ACELYRIN, INC. Reports Full Year 2023 Financial Results and Recent Highlights

March 28, 2024

Reported positive Phase 1/2 proof-of-concept data for lonigutamab, first subcutaneous anti-IGF-1R to demonstrate clinical responses in thyroid eye disease patients

Achieved primary endpoint with high statistical significance in global Phase 2b/3 clinical trial of izokibep in psoriatic arthritis with robust clinical responses also achieved for higher hurdle endpoints

Announced differentiated long-term 32-week data from global Phase 2b clinical trial of izokibep in hidradenitis suppurativa – ongoing Phase 3 trial is enrolling faster than previously expected and topline data now expected in second half of 2024

Cash, cash equivalents and short-term marketable securities of $721.3 million provides runway to support key late-stage data milestones including registrational studies for multiple indications

LOS ANGELES, March 28, 2024 (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 full year ended December 31, 2023 and highlighted recent corporate updates and upcoming milestones.

“Our goal for ACELYRIN remains steadfast: to advance our programs across multiple autoimmune and inflammatory diseases with the goal of delivering transformative medicines for patients,” said Shao-Lee Lin, MD, PhD, Founder and CEO of ACELYRIN. “As we approach the one-year anniversary of our initial public offering last May, we are particularly excited to have announced recently positive and robust data for izokibep and lonigutamab. These data underscore our novel approach to immunology and inflammation drug development and validate the potential of our differentiated product candidates in diseases of unmet need. We look forward to a number of anticipated milestones across multiple indications throughout the balance of the year.”

Full Year 2023 Financial Highlights

Cash Position: Cash, cash equivalents and short-term marketable securities totaled $721.3 million at December 31, 2023. The Company expects these to fund operations into 2026, through key data milestones for late stage registrational studies and Biologic License Application submission-enabling manufacturing activities.

R&D Expenses: Research and development expenses were $355.9 million for the full year ended December 31, 2023, as compared to $55.6 million for 2022. These increases were primarily a result of expansion of the izokibep program across indications and a one-time $123.1 million in-process research and development (IPR&D) expense, plus an additional $10.0 million license payment, both related to the acquisition of ValenzaBio.

G&A Expenses: General and administrative expenses were $66.2 million for the full year ended December 31, 2023, as compared to $13.5 million for 2022. 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 for the full year ended December 31, 2023 was $381.6 million, compared to $64.8 million for 2022.

Upcoming Milestones and Recent Pipeline Highlights
ACELYRIN recently reported positive data for its late-stage programs. Both the izokibep and lonigutamab programs are at the forefront in development progress as the next generation approaches to validated mechanisms in psoriatic arthritis (PsA), hidradenitis suppurativa (HS) and thyroid eye disease (TED).

Upcoming Milestones

- Thyroid Eye Disease: On the strength of the Phase 1/2 proof-of-concept, a Phase 2b/3 trial, designed to be the first of two registrational trials in TED, is planned to be initiated in the second half of 2024.
- Psoriatic Arthritis: The Phase 2b/3 clinical trial is expected to serve as the first of two registrational trials in PsA and 160 mg every two weeks (Q2W) appears to be the optimal dose. A confirmatory Phase 3 trial is targeted to be initiated by year-end 2024.
- Hidradenitis Suppurativa: The ongoing Phase 3 trial in HS is enrolling faster than previously expected, and topline data are now expected in the second half of 2024. A confirmatory Phase 3 trial for registration is targeted to be initiated by year-end 2024.
- Noninfectious Uveitis: The ongoing Phase 2b/3 trial is evaluating approximately 100 participants and is expected to continue out to 48 weeks with topline data anticipated in the second half of 2024.

Recent Pipeline Highlights

Lonigutamab
Thyroid Eye Disease

- ACELYRIN recently announced positive proof of concept for lonigutamab, the first reported subcutaneous anti-IGF-1R to demonstrate clinical responses in thyroid eye disease.

- In the Phase 1/2 trial, lonigutamab demonstrated rapid improvements in proptosis and clinical activity score (CAS) at the first measurement – within three weeks after the first subcutaneous dose.
- These results, along with clinically meaningful improvements in diplopia as well as mean changes in proptosis from baseline, were at least comparable to the IV approaches.

Izokibep
Psoriatic Arthritis

- Reported positive topline data from the Phase 2b/3 clinical trial evaluating izokibep in PsA. The global trial met the primary endpoint of ACR50 at 16 weeks with high statistical significance and showed significant, multi-domain responses for the high hurdles of ACR70, PASI100, as well as composite endpoints ACR50/PASI100 and Minimal Disease Activity.
- The improvements in magnitude of responses relative to the earlier Phase 2 study were notable given the higher burden of disease of the patients in the Phase 2b/3 trial. Further, the results demonstrated higher clinical responses than those reported by the approved IL-17A agents, and responses comparable to those reported by the IL-17A&F agents without evidence of the associated safety liabilities.

