

**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): November 26, 2023**

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

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-41696**  
(Commission  
File Number)

**85-2406735**  
(IRS Employer  
Identification No.)

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

**91301**  
(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 November 26, 2023, ACELYRIN, Inc. (the “Company”) and its EU legal representative and Clinical Research Organization Fortrea, Inc. (“CRO”) notified EU regulatory authorities that the Company had recently identified clinical trial execution errors in its ongoing Phase 2b/3 trial in psoriatic arthritis involving its CRO and one of the vendors engaged by the CRO. The Company has confirmed that the protocol, which outlined dosing sequence, was correct. However, the Company’s protocol was programmed incorrectly by the vendor, resulting in a sequencing error that went further unidentified through the providers’ testing processes. As a result, some patients in the 160mg every other week (Q2W) dosing arm and 80mg every four weeks (Q4W) dosing arm received placebo and active treatment in random order, rather than in an alternating pattern as intended. Importantly, there is no risk to patient safety resulting from the sequencing errors and no patient received more active treatment than was already included in the protocol for the most frequent 160mg every week (QW) dosing arm. The programming error has been addressed and the dosing sequence has been corrected. EU notifications are made publicly available by EU regulatory authorities at <http://www.clinicaltrialsregister.eu/>.

Further details are included in the press release the Company issued today, entitled “ACELYRIN, INC. Provides Update on Izokibep Clinical Development Program”. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release dated November 27, 2023</a>
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

**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: November 27, 2023

By: /s/ Shao-Lee Lin  
Shao-Lee Lin, M.D., Ph.D.  
Chief Executive Officer

**ACELYRIN, INC. Provides Update on Izokibep Clinical Development Program**

LOS ANGELES, Nov. 27, 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 provided an update on its izokibep clinical development program, including its ongoing global Phase 2b/3 trial for izokibep in psoriatic arthritis (“PsA trial”).

***Background***

In September 2023, ACELYRIN disclosed top-line results from Part B of its Phase 2b/3 trial evaluating izokibep for the treatment of moderate-to-severe Hidradenitis Suppurativa (“HS trial”). Given certain confounding factors observed in the trial, including responder discontinuations without adverse events and a marked increase in placebo rates arising in the latter half of the study, the Company implemented quality control measures above and beyond standard protocol for the ongoing open-label extension of the HS trial, the ongoing Phase 3 trial in HS, and the ongoing PsA trial. These trials are being conducted by the same Contract Research Organization (CRO). The CRO does not conduct any trials on behalf of ACELYRIN beyond the izokibep clinical program.

***PsA Trial***

The ongoing PsA trial is designed with four arms: 160mg dosed every week (QW), 160mg dosed every other week (Q2W), 80mg dosed every four weeks (Q4W) and placebo. ACELYRIN’s team recently identified clinical trial execution errors involving its CRO and one of the vendors engaged by the CRO. ACELYRIN has confirmed that the protocol, which outlined dosing sequence, was correct. However, ACELYRIN’s protocol was programmed incorrectly by the vendor, resulting in a sequencing error that went further unidentified through the providers’ testing processes. As a result, some patients in the 160mg Q2W and 80mg Q4W arms received placebo and active treatment in random order rather than in an alternating pattern as intended. Importantly, there is no risk to patient safety resulting from the sequencing errors and no patient received more active treatment than was already included in the protocol for the most frequent 160mg QW dosing arm. The programming error has been addressed and the dosing sequence has been corrected.

Work is ongoing to determine the implications of the sequencing errors in the 160mg Q2W and 80mg Q4W arms. Based on ACELYRIN’s review to date and the fact that the placebo and 160mg QW arms were designed for consistent weekly dosing, the Company has no reason to believe the 160mg QW and placebo arms are impacted.

***Next Steps***

ACELYRIN’s wide-ranging review of the ongoing izokibep trials, including operational execution by the CRO, is continuing. ACELYRIN will contract with a third-party to conduct an independent audit of the trials being conducted by the CRO for ACELYRIN, including the HS trial and the PsA trial. ACELYRIN will not use this CRO for any new trials that it conducts. Based on the outcome of its ongoing evaluation and the planned audit, the Company will determine the best path forward for the development of izokibep on behalf of patients. This will include a determination of whether to transition its ongoing trials to a new CRO or complete the trials with the current CRO.

Pending completion of the evaluation from the third-party auditor, ACELYRIN plans to report top-line data from its PsA trial in the first quarter of 2024.

The Company previously presented differentiated 16- and 46-week data up to 80mg every other week from a Phase 2 trial of izokibep in PsA that was not conducted by the CRO. These results demonstrated dose-ordered responses as early as one month into treatment and increasing over time. Long-term efficacy results from the same trial presented recently at the American College of Rheumatology annual meeting showed that with longer duration of treatment, patients experienced durable and deepening resolution of disease across clinical manifestations of PsA, leading to further improvements in quality of life as measured by the Psoriatic Arthritis Impact of Disease questionnaire. Modeling from the Phase 2 PsA data predicted the potential for increased efficacy with higher doses over the 80mg Q2W. The ongoing PsA trial includes higher doses designed to evaluate the potential to further maximize responses for patients.

“We are disappointed by these developments, especially for the patients who need better treatment options for psoriatic arthritis and hidradenitis suppurativa,” said Shao-Lee Lin, MD, PhD, founder and CEO of ACELYRIN. “However, we are a company founded on truth and transparency, and we are grateful that through the tenacity of our internal team we were able to identify these errors. We are committed to delivering the best possible outcome for patients, physicians and shareholders as we continue to pursue development of izokibep as a potentially differentiated treatment for multiple immunologic conditions.”

The Company reported cash of \$788.4 million at September 30, 2023, which represents a multi-year runway to fund operations through key value-driving milestones across its portfolio of clinical programs.

As a result of these developments, the Company will not attend Piper Sandler’s 35th Annual Healthcare Conference on Tuesday, November 28 or the 6th Annual Evercore ISI HealthCONx Conference on Thursday, November 30, 2023, as previously disclosed.

The Company separately filed a related Form 8-K today.

#### **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](http://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 plan to conduct a third-party independent audit of certain of its trials; the announcement of clinical data from its ongoing Phase 2b/3 trial in PsA and the timing thereof; the overall 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; 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; 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, including the risk that the reported sequencing errors and the related impact to the ongoing Phase 2b/3 trial in PsA may increase ACELYRIN's development costs and extend the izokibep development timeline for such indication, perhaps materially; the completion of ACELYRIN's evaluation and related planned third-party independent audit of its trials conducted by the CRO; ACELYRIN's reliance on independent clinical investigators, CROs and other third-party service providers to carry out preclinical studies and clinical trials; 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, 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. Contact:

Tyler Marciniak  
Vice President of Investor Relations,  
Communications and Corporate Operations  
[investors@acelyrin.com](mailto:investors@acelyrin.com)  
[media@acelyrin.com](mailto:media@acelyrin.com)