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): June 15, 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

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Item 2.02 Results of Operations and Financial Condition.

On June 15, 2023, ACELYRIN, INC. (the "***Company***") issued a press release announcing its financial results for the first quarter ended March 31, 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 June 15, 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: June 15, 2023

By: /s/ Mardi C. Dier
Mardi C. Dier
Chief Financial Officer and Chief Business Officer

Exhibit 99.1

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

Initial Public Offering generated gross proceeds of $621 million; net proceeds of $573.7 million

– *Strong cash position of $289.2 million at end of Q1 2023*

– *$862.9 million from IPO net proceeds and existing cash balance on March 31, 2023 expected to fund key milestones across all three clinical programs*

Accelerated top-line data for P2b/3 randomized controlled study of izokibep in Hidradenitis Suppurativa (HS) from end of year, now anticipated in Q3 2023; Second confirmatory HS P3 trial now initiated and actively enrolling

Lonigutamab and SLRN-517 both now actively enrolling in Phase 1/2 Proof-of-Concept Studies

LOS ANGELES, June 15, 2023 -- 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 first quarter ended March 31, 2023, and highlighted additional recent corporate achievements.

"The past several months have been transformative for ACELYRIN. We continue to work toward our mission to develop clinically meaningful, differentiated medicines by executing on development plans to test our hypotheses and determine how our assets might best address the significant unmet need that remains for patients across a multitude of autoimmune and inflammatory diseases," said Shao-Lee Lin, MD, PhD, founder and CEO, ACELYRIN. "I am particularly pleased for patients that in the past six months we have been able to share izokibep data demonstrating resolution of important manifestations of disease and significant evidence of positive impact on quality of life. With the proceeds of our recent initial public offering, we will continue to drive towards key value-driving milestones to deliver efficiently on our development plans. We are pleased today to be sharing the acceleration of timing for top-line pivotal data for izokibep in Hidradenitis Suppurativa (HS), now expected in the third quarter of 2023, and that a second confirmatory Phase 3 trial in HS is now actively enrolling."

Recent Highlights and Upcoming Milestones

Initial Public Offering

On May 9, 2023, we closed our 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 million.

Izokibep

In March, we shared as a late-breaking presentation at the 2023 American Academy of Dermatology (AAD) Annual Meeting data showing that treatment with izokibep led to high orders of HiSCR response at 12 weeks in the open label Part A of the Phase 2b/3 trial in HS. These responses included achieving HiSCR100, defined as complete resolution of abscesses and nodules with no new fistulae/draining tunnels, in moderate to severe patients representing both Hurley Stage II and III.

Part B of the Phase 2b/3 trial completed enrollment early and top-line results are now anticipated in Q3 2023. An independent Data Monitoring Committee (DMC) conducted a planned interim analysis, reported no safety concerns, and confirmed 160mg weekly (QW) as the dose for the second Phase 3 trial in HS. This Phase 3 trial is now actively enrolling.

In April, we announced 46-week data from the Phase 2 trial of izokibep in Psoriatic Arthritis (PsA) showing that continued treatment of 80mg every two weeks (Q2W) led to further improvements beyond 16 weeks in magnitude of response across key manifestations of the disease including complete resolution of enthesitis in

89% of participants, PASI100 responses in 71% of participants, ACR50 responses in 79% of participants, and ACR70 responses in 50% of participants. A Phase 2b/3 trial in PsA is ongoing and includes further dose ranging up to 160mg QW.

The totality of evidence across these two independent datasets of HS and PsA 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 associated with residual pain and severity of disease.

Lonigutamab
As announced in January, we added to our portfolio lonigutamab, an anti-IGF-1R in development for thyroid eye disease (TED), via our acquisition of ValenzaBio. In March we presented at the North American Neuro-Ophthalmology meeting and in May at the Asia-Pacific Orbital Disease and Thyroid Eye Disease Meeting data from the Phase 1 single-ascending dose study in healthy volunteers demonstrating that lonigutamab administered subcutaneously achieved the drug concentration we believe necessary for optimal therapeutic response in TED. A Phase 1/2 Proof-of-Concept (PoC) trial in TED patients is ongoing with subcutaneous administration.

SLRN-517
We also added to our portfolio SLRN-517, a fully human monoclonal antibody targeting c-KIT, via the acquisition of ValenzaBio. This program has now entered the clinic, and a Phase 1/2 PoC trial in healthy volunteers as well as chronic urticaria patients is actively enrolling.

First Quarter 2023 Financial Highlights

Cash Position: Cash and cash equivalents totaled $289.2 million at March 31, 2023. The subsequent IPO raised $573.7 million in net proceeds and the Company expects the combined cash balance of $862.9 million as of March 31, 2023 to fund operations through key value-driving milestones across all three clinical programs and beyond.

R&D Expenses: Research and development expenses were $167.9 million for the first quarter ended March 31, 2023, as compared to $13.0 million for the same period in 2022. The increase during the quarter was primarily due to a one-time $123.1 million in-process research and development (IPR&D) expense, plus an additional $10.0 million license payment, both related to the acquisition of ValenzaBio, which included lonigutamab and SLRN-517.

G&A Expenses: General and administrative expenses were $11.9 million for the first quarter ended March 31, 2023, as compared to $3.1 million for the same period in 2022. The increase during the quarter was primarily due to increases in head count, consulting, legal, recruiting, audit and accounting services to support our Company's growth and business development.

Net Loss: Net loss totaled $176.5 million for the first quarter of 2023, compared to $16.1 million for the first quarter of 2022. This includes the one-time $123.1 million IPR&D charge and $10.0 million license payment, both related to the acquisition of ValenzaBio.

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 promising product candidates.

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 results in improved pharmacokinetic (PK) properties. 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 anticipated key milestones; the advancement of ACELYRIN's programs and ability to efficiently deliver on its development plans; the expected timing of development activities including establishment of proof of concept and/or the announcement 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 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 ValenzaBio; 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 March 31, 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 March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 167,920	$ 13,003
General and administrative	11,913	3,082
Total operating expenses	179,833	16,085
Loss from operations	(179,833)	(16,085)
Change in fair value of derivative tranche liability	147	-
Interest income	3,299	-
Other income (expense), net	(63)	-
Net loss	$ (176,450)	$ (16,085)
Other comprehensive gain (loss)		
Unrealized gain on short-term marketable securities, net	86	-
Total other comprehensive gain	$ 86	$ -
Net loss and other comprehensive loss	$ (176,364)	$ (16,085)
Net loss per share attributable to common stockholders, basic and diluted	$ (8.61)	$ (17.89)
Weighted-average common shares outstanding, basic and diluted	20,492,101	899,319

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

	March 31,	March 31,
	2023	**2022**
Cash and cash equivalents	$ 289,194	$ 267,110
Total assets	298,519	319,923
Total liabilities	45,278	26,192
Accumulated deficit	(283,528)	(107,078)

Contacts:

Tyler Marciniak,
Vice President of Investor Relations,
Communications and Corporate Operations
investors@acelyrin.com
media@acelyrin.com