)	(316,952)	(46,367)
Change in fair value of derivative liability	-	-	10,291	-
Interest income	10,502	986	20,486	1,399
Other expense, net	(19)	4	(254)	3
Net loss	(83,940)	(14,406)	(286,429)	(44,965)
Other comprehensive gain/(loss)				
Unrealized gain/(loss) on short-term marketable securities, net	(94)	(62)	36	(200)
Total other comprehensive gain/(loss)	(94)	(62)	36	(200)
Net loss and other comprehensive loss	$ (84,034)	$ (14,468)	$ (286,393)	$ (45,165)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.87)	$ (8.17)	$ (4.68)	$ (31.66)
Weighted-average common shares outstanding, basic and diluted	96,872,747	1,764,293	61,138,105	1,420,199

ACELYRIN, INC.
Preliminary Selected Consolidated Balance Sheet Data
(unaudited)
(in thousands)

	September 30,	December 31,
	2023	2022
Cash and cash equivalents	$ 381,738	$ 267,110
Short-term marketable securities	406,693	47,510
Total assets	800,489	319,923
Total liabilities	68,113	26,192
Accumulated deficit	(393,507)	(107,078)

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