Cooley

Chadwick Mills
T: (650) 843-5654
cmills@cooley.com

March 24, 2023

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington, D.C. 20549

Attention: Cindy Polynice
Suzanne Hayes
Ibolya Ignat
Vanessa Robertson

Re: ACELYRIN, INC.
Draft Registration Statement on Form S-1
Submitted on February 10, 2023
CIK No. 0001962918

Ladies and Gentlemen:

On behalf of ACELYRIN, INC. (the "***Company***"), the following information is in response to comments received from the staff (the "***Staff***") of the Securities and Exchange Commission (the "***Commission***") by letter dated March 15, 2023 (the "***Comment Letter***") with respect to the Company's Draft Registration Statement on Form S-1 submitted to the Commission on February 10, 2023. Concurrently with the submission of this response letter, the Company is submitting Amendment No. 1 to the Company's Confidential Draft Registration Statement on Form S-1 ("***DRS Amendment No. 1***"). In addition to addressing the comments raised by the Staff in its Comment Letter, the Company has included other revisions and updates to its disclosure in DRS Amendment No. 1.

For the convenience of the Staff, the numbering of the paragraphs below corresponds to the numbering of the comment in the Comment Letter, the text of which we have incorporated into this response letter for convenience in italicized type and which is followed by the Company's response. In the responses below, page number references are to DRS Amendment No. 1.

Draft Registration Statement on Form S-1 submitted on February 10, 2023

Overview, page 1

1. Throughout your filing you make statements and predictions regarding the safety and efficacy of your product candidates. Safety and efficacy are conclusions that are within the sole authority of the FDA and are assessed throughout the entire development process. Given that none of your candidates have received FDA approval, it is not appropriate to state, imply or predict that they are effective or safe. Please remove all statements related to the safety and efficacy of your product candidates. For example:

- "Lonigutamab has been shown to be markedly more potent than the currently marketed therapy for thyroid eye disease (TED)."
- "izokibep demonstrated clinically meaningful and differentiated benefits..."
- "Izokibep...with a safety profile consistent with that of the anti-IL-17A class as a whole."
- "Izokibep has demonstrated higher orders of clinical response in Part A of our Phase 2b/3 trial in HS, which we believe supports the potential to offer clinically meaningful, differentiated benefit to participants in this severe autoimmune condition..."
- "Clinical responses in this open label portion of our ongoing Phase 2b/3 trial in HS were demonstrated at higher orders of Hidradenitis Suppuativa Clinical Response (HiSCR)..."
- "These results from our trials in HS and PsA offer two independent sets of clinical data supporting our hypothesis that izokibep could offer clinically meaningful differentiated outcomes due to its high potency and small size, and therefore the potential to provide greater benefit to patients.

Please note, this is not an inclusive list of the safety and efficacy claims you have included in your filing. You should include a description of your clinical trials, include a comparison of the objective data from your trials to the trial endpoints, discuss the statistical significance of such results and indicate whether a candidate was well tolerated in the Business section where the information can be discussed in proper context, without describing the results as "positive" or validating the therapeutic potential. To the extent that your product candidates have been well tolerated, you may indicate that this is the case. If there have been any serious adverse events, describe the events and indicate how many instances have occurred. It is only appropriate to compare the results of your candidate's trials to another product or product candidate if head to head trials were conducted.

Response: In response to the Staff's comment, the Company has revised the disclosures throughout DRS Amendment No. 1 to address each of the points above.

Our Pipeline, page 1

2. Please clarify if your global rights to izokibep apply to all indications or are limited to psoriatic arthritis.

Response: In response to the Staff's comment, the Company has revised the pipeline disclosure on pages 2 and 125 of the DRS Amendment No. 1 to reflect that global rights to izokibep apply to all indications.

Summary Overview of Izokibep, page 3

3. Please revise your reference to orphan drug designation to clarify that such a designation neither shortens the development time or regulatory review time of a drug, nor does it provide any approval in the regulatory review or approval process and if your expected plans will change if you do not obtain orphan drug designation.

   Response: In response to the Staff's comment, the Company has revised the disclosures on pages 3, 31, 124 and 127 of the DRS Amendment No. 1.

4. Clarify that the FDA has not consented to your plans to conduct only one Phase 3 clinical trial, rather than the generally required two Phase 3 clinical trials.

   Response: In response to the Staff's comment, the Company has revised the disclosures on pages 8 and 145 of the DRS Amendment No. 1.

Izokibep for the Treatment of Moderate-to-Severe HS, page 4

5. We note that the market research was conducted on our behalf by Skysis. Please file its consent as an exhibit to your registration statement.

