UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 6, 2025

ACELYRIN, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-41696**	**85-2406735**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4149 Liberty Canyon Road	
Agoura Hills, California	**91301**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (805) 730-0360

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	SLRN	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On January 6, 2025, ACELYRIN, INC. (the "***Company***") announced additional Phase 2 data from its dose ranging trial of lonigutamab, an investigational treatment for thyroid eye disease ("***TED***"), and details regarding the design of its Phase 3 LONGITUDE program for lonigutamab.

In these newly announced data, lonigutamab demonstrated (i) clinically meaningful and competitive improvements across all manifestations of TED, including proptosis, Clinical Activity Score ("***CAS***") and diplopia, as well as the Graves Ophthalmology-Quality of Live ("***Go-QoL***") tool, (ii) significant proptosis response with a 50mg loading and 25mg weekly subcutaneous dose of lonigutamab and (iii) efficacy with lower levels of exposure than seen with intravenously-administered anti-IGF-1R agents. In addition, no cases of hearing impairment as measured by audiogram, hyperglycemia or menstrual disorders in TED patients have been reported to date at any dose level. Pharmacokinetic data also showed that a 100mg loading dose achieved target therapeutic concentration within days.

With respect to the Company's proposed Phase 3 LONGITUDE program for lonigutamab, LONGITUDE-1 and 2 is expected to be conducted across approximately 350 patients in two global double-masked, placebo-controlled trials to evaluate the safety and efficacy of a subcutaneously delivered 100mg loading dose of lonigutamab followed by a 50mg dose every two weeks. Patients will be randomized 2:1 to either lonigutamab or placebo arms during the first 24 weeks, and the primary endpoint in both trials will be proptosis response rate at 24 weeks. All patients will receive lonigutamab after 24 weeks through to 52 weeks of treatment, which is designed to potentially enable longer term treatment.

Both LONGITUDE-1 and LONGITUDE-2 will evaluate "active" TED patients and "chronic" TED patients, with LONGITUDE-1 enrolling a minimum of 81 active patients. The primary endpoint for LONGITUDE-1 will be proptosis response rate at 24 weeks for active patients, with a secondary endpoint of proptosis response rate at 24 weeks for all enrolled patients. LONGITUDE-2 will recruit both active and chronic TED patients and have no minimum number of required active patients. The primary endpoint for LONGITUDE-2 will be proptosis response rate at 24 weeks for all patients. Secondary endpoints for both trials include CAS, diplopia response and GO-QoL at week 24.

The Company previously announced it held an end of Phase 2 meeting with the United States Food and Drug Administration and gained alignment on the proposed LONGITUDE-1 and LONGITUDE-2 Phase 3 trial designs. The Company expects to initiate the Phase 3 LONGITUDE program in the first quarter of 2025 and expects topline data from the trial in the second half of 2026.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements including, but not limited to, statements related to the Company's expectations regarding its anticipated development activities including the planned design and initiation of the Company's planned Phase 3 clinical trial of lonigutamab, the clinical data to be generated from the Company's Phase 3

clinical trial of lonigutamab and the timing of the availability of such data, the characteristics of lonigutamab, including its mechanism of action, its potential efficacy and safety profile (including as compared to other products and product candidates), the Company's interactions with regulatory authorities, the Company's expectations regarding its cash runway, and other statements that are not historical fact. These forward-looking statements are based on the Company's current plans, objectives and projections, and are inherently subject to risks and uncertainties that may cause the Company'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 the Company's product candidates; maintaining and defending intellectual property protection; delays or failures to secure adequate supply of its product candidates; the Company'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 the Company including those described from time to time under the caption "Risk Factors" and elsewhere in the Company'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 report are made as of this date, and the Company undertakes no duty to update such information except as required under applicable law.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ACELYRIN, INC.

Dated: January 6, 2025

By: */s/ Amar Murugan*
Amar Murugan
Chief Legal Officer