



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

September 20, 2021

Steve R. Carchedi
Chief Executive Officer
Allarity Therapeutics, Inc.
210 Broadway, Suite 201
Cambridge, MA 02139

Re: Allarity Therapeutics, Inc.
Registration Statement on Form S-4
Filed August 20, 2021
File No. 333-258968

Dear Mr. Carchedi:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Registration Statement on Form S-4 filed August 20, 2021

Cautionary Note Regarding Forward-Looking Statements; Market, Ranking and Other Industry Data, page 3

1. We note your statement here that "investors are cautioned not to unduly rely upon [your] statements" reflecting your beliefs and opinions on the relevant subject that are based on information available to you as of the date of the information statement. We also note your disclosure in a risk factor on page 62 that while you believe you have obtained statistical data, market data and other industry data and forecasts used throughout the information statement from market research, publicly available information and industry publications believed to be reliable, no third-party has verified such research. These statements appear to imply a disclaimer of responsibility for this information in the prospectus. Please either delete these statements or specifically state that you are liable for

the information related to the market and industry data.

Summary of Information Statement/Prospectus, page 12

2. The disclosure in the summary should be a balanced presentation of your business. Please balance the description of your strengths with equally prominent disclosure of the challenges you face and the risks and limitations that could harm your business or inhibit your strategic plans. For example, but without limitation, balance your discussion of your plans for the clinical development of your product candidates along with your companion DRP diagnostics with a discussion of the failures of those product candidates in previous clinical trials and the challenges you may face in obtaining regulatory approval to market a companion diagnostic.
3. We note that on pages 26 and 218 you state there is an indication that substantial doubt exists related to your ability to continue as a going concern. Please expand your disclosure in the Summary to include this information and disclose your history of net losses and provide your accumulated deficit as of the most recent balance sheet date.
4. You state on page 12 and elsewhere throughout the prospectus that you are "pursu[ing] oncology therapeutic candidates that have been "de-risked" through substantiated prior clinical trials by other pharmaceutical companies." However, in a risk factor on page 34, you state that these candidates have failed therapeutic clinical trial endpoints in Phase 2 or later clinical trials and that "[p]otential out-licensees, alliance partners and collaborators may view a therapeutic candidate identified with our proprietary DRP companion diagnostics platform with more skepticism because of its history of failed clinical trials [...]." Given the uncertainty of developing product candidates through clinical trials and commercialization, it is inappropriate to state or imply that you have mitigated or will mitigate development risk. Accordingly, please remove the references to your product candidates as "de-risked" throughout your registration statement.
5. We note your disclosure that you believe you "will be able to realize the promise of personalized medicine by selecting the patients most likely to benefit from each of our therapeutic candidates, thereby increasing the likelihood of clinical success." Please revise disclosure here and elsewhere in the prospectus as appropriate to remove references to "realizing the promise of personalized medicine" and to "increasing the likelihood of clinical success" as these statements are speculative in light of the regulatory status of the product candidates you are currently pursuing. As an example only, we note your disclosure on page 14 that your DRP may substantially improve the overall treatment response in your clinical trials and increase the likelihood for regulatory approval to market your therapeutic candidates while potentially reducing the time, cost and risk of clinical development.
6. We note your statement here that "[you] may additionally conduct a near-term clinical trial for stenoparib to test the anti-viral activity of this therapeutic candidate as a potential treatment for SARS-CoV-2 (COVID-19) applications." We also note your statement on

page 14 that you believe that your DRP-guided clinical programs "may potentially be considered for the FDA's accelerated approval process." Please revise your disclosure on page 12 as well as similar disclosure on page 102 to clarify that while you have submitted a phase 2/3 protocol through the BARDA portal to be an arm in the NIH clinical trials, you have not yet submitted an IND to the FDA and there is no guarantee that you will become a participant in the NIH clinical trials or that the FDA will grant you an IND to commence a clinical trial to test the anti-viral activity of stenoparib as a potential treatment for COVID-19 applications. Please also revise your disclosure on page 14 to clarify that you have not submitted an application for the FDA's accelerated approval process and that there is no guarantee that the FDA will grant you approval. Please also revise to affirmatively state that the FDA's accelerated approval pathways do not guarantee an accelerated review by the FDA.

