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): August 14, 2023

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:

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

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

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

o 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 x

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. o

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2023, ACELYRIN, INC. (the "***Company***") issued a press release announcing its financial results for the quarter ended June 30, 2023. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

All of the information furnished in this Item 2.02 and Exhibit 99.1 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), or otherwise subject to the liabilities of that Section, and shall not be incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated August 14, 2023.
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: August 14, 2023

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

Exhibit 99.1

ACELYRIN, INC. Reports Second Quarter 2023 Financial Results and Recent Highlights

New data from Part A of Phase 2b/3 trial of izokibep in Hidradenitis Suppurativa demonstrated improvements in number of draining tunnels in two-thirds of patients as early as week 4; the placebo-controlled Part B remains on track for top-line data in the third quarter 2023.

Enrollment completed in Phase 2b/3 randomized controlled trial of izokibep in Psoriatic Arthritis; top-line data now accelerated to first quarter 2024 from mid-2024.

Strong cash position of $823.0 million, including gross proceeds from recent IPO of $621.0 million, supports multiple late-stage clinical programs through key milestones across all three clinical programs.

Company to host conference call and webcast at 4:30 p.m. ET today.

LOS ANGELES, August 14, 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 reported financial results for the second quarter ended June 30, 2023 and highlighted additional recent corporate updates and milestones.

“The first half of 2023 has been productive and rewarding as we marked a number of clinical and corporate milestones supporting our mission to identify, acquire and accelerate the development and commercialization of transformative medicines for patients,” said Shao-Lee Lin, MD, PhD, founder and CEO of ACELYRIN. “From our successful initial public offering in May to our continued clinical progress across the portfolio including izokibep, lonigutamab and SLRN-517, we are aggressively executing against our plans for the potential to accelerate better treatment options for patients and value for shareholders. We’re very pleased to share today new data from Part A of the Phase 2b/3 trial of izokibep in Hidradenitis Suppurativa, or HS, demonstrating that the majority of patients are achieving improvements in the number of draining tunnels within the first month of therapy. The totality of evidence across our HS and Psoriatic Arthritis trial results continues to support the hypothesis that the high potency and small molecular size of izokibep can lead to clinically meaningful, differentiated benefits for patients, including resolution of important manifestations of each disease that otherwise lead to pain, disability and poorer overall quality of life.”

“In addition to our consistent clinical progress, we continue to build out our exceptional senior leadership team with the addition of veteran immunology sales and marketing leader Ken Lock as our Chief Commercial Officer. His appointment to our management team is timely and important as we continue to advance a robust clinical pipeline including multiple late-stage programs toward potential regulatory approval and commercial launch,” added Dr. Lin.

Recent Highlights and Upcoming Milestones

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. Our recent data in Hidradenitis Suppurativa (HS) and Psoriatic Arthritis (PsA) demonstrate – in two independent data sets across two indications – the potential for resolution of disease in difficult-to-treat tissues, and that improves over time. Trials designed for the potential to be part of registrational packages are underway in moderate-to-severe HS, PsA and uveitis, with plans to initiate an additional Phase 3 program in axial spondyloarthritis (AxSpA).

- A new analysis from Part A of the Phase 2b/3 trial in HS suggests that treatment with izokibep results in improvement of at least one draining tunnel as early as week 4 in two-thirds of continuing patients. Week 4 was the first timepoint assessed and this result remained consistent through week 12. Furthermore, half of continuing patients improved by at least two draining tunnels by week 8 and remained consistent through week 12. The speed of response, as well as the magnitude of response at the later time points, is a promising development. It is important to note that this analysis is based off a small dataset with numbers of patients in the high single digit to low double digits. Additional understanding of izokibep's impact on draining tunnels will be informed by the Part B data set.

    - Enrollment of the double-blind, placebo-controlled Part B of the Phase 2b/3 trial evaluating izokibep in HS completed ahead of schedule, accelerating anticipated top-line results into the third quarter 2023.