Hidradenitis Suppurativa

- Reported differentiating long-term data for izokibep in a global Phase 2b clinical trial in HS with results demonstrating rapid, dose ordered improvement across multiple disease manifestations through week 32, with HiSCR100 consistently achieved in approximately 1/3 of patients on the 160 mg every week (QW) dose including in those patients who switched from placebo to izokibep at week 16.
- The results showed consistent improvement in resolution of abscesses, nodules, and draining tunnels with marked reduction in skin pain and clinically meaningful improvements in overall quality of life.
- Moreover, HiSCR100 was achieved earlier than reported by other IL-17A agents and the IL-17A&F agents without evidence to date for increased risk of infection, especially fungal, or suicidal ideation and behavior, in a patient population predisposed to infection and clinical depression.

Noninfectious Uveitis

- Izokibep is also being evaluated in a Phase 2b/3 clinical trial as a treatment for noninfectious uveitis, an autoimmune inflammation of the lining of the back of the eye, which affects the cells required for vision.

Leadership Updates
The Company recently appointed Agnes Lee as Senior Vice President, Investor Relations and Corporate Communications and a member of the company's Senior Leadership Team. Ms. Lee most recently served as Senior Vice President of Investor Relations and Strategic Planning at Inogen, Inc.

In December 2023, the Company announced the appointment of Lynn Tetrault to its Board of Directors. Ms. Tetrault is the founder of Anahata Leadership and currently chairs the Board of Directors for NeoGenomics, Inc.

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. The late-stage izokibep PsA and HS data have demonstrated levels of clinical response comparable with next generation approaches to IL-17 inhibition. These data also demonstrate that targeting IL-17A alone with greater potency can achieve the same or better clinical responses than agents targeting IL-17 subunits more broadly than IL-17A, without their associated safety liabilities. Izokibep is currently being evaluated in multiple late-stage trials in moderate-to-severe hidradenitis suppurativa (HS), moderate-to-severe psoriatic arthritis (PsA), and noninfectious uveitis.

About Lonigutamab
Lonigutamab is a humanized IgG1 monoclonal antibody targeting the IGF-1 receptor and is delivered subcutaneously. Relative to standard of care, lonigutamab binds to a distinct epitope, which results in internalization of the receptor within minutes, and in preclinical binding and functional laboratory assays, it has been shown to be 75-fold more potent. The characteristics of lonigutamab that enable subcutaneous delivery also enable the potential for longer-term dosing, which can potentially improve depth and durability of clinical response, while attempting to limit safety liabilities by avoiding the high maximal concentrations resulting from IV administration, while maintaining optimal therapeutic levels.

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. ACELYRIN has two programs in late-stage clinical development. Izokibep is a next generation inhibitor of IL-17A in Phase 3 development for the treatment of psoriatic arthritis, hidradenitis suppurativa and uveitis. Lonigutamab is a subcutaneously delivered monoclonal antibody targeting IGF-1R being investigated for the treatment of TED.

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

Forward Looking Statements
This press release contains forward-looking statements including, but not limited to, statements related to the overall advancement of ACELYRIN's

programs and ability to accelerate the development and delivery of transformative medicines; the therapeutic potential of ACELYRIN's product candidates, including their ability to offer clinically meaningful, differentiated benefits that may improve over time, move patients towards disease resolution and limit safety liability versus other treatment options; anticipated development activities including the planned initiation of a Phase 2b/3 trial in thyroid eye disease and the ability for such trial to serve as the first of two registrational studies in TED, the expectation that the Phase 2b/3 trial in PsA will serve as the first of two registrational trials in PsA which is subject to remediation and regulatory agency review amongst other factors, targeted commencement of a second Phase 3 trial in HS, the anticipated availability of clinical data for uveitis; 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, the risk that future results could differ materially and adversely from early clinical data 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. 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.
Consolidated Statement of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year ended December 31,		
	2023	**2022**	**2021**
Operating expenses			
Research and development	$ 355,886	$ 55,632	$ 38,230
General and administrative	66,178	13,547	3,564
Total operating expenses	422,064	69,179	41,794
Loss from operations	(422,064)	(69,179)	(41,794)
Change in fair value of derivative tranche liability	10,291	487	-
Interest income	30,555	4,052	-
Other expense, net	(423)	(132)	(45)
Net loss	$ (381,641)	$ (64,772)	$ (41,839)
Other comprehensive loss			
Unrealized gain (loss) on short-term marketable securities, net	248	(86)	-
Total other comprehensive gain (loss)	$ 248	$ (86)	$ -
Net loss and other comprehensive loss	$ (381,393)	$ (64,858)	$ (41,839)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.43)	$ (41.59)	$ (60.87)
Weighted-average common shares outstanding, basic and diluted	70,249,580	1,557,534	687,398

ACELYRIN, INC.
Selected Consolidated Balance Sheet Data

(in thousands)

	December 31, 2023	**December 31, 2022**
Cash and cash equivalents	$ 218,097	$ 267,110
Short-term marketable securities	503,229	47,510
Total assets	742,690	319,923
Total liabilities	86,353	26,192
Accumulated deficit	(488,719)	(107,078)

ACELYRIN Contacts:
investors@acelyrin.com
media@acelyrin.com