7. We note your statement on page 13 and throughout the prospectus that the DRP platform has been "retrospectively validated in 35 clinical trials." Please revise your disclosure here to explain what you mean by "retrospectively validated" and also to clarify that you have not yet received approval from the FDA or other regulatory agency to market a companion diagnostic and you will need this approval in order to market any of your therapeutic candidates. Please also explain whether you expect to be able to rely on your "retrospective" analyses in support of your application for pre-market approval of your companion diagnostics.
8. We note your statement that your product candidates have shown "promising signs of anti-tumor activity." Please revise this disclosure and similar references to "encouraging signs of anti-cancer effects" and "encouraging anti-tumor activity" throughout your prospectus that imply that your product candidates are effective as such determinations are made solely by the FDA and comparable foreign regulators.
9. We note your press release dated June 14, 2021 announcing that you entered into binding terms sheets for agreements under which Oncoheroes Biosciences, Inc. will acquire certain rights to dovitinib and stenoparib. Please revise your disclosure to provide the materials terms of the term sheets or tell us why you believe such information is not material.

Our Pipeline of Therapeutic Candidates, page 14

10. We note that you have included Irofulven in your pipeline table here and on page 101. Given that you suspended your study of Irofulven in 2019, that you then sold Irofulven to Lantern Pharma, Inc. in July 2021 and that you will no longer devote any of your development resources to this program, please remove this product candidate from your pipeline table or explain why the program is sufficiently material to your business to warrant its inclusion. Additionally, please revise the column heading "Phase 1/2" to reflect "Phase 1."

Interests of Certain Persons in the Recapitalization Share Exchange, page 16

11. We note your disclosure here that "[c]ertain of Allarity A/S's executive officers and directors may have interests in the recapitalization share exchange that may be different from, or in addition to, the interests of Allarity A/S's shareholders" and that "[t]he members of the Allarity A/S board of directors were aware of and considered these interests, among other matters, when they approved the Reorganization Agreement and recommended that Allarity A/S shareholders approve the proposals required to effect the reorganization." Please revise to discuss how the board considered those interests in approving and recommending the reorganization.

Summary Historical Financial Information, page 22

12. Pursuant to Item 5 of the Form S-4, please provide pro forma financial information which gives effect to the Recapitalization Share Exchange Transactions as well as the PIPE Investment. Refer to Rule 8-05 of Regulation S-X.

Comparative Per Share Data, page 23

13. Please provide us with your calculations for the historical book value per share for the six months ended June 30, 2021 and June 30, 2021. It appears as though these amounts would not be negative since you had positive total equity.

Risk Factors, page 25

14. Please revise this section to relocate any generic risk factors you present to the end of the section under the caption "General Risk Factors." Refer to Item 105(a) of Regulation S-K.

Our Certificate of Incorporation designates the Court of Chancery of the State of Delaware, page 78

15. We note that your forum selection provision identifies a state court located within the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) as the exclusive forum for certain litigation, including any "derivative action." We also note your disclosure on page 244 that your exclusive forum provision does not apply to claims under the federal securities laws or any other claim for which the federal courts have exclusive jurisdiction. Please clarify in this risk factor whether this provision applies to actions arising under the Securities Act or Exchange Act. If this provision does not apply to actions arising under the Securities Act or Exchange Act, please also ensure that the exclusive forum provision in the governing documents states this clearly.

Material U.S. Federal Income Tax Consequences of the Recapitalization Share Exchange as a Tax-Free Reorganization, page 86

16. We note your disclosure on page 232 that it is “intended” that the Reorganization Share Exchange qualify as a “reorganization” within the meaning of Section 368(a) of the Code. Please revise your disclosure in this section to state that it is the opinion of counsel, to clearly identify and articulate the opinion being rendered and to remove the language stating that this section is a summary. Please ensure that you provide a firm opinion for each material tax consequence or explain why such an opinion cannot be given. If the opinion is subject to uncertainty, please provide an opinion that reflects the degree of uncertainty (ex: “should” or “more likely than not”). For guidance, refer to Staff Legal Bulletin No. 19, Sections III.C.1 and 4.

Information about Allarity A/S
Strategy, page 104

17. We note your reference to “rapidly” advancing the U.S. approval of dovitinib. Please revise this statement here and throughout your prospectus to remove any implication that you will be successful in commercializing your product candidates in a rapid or accelerated manner.
18. We note your statement on page 105 that “[t]he change of the U.S. Presidential administration in early 2021 may adversely impact [y]our participation in Operation Warp Speed.” Please expand your disclosure to explain what you mean and the basis for your belief.

Companion Diagnostics, page 111

19. Your statement that your Dovitinib-DRP companion diagnostic is “first-in-class” implies the likelihood of regulatory approval and comparisons to other companion diagnostics. Please remove the “first-in-class” reference as the statement is speculative in light of the regulatory status of the companion diagnostic.