   Response: In response to the Staff's comment, the Company has included Exhibit 23.3, containing the consent of Skysis, to DRS Amendment No. 1.

Our Strategy, page 8

6. Explain what "pipeline-in-a-program" means and its impact on your strategy.

   Response: In response to the Staff's comment, the Company has revised the disclosures on page 10 of the DRS Amendment No. 1.

We are a clinical stage biopharma company with a limited history and no products approved for commercial sale, page 16

7. Revise your risk factor heading to indicate you have a history of losses and highlight the explanatory paragraph in your audit opinion raising substantial doubt about your ability to continue as a going concern. Additionally, disclose the potential effect the going concern opinion may have on your ability to raise additional funds through equity or debt financing.

   Response: In response to the Staff's comment, the Company has revised the heading of the risk factor on page 20 of the DRS Amendment No. 1. The Company respectfully advises the Staff that the financial statements of the Company for the year ended December 31, 2022 and the related audit opinion do not contain an explanatory paragraph about the Company's ability to continue as a going concern.

Our product candidates licensed from various third parties may be subject to retained rights, page 50

8. Revise your discussion to identify licenses that provide that the licensors retain certain rights, and describe the rights that the licensors have retained. Additionally, identify the licenses that are subject to "march-in rights."

   Response: In response to the Staff's comment, the Company has revised the disclosures on Page 54 of the DRS Amendment No. 1.

Use of Proceeds, page 83

9. Please enhance your disclosure to quantify the amount of proceeds you intend to use for each stated purpose and indicate the stage of development you expect to achieve for each proposed use for izokibep.

Response: In response to the Staff's comment, the Company has revised the disclosures on page 87 of the DRS Amendment No. 1.

Affibody Agreement, page 100

10. Please explain what priority review vouchers are and how the fair market value will be determined in accordance with the Affibody Agreement.

Response: In response to the Staff's comment, the Company has revised the disclosures on pages 106 and 157 of the DRS Amendment No. 1.

Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates Stock-Based Compensation Expense, page 109

11. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances. Please discuss with the staff how to submit your response.

Response: The Company acknowledges the Staff's comment and undertakes that, once an estimated offering price is available, it will provide the Staff with a supplemental letter containing the fair value underlying its equity issuances and an analysis explaining the reasons for any differences between the Company's recent fair value determinations and the estimated offering price, if any.

Targeting IL-17A in the Treatment of HS, page 123

12. Clarify that secukinumab and bimekizumab are being developed by a third party and indicate whether they have received FDA approval. If they have not received FDA approval, clearly state that they have not been determined to be safe or effective.

Response: In response to the Staff's comment, the Company has revised the disclosures on pages 5, 132, 133 and 136 of the DRS Amendment No. 1.

Our Ongoing Phase 2b/3 Trial of Izokibep, page 126

13. Please describe the relevant preclinical and clinical trials and objective results of such trials supporting the INDs for your planned trial for AxSpa and ongoing trials for HS, PsA and uvetisis. Your discussion should identify the trial endpoints, the objective results, the p-values and statistical significance of the results.

Response: In response to the Staff's comment, the Company has revised the disclosures throughout the Business section of the DRS Amendment No. 1 to expand on the planned program for AxSpA and ongoing clinical trials for HS, PsA and uveitis, including a description of the preclinical studies and clinical trials and objective results from each, as applicable.

14. Please Include a textual discussion of the table included on page 126. Your table should not be included in lieu of a thorough descripting of your ongoing trial. Similarly, describe the table depicting your ongoing Phase 2b/3 Trial in PsA on page 132 and your ongoing Phase 2b/3 Trial in Uveitis on page 136.

    Response: In response to the Staff's comment, the Company has revised the disclosures on pages 136, 140, 143 and 148 of the DRS Amendment No. 1.

Current Treatments for PsA, page 127

15. Please include a textual discussion explaining Figure 10 on page 128. Your discussion should explain the terms ACR50, PAS175 and enthesitis. Additionally, explain which therapies are the standard of care for each manifestation depicted.

    Response: In response to the Staff's comment, the Company has revised the disclosures on page 140 of the DRS Amendment No. 1 and expanded on the disclosure of therapies included in the standard of care for each manifestation depicted on page 139.

Summary of the Completed Phase 2 Trial of Izokibep in PsA, page 128

16. Please revise to include a textual description of your Phase 2 trial for PsA, rather than, or in addition to, a table. Your description should explain the acronyms and industry jargon included in your table so that a reader without specialized medical knowledge can understand who can participate in the trial, what the safety and efficacy endpoints are and the meaning of the terms Q2W, 16W, 24W and the significance of the axis along the bottom of the table. Please note, industry terms should be explained in the context of the discussion.