- Based on the results seen in the open-label Part A of the trial as presented at AAD in March 2023, we remain focused on resolution of disease as approximated by high orders of response such as HiSCR100. HiSCR100 is a stringent measure of disease control in HS as it requires the same individual to achieve both abscess/nodule resolution without formation of new draining tunnels. We believe that full control of active inflammation enables the early improvements observed in the number of draining tunnels in Part A.

- Also during the quarter, an independent Data Monitoring Committee (DMC) conducted a pre-planned review of unblinded efficacy and safety data from Part B of the P2b/3 trial in HS and confirmed the dose of 160mg QW for the second Phase 3 trial in HS. While the company remains blinded to the data, this confirmation is consistent with the understanding that higher exposures are required in HS and aligns with our hypothesis that the high potency and small size of izokibep could lead to clinically meaningful differentiated benefits.

    - With the dose confirmed in May, we dosed the first patient in the second HS Phase 3 trial in June, and that trial continues to actively enroll.

- In April, the Company reported 46-week results from the Phase 2 trial in PsA that showed continued, deepening improvements beyond 16 weeks across key manifestations of the disease. Of participants receiving izokibep 80 mg Q2W, 79% achieved ACR50 response versus 52% at week 16 and even higher measures of clinical response – including significant control or resolution of disease – were observed with 50% achieving ACR70 response, 71% achieving PASI100 response, and 89% achieving enthesitis resolution. This was predicted by internal modeling that suggested the magnitude of clinical response would continue to increase with longer duration of treatment. The model also predicts further differentiation may be achieved with increasing dose levels, which we are testing in the ongoing Phase 2b/3 trial in PsA.

    - Enrollment in the PsA Phase 2b/3 trial has been completed, and top-line results are now anticipated to be accelerated into first quarter 2024 from mid-2024.

- A Phase 2b/3 trial evaluating izokibep in uveitis is enrolling. Previously reported data for secukinumab have validated the inhibition of IL-17A in uveitis by demonstrating a clinical response with IV levels of exposure. Izokibep can achieve secukinumab IV level exposures with a single subcutaneous injection. This provides the potential to unlock inhibition of IL-17A as an approach to treating uveitis where significant unmet need remains.

- The Company also plans to initiate a Phase 3 program to evaluate izokibep for the treatment of AxSpA in 2024. Enthesitis is a central feature of AxSpA, and we believe the rates of

enthesitis resolution demonstrated in the Phase 2 PsA trial suggest the potential for clinically meaningful, differentiated benefits for patients with this disease.

Lonigutamab
Lonigutamab is a subcutaneously delivered anti-IGF-1R monoclonal antibody with high potency in development for thyroid eye disease (TED). The understanding of TED as a chronic inflammatory condition continues to evolve, especially with recent studies demonstrating efficacy in subjects considered chronic rather than acute. Recent updates from the FDA to the warnings and precautions of the teprotumumab label also highlight hearing impairment as a serious, potentially permanent side effect. We hypothesize that the characteristics of lonigutamab can optimize clinical response by maintaining minimum drug levels needed to achieve improved depth and durability of response, limit safety liability – including hearing impairment/loss – potentially associated with high maximum drug concentrations, and maximize patient convenience through single injection subcutaneous delivery.

- The Phase 1/2 Proof-of-Concept (PoC) trial of lonigutamab delivered subcutaneously in TED patients is ongoing and the Company expects to announce top-line results by late 2023/early 2024.

SLRN-517
SLRN-517 is a fully human monoclonal antibody targeting c-KIT, the inhibition of which reduces mast cell proliferation and activity in various allergy and inflammatory diseases. The high potency and fully human design of SLRN-517 is hypothesized to enable greater exposures, reduce potential for immunogenicity and therefore potentially limit acute reactions to the drug itself, and rapidly deplete mast cells while limiting opportunity for other effects of inhibiting c-KIT in other sensitive tissues (spermatogenesis, hair color, hematopoietic cells (neutropenia)). In addition to chronic urticaria (CU), SLRN-517 also has the potential to address several other mast cell-driven disorders such as prurigo nodularis, bullous pemphigoid and eosinophilic esophagitis.

