ACELYRIN, INC. Reports Third Quarter 2024 Financial Results and Recent Highlights

November 13, 2024

Topline data from Phase 2b/3 trial of izokibep as a treatment for non-infectious non-anterior uveitis expected in December 2024

Positive lonigutamab EOP2 FDA interaction completed and initiation of subcutaneous Phase 3 development program in thyroid eye disease (TED) expected in Q1 2025

Cash, cash equivalents, and short-term marketable securities at September 30, 2024 of $562.4 million projected to provide cash runway to mid-2027

Company to hold webcast and conference call at 4:30pm ET today

LOS ANGELES, Nov. 13, 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 third quarter ended September 30, 2024 and highlighted other corporate updates and milestones.

"We are executing on our refocused pipeline strategy and are excited by the near-term catalysts ahead for ACELYRIN, particularly as we advance subcutaneous lonigutamab into Phase 3 development as the next generation IGF-1R inhibitor for thyroid eye disease. We recently concluded a positive end of phase 2 interaction with the FDA, established a world-class scientific and patient advisory board, and remain on track to initiate our Phase 3 development program in TED next quarter," said Mina Kim, Chief Executive Officer of ACELYRIN. "We are also looking forward to announcing topline results from our Phase 2b/3 trial of izokibep in uveitis in December 2024 and hosting a lonigutamab investor event in early 2025."

Recent Pipeline Updates and Upcoming Milestones

Lonigutamab

Lonigutamab is a subcutaneously (SC) delivered humanized IgG1 monoclonal antibody targeting the insulin-like growth factor-1 receptor (IGF-1R), a validated mechanism of action (MoA) for the treatment for thyroid eye disease (TED).

- ACELYRIN recently completed a positive end of Phase 2 (EOP2) interaction with the U.S. Food and Drug Administration (FDA), achieving alignment on important elements of the Phase 3 registrational program design including size, primary and secondary endpoints, and proposed dose selection. The Company will host a webcast event in early 2025 to review the Phase 2 data, FDA feedback and Phase 3 program design.
- Earlier this year, ACELYRIN reported the first positive proof of concept data for an anti-IGF-1R in TED patients, which showed that lonigutamab was well-tolerated and demonstrated rapid improvements in proptosis and clinical activity score (CAS) – within three weeks after the first dose. Additional data from the ongoing Phase 2 trial has been recently presented by leading clinicians at international medical congresses including those of the American Society of Ophthalmic Plastic and Reconstructive Surgery, the European Society of Ophthalmic Plastic and Reconstructive Surgery, and the American Academy of Ophthalmology. These presentations can be found on the "Presentations and Publications" section of ACELYRIN's website at www.acelyrin.com.
- The Phase 2 dose exploration trial is continuing with additional cohorts to establish both a minimum effective and optimal dose level and dose regimen for the Phase 3 registrational program. Cohort 3 testing 50mg of lonigutamab administered every four weeks has been completed and Cohort 4 testing 70-100mg of lonigutamab administered every four weeks is ongoing.
- Finally, ACELYRIN established a scientific and patient advisory board convening world class clinicians and advocates to provide important strategic input, clinical expertise and patient perspectives as the Company prepares to advance lonigutamab into Phase 3 clinical development for TED.

Izokibep

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.

ACELYRIN previously announced that enrollment in a Phase 2b/3 trial evaluating 160mg of izokibep administered weekly as a treatment for non-infectious, non-interior uveitis had been completed in May 2024 with 96 patients. The Company expects to report topline data from the trial in December 2024.

Third Quarter 2024 Financial Highlights

Cash Position: Cash, cash equivalents and short-term marketable securities totaled $562.4 million at September 30, 2024. The Company expects these to fund operations to mid-2027.

R&D Expenses: Research and development expenses were $31.6 million for the third quarter ended September 30, 2024, as compared to $74.6 million for the same period in 2023. The decreases were primarily a result of reduced clinical development activity as the Phase 3 trials for izokibep move toward completion.

G&A Expenses: For the third quarter ended September 30, 2024, general and administrative expenses were $12.3 million, compared to $19.9 million for the same period in 2023. The decreases were primarily a result of lower stock-based compensation expenses.

Net Loss: Net loss for the third quarter ended September 30, 2024 totaled $48.5 million, compared to $83.9 million for the same period in 2023. The net loss for the third quarter ended September 30, 2024 includes non-recurring restructuring expenses of $10.8 million related to the August 2024 announcement of a refocused pipeline strategy that prioritizes development of lonigutamab in thyroid eye disease. These restructuring expenses are net of a $35.7 million credit voucher that can be used to offset cash obligations for manufacturing costs including those for the lonigutamab program.

Webcast and Conference Call Information
ACELYRIN will host a conference call and webcast today, November 13, 2024, at 4:30pm ET to discuss these recent corporate updates. A live webcast of the conference call can be accessed in the "Events & Presentations" 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 approximately 30 days.

Upcoming Investor Presentation
ACELYRIN management will attend the Jefferies London Healthcare Conference 2024 taking place from November 19-21, 2024, holding 1x1 meetings and a webcasted fireside chat on November 20, 2024. An archive of the webcast will be available in the "Events & Presentations" section of ACELYRIN's website at www.acelyrin.com.

About ACELYRIN
ACELYRIN, INC. (Nasdaq: SLRN) is focused on providing patients life-changing new treatment options by identifying, acquiring, and accelerating the development and commercialization of transformative medicines. ACELYRIN's lead program, lonigutamab, is a subcutaneously delivered monoclonal antibody targeting IGF-1R being investigated for the treatment of thyroid eye disease.

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 ACELYRIN's expectations regarding its cash runway and ability to fund several key milestones; 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 Phase 3 clinical trial of lonigutamab, establishment of proof of concept and/or the availability of clinical data; the therapeutic potential of ACELYRIN's product candidates; the potential commercial launch of ACELYRIN's product candidates; 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 September 30, 2024. 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.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 31,612	$ 74,562	$ 166,026	$ 272,512
General and administrative	12,326	19,861	53,711	44,440
Restructuring	10,809	-	10,809	-
Total operating expenses	54,747	94,423	230,546	316,952
Loss from operations	(54,747)	(94,423)	(230,546)	(316,952)
Change in fair value of derivative tranche liability	-	-	-	10,291
Interest income	7,535	10,502	25,132	20,486
Other income (expense), net	(1,336)	(19)	36,221	(254)
Net loss	$ (48,548)	$ (83,940)	$ (169,193)	$ (286,429)
Other comprehensive gain (loss)				
Unrealized gain (loss) on short-term marketable securities, net	551	(94)	222	36
Total other comprehensive gain (loss)	$ 551	$ (94)	$ 222	$ 36
Net loss and other comprehensive loss	$ (47,997)	$ (84,034)	$ (168,971)	$ (286,393)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.49)	$ (0.87)	$ (1.71)	$ (4.68)

Weighted-average common shares outstanding, basic and diluted	99,835,707	96,872,747	98,973,518	61,138,105

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

	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 216,326	$ 218,097
Short-term marketable securities	346,047	503,229
Total assets	618,310	742,690
Total liabilities	90,029	86,353
Accumulated deficit	(657,912)	(488,719)

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