    Response: In response to the Staff's comment, the Company has revised the disclosures on page 140 of the DRS Amendment No. 1.

17. Revise the statement preceding Figure 12 on page 129 to remove the statement that you believe the results demonstrate izokobep has the potential to provide clinically meaningful, differentiated benefits in the treatment of PsA over existing therapies.

    Response: In response to the Staff's comment, the Company has revised the disclosures on page 140 of the DRS Amendment No. 1.

18. Explain what Figure 12 is attempting to depict. How are improvements measured? Explain what the percentages represent and how the information was gathered. Disclose the applicable p-vales and explain their meaning or indicate that the results were not statistically meaningful.

    Response: In response to the Staff's comment, the Company has revised the disclosures on pages 6, 140 and 141 of the DRS Amendment No. 1.

Pharmacokinetic-pharmacodynamic (PK-PD) Modeling Supports Higher Doses, page 131

19. Revise our disclosure to provide the objective data that led you to conclude there was a lack of plateau without providing your conclusion. Additionally, revise the discussion to ensure that it is understandable for a person without specialized medical knowledge.

Response: In response to the Staff's comment, the Company has revised the disclosures on pages 142 and 143 of the DRS Amendment No. 1.

Izokibep for the treatment of AxSpA, page 133

20. Please clarify whether the FDA has approved your Phase 3 clinical trials in AxSpA. If it has not, please explain the basis for your strategy for going directly to Phase 3 trials and discuss the possibility that the FDA may require a Phase 2 trial.

Response: In response to the Staff's comment, the Company has revised the disclosures on pages 8 and 145 of the DRS Amendment No. 1.

21. Please disclose the known aspects of your trials, such as the meaning of radiographic and non-radiographic, the clinical trial endpoints, and the number of participants.

Response: In response to the Staff's comment, the Company has revised the disclosures on pages 8 and 145 of the DRS Amendment No. 1. The Company respectfully advises the Staff that we have not yet determined the number of participants for our planned Phase 3 program in AxSpA.

Evidence for the Role of IL-17A Inhibitors in the Treatment if Non-Infectious Uveitis, page 135

22. Unless secukinumab was approved for the treatment of uveitis, delete the statements that it demonstrated clinical benefits. You may present objective information from the trial providing the conclusion that it provided a clinical benefit.

Response: In response to the Staff's comment, the Company has revised the disclosures on page 147 of the DRS Amendment No. 1.

Our Lonigutamab (IGF-1R Monoclonal Antibody) Program, page 137

23. Please describe the preclinical trials related to Lonigutamab for the treatment of TED.

Response: In response to the Staff's comment, the Company has revised the disclosures on page 151 of the DRS Amendment No. 1.

Clinical Development, page 142

24. Describe the early proof-of-concept data your Phase 1 trial is designed to generate.

Response: In response to the Staff's comment, the Company has revised the disclosures on page 155 of the DRS Amendment No. 1.

Our XLRN-517 (c-KIT Monoclonal Antibody) Program, page 142

25. Please provide a textual description of Figure 23, including the relevance of the information in the column on the right of the table.

Response: In response to the Staff's comment, the Company has revised the disclosures on page 156 of the DRS Amendment No. 1.

26. Your pipeline table appearing on pages 2 and 117 indicates you have completed preclinical trials for chronic urticaria. Revise to describe the preclinical trials.

Response: In response to the Staff's comment, the Company has revised the disclosures on pages 2 and 125 of the DRS Amendment No. 1.

General

27. Please provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Response: The Company is providing to the Staff, on a supplemental basis, copies of the written communications, as defined in Rule 405 under the Securities Act of 1933, as amended (the "***Securities Act***"), that have been used in meetings with potential investors in reliance on Section 5(d) of the Securities Act. These materials were only made available for viewing by potential investors during the Company's presentations, and no copies were retained by any potential investor. Pursuant to Rule 418 under the Securities Act, the copies supplementally provided shall not be deemed to be filed with, or a part of, or included in, the Registration Statement.

* * *

Please contact me at (650) 843 5654 with any questions or further comments regarding our responses to the Staff's comments.

Sincerely,

/s/ Chadwick Mills

Chadwick Mills

cc: Shao-Lee Lin, *ACELYRIN, INC.*
Mina Kim, *ACELYRIN, INC.*
Charlie S. Kim, *Cooley LLP*
Anitha Anne, *Cooley LLP*
Alan F. Denenberg, *Davis Polk & Wardwell LLP*