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): March 20, 2024

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 7.01 Regulation FD Disclosure

On March 20, 2024, ACELYRIN, INC. (the "Company") issued a press release, entitled "ACELYRIN, INC. Announces Positive Phase 1/2 Proof-of-Concept Data for Lonigutamab, First Subcutaneous Anti-IGF-1R to Demonstrate Clinical Responses in Thyroid Eye Disease". A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information disclosed under this Item 7.01 and in the related exhibit hereto is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and shall not be deemed incorporated by reference into any filing made under the Securities Act of 1933, except as expressly set forth by specific reference in such filing. The furnishing of information pursuant to this Item 7.01 will not be deemed an admission that any information in this report is material or required to be disclosed by Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, titled "ACELYRIN, INC. Announces Positive Phase 1/2 Proof-of-Concept Data for Lonigutamab, First Subcutaneous Anti-IGF-1R to Demonstrate Clinical Responses in Thyroid Eye Disease", dated March 20, 2024
104	Cover Page Interactive Data File (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: March 20, 2024

By: */s/ Gil M. Labrucherie*
Gil M. Labrucherie
Chief Financial Officer

Exhibit 99.1

ACELYRIN, INC. Announces Positive Phase 1/2 Proof-of-Concept Data for Lonigutamab, First Subcutaneous Anti-IGF-1R to Demonstrate Clinical Responses in Thyroid Eye Disease

Rapid improvements demonstrated for proptosis, clinical activity scores, and diplopia versus placebo with a favorable safety profile

Phase 2b/3 trial to be initiated in the second half of 2024

Conference call to review these data to be held at 8:30 a.m. ET today

LOS ANGELES, March 20, 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 announced positive proof-of-concept data from an ongoing Phase 1/2 trial of lonigutamab in thyroid eye disease (TED). 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 for the treatment for TED.

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 are the first reported clinical data for the anti-IGF-1R mechanism delivered subcutaneously and demonstrating clinical benefit in thyroid eye disease patients. The data support our hypothesis that lonigutamab has the potential to optimize benefit-risk by enabling longer-term subcutaneous dosing to increase 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," said Shao-Lee Lin, MD, PhD, Founder and CEO of ACELYRIN. "Tackling thyroid eye disease has special meaning for our team, and we are thankful to the patients and investigators who have partnered with us. We are delighted to have achieved proof of concept for lonigutamab in TED and intend to advance clinical development with the potential to move patients toward resolution of their disease."

Lonigutamab Phase 1/2 Study Results

This multi-center, dose-ranging Phase 1/2 clinical trial is evaluating the safety and efficacy of lonigutamab dosed in TED patients. Cohort 1 was placebo-controlled with six patients receiving lonigutamab and two receiving placebo. Cohort 2 is open label with data available from six patients at six weeks.

Endpoint (% of patients achieving response at 6 weeks)	**Cohort 1**		**Cohort 2**
	Placebo (n=2)	**Lonigutamab 40mg Q3W** (n=6)	**Lonigutamab 50mg Loading, 25mg QW** (n=6)
Proptosis Response (≥ 2 millimeter reduction in proptosis from baseline[i])	0%	50%	67%
CAS Response (≥ 2 point reduction in CAS[i])	0%	100%	83%
Diplopia Response (≥ 1 Bahn-Gorman improvement[i,ii])	0%	25%	40%

[i] Clinically meaningful results across each measurement
[ii] Teprotumumab Smith, et al NEJM 2017 21% placebo-adjusted rate at 6 weeks; Douglas, et al NEJM 2020 39% placebo-adjusted rate at 24 weeks

Overall, lonigutamab has been well-tolerated across our clinical experience to date. There have been no reports of hyperglycemia or hearing impairment and no serious adverse events.

“It is very encouraging to see the results of subcutaneous administration of an anti-IGF-1R therapy. The data shown suggest that there is a clinically meaningful response in patients as early as 3 weeks after a single subcutaneous dose of lonigutamab. In addition, it appears that the safety profile of medication through the subcutaneous route may be favorable when compared to standard of care,” said Shoaib Ugradar, MD, Department of Orbital and Oculoplastic Surgery, private practice, Beverly Hills, California. “It is important to note that this is preliminary data in a small group, however the positive results are highly promising. Given the growing body of evidence that suggests thyroid eye disease may have long-term sequelae, the convenience of a subcutaneous administered medication with a potentially favorable side effect profile becomes critical.”

A presentation of these data can be found on the “Events & Presentations” section of the ACELYRIN website via this link ACELYRIN.com. Further data from this ongoing trial will be presented at future scientific meetings.

Next Steps
With proof of concept achieved in Cohort 1, and Cohort 2 further validating these results, a Phase 2b/3 trial is planned to be initiated in the second half of 2024, designed to be the first of two registrational trials in TED.

Given the close proximity of the recent data announcements for izokibep and lonigutamab and today’s conference call, ACELYRIN will forego hosting a fiscal year 2023 earnings call. The company will instead announce its financial results in a press release and file the related 10-K report no later than April 1, 2024.

Conference Call Information
ACELYRIN will host a conference call and webcast today, March 20, 2024, at 8:30 a.m. ET to review these positive clinical data. A live webcast of the conference call can be accessed in the “Events & Presentations” section of ACELYRIN’s website at ACELYRIN.com. A recording of the webcast will be available approximately two hours after the event, and will be archived on the Company’s website for approximately 30 days.

About the Phase 1/2 Trial
The Phase 1/2 clinical trial (NCT05683496) is a multi-center trial evaluating the safety and efficacy of lonigutamab dosed subcutaneously in three cohorts of patients with active thyroid eye disease (TED). Cohort 1 is placebo-controlled testing lonigutamab 40mg every three weeks (Q3W) through six weeks, cohort 2 is open label testing a 50mg loading dose followed by 25mg every week (QW), and cohort 3 is testing every four weeks (Q4W) dosing.

For more information about the Phase 1/2 trial, please visit www.clinicaltrials.gov.

About Thyroid Eye Disease
Thyroid Eye Disease (TED) is a vision-threatening autoimmune disease in which there is both inflammation and expansion of the tissues behind the eye, resulting in eye bulging, known as proptosis, and the subsequent inability to close the eyelids. Double vision, or diplopia, can occur, as well as the potential for compression of the retinal nerve, which can lead to blindness. Thus, TED is a progressive, chronic inflammatory disease where longer-term treatment has the potential to improve depth and durability of response. More than 100,000 people in the United States are estimated to suffer from TED.

About Lonigutamab (anti-IGF-1R)
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 we believe can improve depth and durability of clinical response. Based on our preclinical and

pharmacodynamic data from our completed single ascending dose study with lonigutamab, we can optimize the therapeutic window utilizing the SC route of administration. The characteristics of lonigutamab also allow the potential to minimize exposures relative to IV therapy. IGF-1 is neuroprotective to cochlear cells of the inner ear and serves to repair damage that can occur over time. We hypothesize that high concentrations of anti-IGF-1R due to Cmax from IV administration can penetrate the blood-labyrinth barrier and interfere with this normal function. Lonigutamab originated from Pierre Fabre Laboratories, a French pharmaceutical group.

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 ACELYRIN's ability to accelerate the development and delivery of transformative medicines; the advancement of ACELYRIN's product candidate lonigutamab and its therapeutic potential, including its ability to offer clinically meaningful, differentiated benefits for TED patients 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; 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, 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.

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