Gregory J. Flesher President and Chief Executive Officer Reneo Pharmaceuticals, Inc. 18575 Jamboree Road, Suite 275-S Irvine, CA 92612

Re: Reneo Pharmaceuticals, Inc.
Registration Statement on Form S-4
Filed June 21, 2024
File No. 333-280369

Dear Gregory J. Flesher:

response.

We have reviewed your registration statement and have the following comments.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe a comment applies to your facts

and circumstances or do not believe an amendment is appropriate, please tell us why in your

After reviewing any amendment to your registration statement and the

information you provide in response to this letter, we may have additional comments.

Registration Statement on Form S-4

Following the Mergers, will Reneo's securities be traded on a stock exchange?, page 12

1. We note your disclosure that it is expected that the NewCo Class A Common Stock will

trade on the Nasdaq Global Market after completion of the Proposed Transactions. Please  $\,$ 

revise to disclose if the terms of the merger agreement permit that the Nasdaq listing  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left($ 

closing condition could be waived without recirculation or resolicitation. If so, please  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left$ 

revise your risk factors to reflect the risks associated with any such waiver and revise to  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

indicate that shareholders may not have certainty at the time of the vote that the shares of

NewCo will be listed on Nasdaq following the merger or revise your disclosure in a pre-  $\,$ 

 $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left($ 

Nasdaq listing of the NewCo Class A Common Stock.

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Prospectus Summary

OnKure, Inc., page 20

2. We note your disclosure here that OnKure is focused on developing "best-in-

class" precision medicines. Please revise this and similar statements throughout the proxy  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

statement/prospectus that OnKure's product candidates may be "best-in-class" as these

statements appear to be speculative given the current development status of those product  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +$ 

candidates and the noted length and uncertainty of the drug approval and commercialization processes.

3. Please tell us your basis for your statement asserting that OnKure's design platform is

"proven" given that OnKure has no products approved for commercial sale. Risk Factors, page  $34\,$ 

4. We note from Section 10.1 of the Merger Agreement that, in general, the representations

and warranties of the parties contained in the Merger Agreement do not survive the  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

Closing and that there are no indemnification rights. Please include appropriate risk factor  $% \left( 1\right) =\left( 1\right) +\left( 1\right$ 

disclosure.

OnKure contracts with third parties for the manufacture of its product candidates for preclinical studies..., page  $80\,$ 

5. Please revise this risk factor to name the single-source supplier OnKure

currently relies

upon and clarify if OnKure has entered into any supply agreements with them.

The Amended Bylaws will provide that, unless NewCo consents in writing to the selection of an

alternative forum..., page 91

6. We note that your forum selection provision identifies the Court of Chancery of the State  $\,$ 

of Delaware as the exclusive forum for certain litigation, including any "derivative  $% \left( \frac{1}{2}\right) =0$ "

action." Please disclose whether this provision applies to actions arising under  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left$ 

the Exchange Act. In that regard, we note that Section 27 of the Exchange Act creates

exclusive federal jurisdiction over all suits brought to enforce any duty or liability created

by the Exchange Act or the rules and regulations thereunder. If this provision does not

apply to actions arising under the Exchange Act, please also ensure that the exclusive

forum provision in the governing documents states this clearly, or tell us how you will

inform investors in future filings that the provision does not apply to any actions arising  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

under the Exchange Act.

The Mergers

Background of the Mergers, page 104

7. Please revise this section to provide a more fulsome description of the negotiations related

to the Concurrent PIPE Investments.

8. Please revise to explain why the board of Reneo found the proposal from  $\mbox{\tt OnKure}$  "more

attractive" than the proposal from Party B. Please also clearly disclose when Reneo's  $\,$ 

board decided to stop considering the proposal from Party B.

9. Please briefly explain why the Reneo board decided to also retain Cooley LLP in

connection with this transaction. In your revisions, provide a more fulsome discussion of

the role Cooley played in negotiating the merger agreement with OnKure. July 18, 2024 Page 3  $\,$ 

10. Please specify which terms remained under negotiation on April 26, 2024. Opinion of Leerink Partners LLC Certain Unaudited Financial Projections of OnKure, page 130

11. Please revise to disclose the material assumptions underlying the Reneo-prepared OnKure

financial projections that were made available to Leerink Partners.

12. We note the disclaimers throughout this section that readers are cautioned not to rely on

the prospective financial projections. While it is acceptable to include qualifying language  $% \left( \frac{1}{2}\right) =\frac{1}{2}\left( \frac{1}{2}\right) +\frac{1}{2}\left( \frac{1}{2}\right) +\frac{1$ 

concerning subjective analyses, it is inappropriate to indicate that investors cannot rely on

disclosure. Please revise accordingly.

13. We see in the OnKure Forecasts on page 132 the significant variances among the amounts

shown as projected net sales, adjusted net sales and adjusted net revenue for the years  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left($ 

presented. Briefly indicate how these terms were defined for purposes of the forecasts and

the reasons for the material differences.