- The Phase 1/2 PoC trial of SLRN-517 is ongoing and will include healthy volunteers and CU patients. The Company expects to announce top-line results in the second half of 2024.

Leadership Updates
The Company announced the appointment of veteran immunology leader Ken Lock as Chief Commercial Officer. Ken brings decades of commercial leadership expertise in dermatology and rheumatology to ACELYRIN, and his arrival is timely as we continue to advance izokibep through registrational clinical trials and prepare for multiple, consecutive potential commercial launches.

The Company also announced that Mardi Dier, Chief Financial Officer (CFO) and Chief Business Officer, had resigned. Mardi served during important times for the company, and we thank her for her contributions and wish her well in her future endeavors. Gil Labrucherie had been named interim CFO, and previously served as CFO of the Company from July until November 2022 when he left biotech to address personal family matters. His availability at this time to serve in an interim capacity enables seamless continuity of ongoing activities. From June 2016 until July 2022, he served as CFO for Nektar Therapeutics, and added the role of Chief Operating Officer in October 2019.

Second Quarter 2023 Financial Highlights

Initial Public Offering
On May 9, 2023, ACELYRIN closed an upsized initial public offering of 34,500,000 shares of common stock, which included the full exercise of the underwriters' option to purchase up to 4,500,000 additional shares, at a price to the public of $18.00 per share. The aggregate gross proceeds to ACELYRIN from the offering, before

deducting underwriting discounts and commissions and other offering expenses payable by ACELYRIN, were $621.0 million.

Cash Position: Cash, cash equivalents and short-term marketable securities totaled $823.0 million at June 30, 2023. The Company expects these to fund operations through key value-driving milestones across all three clinical programs.

R&D Expenses: Research and development expenses were $30.0 million for the second quarter ended June 30, 2023, as compared to $12.7 million for the same period in 2022. Comparing 2023 to 2022, the Company has undergone significant growth including expansion of the izokibep program across indications, and the addition of two programs in 2023, both of which are now in clinical-stage development.

G&A Expenses: General and administrative expenses were $12.7 million for the second quarter ended June 30, 2023, as compared to $2.2 million for the same period in 2022. These increases in expenses were primarily a result of expanding our organizational capability to support the development and commercialization of our broad portfolio of immunology product candidates.

Net Loss: Net loss totaled $26.0 million for the second quarter of 2023, compared to $14.5 million for the second quarter of 2022.

Conference Call Information

ACELYRIN will host a conference call and webcast today, August 14, 2023, at 4:30 p.m. ET to review its second quarter 2023 financial results. A live webcast of the conference call can be accessed in the "Investors & Media" section of ACELYRIN's website at www.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 ACELYRIN

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.

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 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 clinical trials, establishment of proof of concept and/or the availability of clinical data; 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; 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 June 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.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 30,030	$ 12,710	$ 197,950	$ 25,713
General and administrative	12,666	2,176	24,579	5,258
Total operating expenses	42,696	14,886	222,529	30,971
Loss from operations	(42,696)	(14,886)	(222,529)	(30,971)
Change in fair value of derivative tranche liability	10,144	-	10,291	-
Interest income	6,685	413	9,984	413
Other expense, net	(172)	(1)	(235)	(1)
Net loss	$ (26,039)	$ (14,474)	$ (202,489)	$ (30,559)
Other comprehensive gain (loss)				
Unrealized gain (loss) on short-term marketable securities, net	44	(138)	130	(138)
Total other comprehensive gain (loss)	$ 44	$ (138)	$ 130	$ (138)
Net loss and other comprehensive loss	$ (25,995)	$ (14,612)	$ (202,359)	$ (30,697)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.40)	$ (9.12)	$ (4.71)	$ (24.54)
Weighted-average common shares outstanding, basic and diluted	65,210,117	1,587,471	42,974,640	1,245,300

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

	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 556,169	$ 267,110
Short-term marketable securities	266,821	47,510
Total assets	835,126	319,923
Total liabilities	34,060	26,192
Accumulated deficit	(309,567)	(107,078)

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