



DIVISION OF
CORPORATION FINANCE

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

July 18, 2024

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:

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 response.

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 closing condition could be waived without recirculation or resolicitation. If so, please revise your risk factors to reflect the risks associated with any such waiver and revise to 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-effective amendment as appropriate if and when there is more certainty regarding the 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 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 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 Closing and that there are no indemnification rights. Please include appropriate risk factor 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 action." Please disclose whether this provision applies to actions arising under 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 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 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.

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 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 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 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 α inhibitors. Please remove these statements, and any others like them, or revise these statements to instead present the objective data resulting from your clinical trials.
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 OnKure's Business section, please explain why they are sufficiently material to OnKure's business to warrant inclusion here. If they are material, please expand the disclosure in the Business section related to these candidates to provide a more fulsome discussion of any development activities conducted. Alternatively, remove this pipeline table.

OKI-219, a Targeted Inhibitor of PI3K α , 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 ATP-competitive kinase inhibitor or works by some other mechanism of action.

19. We note your disclosure that OnKure has shown preclinical data supporting the selectivity of OKI-219 and that OKI-219 targets the H1047R mutated PI3K α with approximately 80-fold selectivity over the wild-type PI3K α . 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 α . 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 these patents are licensed from and discuss the material terms of the licensing agreements related to these patents. Please also file these agreements as exhibits to your registration statement. Refer to Item 601 of Regulation S-K for guidance.

PI3K Platform, page 228

25. Please revise this section to 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

26. 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

27. 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

28. 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.