OnKure Business, page 212

14. Please revise your disclosure to remove any implication that OnKure's product candidates

will be safe or effective, as such conclusions are within the sole authority of the  $\ensuremath{\mathtt{FDA}}$ 

and comparable foreign regulators. By way of example only, on page 216 you state that

OKI-219 causes "tumor regression" and has a "favorable safety profile." We also note

statements throughout OnKure's business section claiming your product candidates are

"more effective" than approved products or can "minimize known side effects" observed

in other PI3K inhibitors. Please remove these statements, and any

others like them, or revise these statements to instead present the objective data resulting

clinical trials.

from your

15. Please indicate if the data presented in figure 1 (page 216), figure 7 (page 223) and

figure 8 (page 224) was statistically significant, and include p-values if appropriate.

OnKure's Clinical Pipeline, page 214

16. Please revise your pipeline table to present all phases of clinical development.

OnKure's Preclinical Pipeline, page 214

17. We note the inclusion of OnKure's preclinical pipeline in this section. Given the limited

disclosure related to the programs contained in this pipeline table throughout  $\mbox{OnKure's}\xspace$ 

Business section, please explain why they are sufficiently material to  ${\tt OnKure's}$  business

to warrant inclusion here. If they are material, please expand the disclosure in the  $% \left( 1\right) =\left( 1\right) +\left( 1\right$ 

Business section related to these candidates to provide a more fulsome discussion of any  $\ensuremath{\mathsf{L}}$ 

development activities conducted. Alternatively, remove this pipeline table.

OKI-219, a Targeted Inhibitor of PI3K , page 216

18. We note your disclosure in the last paragraph on page 215 that both alpelisib and

capivasertib are ATP-competitive kinase inhibitors. Please indicate if OKI-219 is also an

 $\ensuremath{\mathsf{ATP}\text{-}\mathsf{competitive}}$  kinase inhibitor or works by some other mechanism of action.

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19. We note your disclosure that OnKure has shown preclinical data supporting the selectivity

of OKI-219 and that OKI-219 targets the  $\rm H1047R$  mutated PI3K  $\,$  with approximately 80-

fold selectivity over the wild-type  ${\tt PI3K}$  . Please disclose the material data underlying

this disclosure and indicate if such data was statistically significant, providing p-values, if

appropriate.

Commercial Opportunity in Breast Cancer, page 217

20. Please revise this section to clearly state that you will need to receive FDA approval prior

to commercialization of any of your product candidates. Limitations of Currently Approved PI3K Inhibitors, page 218

21. Please identify the parties that conducted the clinical studies referenced in this section that

targeted mutated PI3K  $\,$  . Please also clarify, if true, that OnKure did not conduct any of

the studies referenced here.

Phase 1 PIKture-01 Trial, page 224

22. Please disclose the planned endpoints for all three parts of your Phase 1 PIKture-

01 trial. Please also explain how this trial will be powered to assess efficacy.

Figure 9. PIKture-01 trial design and timeline, page 225

23. Please revise this graphic to ensure that all text is legible without magnification.

Intellectual Property, page 228

24. We note your statement here that OnKure's owned and licensed patent portfolio consists

of 128 patents and patent applications, including two licensed issued patents. Please revise

to clarify if any of the licensed patents are material to OnKure's business. To the extent

they are, please revise wherever appropriate to disclose the name of the party or parties  $\ensuremath{\mathsf{S}}$ 

these patents are licensed from and discuss the material terms of the licensing agreements  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

 $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left($ 

statement. Refer to Item 601 of Regulation S-K for guidance. PI3K Platform, page 228

Please revise this section to the disclose the type of patent protection and potential

expiration dates, if granted, for each of the eleven patent families relating to your PI3K

platform. Please also discuss what a provisional patent application is and what rights flow

from this type of application.

Principal Stockholders of the Combined Company, page 326

Please revise the footnotes to the table on page 327 to identify the natural person(s) with

voting and/or dispositive control over the shares in the combined company that will

be held by Acorn Bioventures, L.P., Cormorant Asset Management LP, Perceptive Life

Sciences Master Fund, Ltd. and Samsara BioCapital, L.P.

Exhibits

We note you intend to file the form of preliminary proxy card as Exhibit 99.1. Please note

that the form of proxy card should be filed as an appendix rather than as an exhibit to the

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registration statement. Refer to the Note to paragraph (a)(3) of Exchange Act Rule 14a-4. General

Please provide us your analysis as to whether Reneo Pharmaceuticals, Inc. is a shell

company as defined in Rule 12b-2 of the Exchange Act or whether it could become one

prior to the closing of the merger. For guidance, see Special Purpose Acquisition

Companies, Shell Companies, and Projections, Release No. 33-11265 (January 24, 2024)

at nt. 943.

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.

Please contact Gary Newberry at 202-551-3761 or Lynn Dicker at 202-551-3616 if you

have questions regarding comments on the financial statements and related matters. Please

contact Tyler Howes at 202-551-3370 or Tim Buchmiller at 202-551-3635 with any other

questions.

Sincerely,

Division of

Corporation Finance

Office of Life

Sciences

cc: Jonn R. Beeson, Esq.