Priority Therapeutic Programs, page 111

20. For each of your priority assets that are former drug candidates of large pharmaceutical companies, please include in your description of the pre-clinical and clinical trials for those candidates a discussion of any failures in past clinical studies and why those studies may have been stopped or abandoned.
21. To the extent not disclosed, please revise your discussion of the preclinical and clinical trials for each of your product candidates conducted to date to specify the primary and secondary endpoints of the different trials, the results as they relate to the endpoints and any statistical analysis that was done. Also add an explanation of how statistical significance relates to the approval process of the FDA and other regulators. Additionally, please ensure you disclose all serious adverse events (SAEs) and the number of patients

who experienced them for SAEs that were determined to be treatment-related or that the investigator could not determine were not treatment related.

Anticipated NDA Filing for RCC, page 121

22. We note your disclosure here that you anticipate submitted an NDA filing for dovitinib for the treatment of advanced RCC and that the NDA will be supported primarily by data from one randomized Phase 3 trial (A2302) and from one Phase 1/2 trial (A2107). Please expand your descriptions of these trials starting on page 115 to clearly identify and explain the data from each trial that will be used to support your NDA filing. In particular, we note your statement regarding the Phase 3 trial (A2303) that "[t]he trial failed its primary anti-cancer activity endpoint [...]." Please clarify whether other trial endpoints were met and explain the impact of the trial's failure to meet this endpoint.

Intellectual Property, page 172

23. Please revise to disclose for each material patent and patent application the specific products or diagnostics to which such patents or patent applications relate, whether the patents are owned or licensed, the type of patent protection, the expiration dates, and applicable material jurisdictions, including any foreign jurisdiction. Consider disclosure in tabular format by patent family or otherwise in addition to the narrative provided.
24. We note your disclosure that certain patents covering your portfolio assets and that certain patents that may issue in the future from your pending patent applications have or are projected to have expiration dates in 2021. Please revise to disclose what effect you expect the expiration of these patents to have on your patent portfolio and your business and if you intend to take any action to mitigate such effect.

License Agreement with Novartis Pharma for Dovitinib, page 174

25. We note your disclosure on pages 174 through 178 outlining your various license and development agreements. For each agreement, please expand your disclosure to describe all material terms of the agreement including:
- any upfront or execution payments received or paid;
 - quantification of all milestone payments received or paid to date; and
 - quantification of the royalty rate, or a range no greater than 10 percentage points per tier.

Please also expand your description of the out-license agreement with SMERUD to specify, in addition to the above terms, the duration of the agreement and the royalty term as well as the termination provision.

Please also add disclosure in the Summary and under an appropriate heading in the Risk Factors section discussing your dependence on these agreements in order to develop dovitinib and stenoparib.

Research and Development Expenses, page 215

26. Please disclose your research and development expenses by product candidate for each period presented. To the extent that you do not track expenses by product candidate, please disclose as such, and provide a breakdown by nature of type of expense.

Accounting Treatment of the Recapitalization Share Exchange, page 229

27. Please also address your planned accounting of the PIPE Investment Agreement, specifically how you intend to account for the shares of preferred shares that will be issued.

The Reorganization Agreement
Conditions to Closing, page 236

28. Please clarify which conditions are subject to waiver.

2. Summary of Significant Accounting Policies
(m) Acquired In-Process Research and Development (IPR&D), page F-12

29. Your disclosures on page F-30 indicate that you in-licensed the exclusive worldwide rights to both Stenoparib and Dovitinib rather than acquiring as part of a business combination. In this regard please address the following:
- Given that these two amounts represent your entire IPR&D assets recorded at December 31, 2020, please expand your accounting policy disclosures to also address IPR&D assets not acquired in a business combination; and
 - Please help us understand how you determined these should be recorded as indefinite-lived intangible assets pursuant to ASC 350. Please include your consideration of ASC 730-10-25-2(c) and how you determined there is alternative future use.

Condensed Consolidated Balance Sheets (Unaudited), page F-40

30. Please disclose what the obligation to issue shares represents on your balance sheet as of June 30, 2021.

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited), page F-41

31. Please provide us with the calculation for the basic and diluted net loss per common share of \$ (0.01) as it appears the amount should be \$ (0.02) as disclosed on pages 23 and F-55.

General

32. We note that you refer to your document throughout as an "information statement" and further note your disclosure on page 84 that Allarity A/S is soliciting votes for the approval of the proposals in accordance with Danish law. Please tell us why you refer to

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your document as an "information statement" given that you are soliciting proxies for the extraordinary general meeting.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Nudrat Salik at (202) 551-3692 or Vanessa Robertson at (202) 551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Jessica Ansart at (202) 551-4511 or Christine Westbrook at (202) 551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Scott E. Bartel, Esq.