United States securities and exchange commission logo

April 6, 2023

Shao-Lee Lin, MD
Chief Executive Officer
ACELYRIN, Inc.
4149 Liberty Canyon Road
Agoura Hills, CA 91301

Re: ACELYRIN, Inc.
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted on March 24, 2023
CIK 0001962918

Dear Shao-Lee Lin:

We have reviewed your amended draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Amendment No.1 to Draft Registration Statement submitted March 24, 2023

Prospectus Summary
Summary Overview of Izokibep, page 3

1. We note your response to our prior comment one and reissue our comment. Throughout your filing you continue to make statements and predictions regarding the efficacy of your product candidates. As stated, efficacy conclusions are within the sole authority of the FDA and are assessed throughout the entire development process. Please remove all statements related to the safety and efficacy of your product candidates here and throughout your registration statement. For example:
"izokibep has demonstrated clinically meaningful responses"
"we believe the enthesitis resolution response of izokebep demonstrated in PsA could also be indicative of similar clinically meaningful responses . . ."
"In the trial, both the 40mg and 80mg doses of izokibep demonstrated significant improvements compared to placebo."
"The PsAID results for the overall population in this trial revealed statistically

significant and dose-dependent improvements in all quality-of-life sub-domains of
the PsAID instrument . . ."

Please note that you should present the objective data from your trials without drawing
conclusions as to whether they demonstrated efficacy. Additionally, note this is not an
inclusive list of the efficacy claims you have included in your filing. Please review your
filing thoroughly and remove all claims related to the efficacy your your product
candidates.

2. We note your response to comment three and note you have revised your disclosure to
indicate that orphan drug status does not guarantee that a regulatory authority will accept
fewer trials or accelerate regulatory review. However, it is not until page 167 that you
clarify that orphan drug status does not provide any advantage with respect to shortening
the duration of the regulatory review and approval process. The revised disclosure on
pages 3, 31, 124 and 127 continues to imply that orphan drug status may result in a shorter
process. Please revise to clarify that it conveys no advantage in or shorten the duration of
the regulatory review and approval process.

3. We note your response to comments 4 and 20. However, your revised disclosure indicates
that you are relying on a demonstrated response from an ongoing trial to determine that
the candidate may also demonstrate clinically meaningful responses for patients with
AxSpA. Please remove the references to "the enthesitis resolution response izokibep
demonstrated in PsA" and clarify that the FDA has not consented to your plans to conduct
only one Phase 3 clinical trial for Izokibep for AxSPA. You may indicate that you are
relying on data related to enthesitis from your PsA trials in seeking FDA approval to
proceed directly to a Phase 2b/3 trial without indicating your conclusions with respect to
the efficacy of that trial. Additionally, revise your pipeline table to clarify that you have
not completed a Phase 2 trial. Until the FDA clarifies that a Phase 2 trial is not required, it
is not appropriate to indicate that you have completed Phase 2 in your pipeline table on
pages 2 and 125.

Unaudited Pro Forma Condensed Combined Financial Information
3. Pro Forma Adjustments, page 100

4. For the amount allocated to in-process research and development, please disclose a
breakout of the amount due to the lonigutamab and XLRN-517 product candidates,
separately.

Affibody Agreement, page 106

5. We note your response to comment ten. Please further expand your disclosure to clarify



what "certain marketing applications" qualify for priority review vouchers. For example,
clarify whether all candidates with orphan drug status qualify for priority review
vouchers. If not, describe the factors the FDA considers in determining whether to to
award a priority review voucher.

Business, page 123

6. Throughout your business section you compare your product candidates to efficacy
information related to potential competitors. For example, on page 139, you state that you
have used published data for all approved therapies for treatment of PsA.

While you may
indicate that ACR50 response rates at 16 weeks ranging from 35-45% was your trial
endpoint if that was the case, you may not present the comparison of your candidate to
other products or third party product candidates unless you have conducted head to head
trials. Please revise your registration statement accordingly.

Our ongoing Phase 2b/3 Trial of Izokibep in HS, page 136

7. Please explain why you have provided the placebo response rates that have been reported
by by other agents in their historical clinical trials and clarify whether and how the FDA
has agreed to allow you to use these results in your trial.

8. Please delete the statement that "achievement of HiSCR100 response at Week 12 does not
appear, to our knowledge, to have been previously for any other product."

Ongoing Phase 2b/3 Trial in Uveitis, page 147

9. Please clarify that the ongoing Phase 2b/3 trial is your first clinical trial for uveitis.
Similarly, clarify this information by footnote or otherwise in your pipeline table on pages
2 and 125.

You may contact Ibolya Ignat at 202-551-3636 or Vanessa Robertson at 202-551-3675 if
you have questions regarding comments on the financial statements and related matters. Please
contact Cindy Polynice at 202-551-8707 or Suzanne Hayes at 202-551-3675 with any other
questions.

Sincerely,

FirstName LastNameShao-Lee Lin, MD

Division of Corporation Finance

Comapany NameACELYRIN, Inc.

Office of Life Sciences



cc: Anitha Anne., Esq.