RENEO PHARMACEUTICALS, INC.
18575 Jamboree Road, Suite 275-S
Irvine, CA 92612

July 26, 2024

VIA EDGAR

United States Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington, D.C. 20549
Attention: Gary Newberry
Lynn Dicker
Tyler Howes
Tim Buchmiller

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

Ladies and Gentlemen:

Reneo Pharmaceuticals, Inc., a Delaware corporation ("**Reneo**," the "**Company**," "**we**," or "**our**"), is in receipt of the comments of the staff (the "**Staff**") of the Securities and Exchange Commission (the "**Commission**") set forth in the Commission's letter dated July 18, 2024 (the "**Comment Letter**") with respect to the Company's Registration Statement on Form S-4 filed with the Commission on June 21, 2024 (the "**Form S-4**").

An amended Form S-4 is being filed with the Commission on July 26, 2024 (the "**Amended Form S-4**"). Below are the Company's responses to the Comment Letter. For your convenience, the italicized numbered responses set forth below correspond with the comments contained in the Comment Letter. Unless otherwise indicated, page references in the responses correspond to the page numbers in the Amended Form S-4. Capitalized terms used in this letter but otherwise not defined herein shall have the meanings set forth in the Amended Form S-4.

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 preeffective amendment as appropriate if and when there is more certainty regarding the Nasdaq listing of the NewCo Class A Common Stock.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on pages 12 and 156 of the Amended Form S-4.

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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure throughout the Amended Form S-4 to remove all references to "best-in-class" and similar statements.

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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure throughout the Amended Form S-4 to remove the reference to the OnKure drug design platform being "proven."

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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on pages 36–37 of the Amended Form S-4.

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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 82 of the Amended Form S-4 to name the two single-source suppliers that OnKure currently relies upon and disclosed that it has entered into a master services agreement with each of these suppliers.

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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 93 of the Amended Form S-4 and respectfully advises the Staff that the Amended Bylaws state the exception for exclusive federal jurisdiction over suits brought to enforce any duty or liability created by 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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on pages 117–119 of the Amended Form S-4 to provide additional disclosure regarding 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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 115 of the Amended Form S-4.

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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 116 of the Amended Form S-4.

10. ***Please specify which terms remained under negotiation on April 26, 2024.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on pages 118-119 of the Amended Form S-4.

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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on pages 135-136 of the Amended Form S-4 to add footnote disclosure describing the material assumptions underlying the OnKure Forecasts.

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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 133 of the Amended Form S-4.

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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on pages 135-136 of the Amended Form S-4 to add footnote disclosure describing how the financial measures set forth in the OnKure Forecasts are defined and the reasons for the differences among those measures.

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 PI3Kα 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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure throughout the Amended Form S-4 to remove any claim that OnKure's product candidates will be safe or effective.

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.***

Response:

In response to the Staff's comment, the Company has revised figures 1, 7 and 8 on pages 223 and 229 of the Amended Form S-4, respectively.

OnKure's Clinical Pipeline, page 214

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

Response:

In response to the Staff's comment, the Company has revised the pipeline table on page 221 of the Amended Form S-4 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.***

Response:

In response to the Staff's comment, the Company has removed the pre-clinical pipeline table from page 221 of the Amended Form S-4.

OKI-219, a Targeted Inhibitor of PI3Kα, 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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 222 of the Amended Form S-4.

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 PI3Kα with approximately 80-fold selectivity over the wild-type PI3Kα. Please disclose the material data underlying this disclosure and indicate if such data was statistically significant, providing p-values, if appropriate.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 225 of the Amended Form S-4.

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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 223 of the Amended Form S-4.

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 PI3Kα. Please also clarify, if true, that OnKure did not conduct any of the studies referenced here.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 225 of the Amended Form S-4 to identify the parties that conducted the clinical studies referenced and clarify that OnKure has not independently conducted similar studies.

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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure on page 231 of the Amended Form S-4.

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

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

Response:

In response to the Staff's comment, the Company has revised the graphic on page 232 of the Amended Form S-4.

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.***

Response:

OnKure respectfully advises the staff that the licensed patents are not material to OnKure's business and the related license agreements are not material agreements within the definition of Item 601 of Regulation S-K. The Company has revised the disclosure on page 235 of the Amended Form S-4.

PI3K Platform, page 228

25. ***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.***

Response:

In response to the Staff's comment, the Company has revised the disclosure beginning on page 235 of the Amended Form S-4.

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.***

Response:

In response to the Staff's comment, the Company has revised the footnotes on pages 335, 337 and 338 of the Amended Form S-4.

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

Response:

In response to the Staff's comment, the Company has revised the Amended Form S-4 to include a form of the preliminary proxy card as Annex N.

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.***

Response:

The Company respectfully advises the Staff that the Company does not meet the SEC's definition of a shell company, nor could it become one prior to Closing, because (1) it had substantial pre-combination assets and/or activities, including a clinical product candidate, an intellectual property portfolio and key research and development personnel, prior to its decision to seek strategic alternatives for the business and (2) it will continue to own and maintain its substantial intellectual property portfolio through the Closing of the Mergers.

Rule 12b-2 of the Securities Exchange Act of 1934, as amended, defines a "shell company" as a registrant that has:

(1) No or nominal operations; and

(2) Either: (i) no or nominal assets; (ii) assets consisting solely of cash and cash equivalents; or (iii) assets consisting of any amount of cash and cash equivalents and nominal other assets.

The Company historically focused its business on the development and commercialization of therapies for patients with rare genetic mitochondrial diseases, which are often associated with the inability of mitochondria to produce adenosine triphosphate. The Company's most advanced program involved its lead product candidate, mavodelpar, which it was developing as a selective agonist of the peroxisome proliferator-activated receptor delta (PPARd). Until December 2023, the Company had an ongoing clinical-stage program for mavodelpar.

As described in the Registration Statement, in December 2023, the Company announced that its Phase 2b trial of mavodelpar did not meet its endpoints and that the Company intended to suspend development of its mavodelpar program. In January 2024, following a comprehensive review of its business, the Company initiated a formal process to explore strategic alternatives focused on maximizing stockholder value, which may include, but are not limited to, an acquisition, a merger, business combination or divestiture.

Guidance in (i) Use of Form S-8, Form 8-K, and Form 20-F by Shell Companies, Release No. 33-8587 (July 15, 2005) (the "2005 Adopting Release") and (ii) Special Purpose Acquisition Companies, Shell Companies, and Projections, Release No. 33-11265 (January 24, 2024) (the "2024 Adopting Release")

More than "nominal" operations

In the 2005 Adopting Release, the SEC stated that it intentionally did not define the term "nominal" and it did not set a quantitative threshold of what constitutes a shell company. As such, the threshold of what is "nominal" is based on the facts and circumstances of each individualized case. While the Company has taken actions to suspend the further internal development of its mavodelpar program in December 2023, the Company has continued to engage in operational activities to meet continuing contractual obligations following this decision. For example, the Company had active clinical studies with clinical research organizations and clinical sites which it had to wind down formally in order to meet all regulatory reporting and archive retention requirements. These activities involved agreements with vendors with material outstanding obligations through April 2024 and required significant continuing engagement between Company personnel and vendors.

The Company has been engaged in activities to wind down its clinical trial in a way that best preserves the ability for others to conduct future research and development and to document the technical aspects and current stage of its assets and other trade secrets and clinical activities. Additionally, the Company has continued to prosecute its material pending patent applications related to mavodelpar.

Further, the Company has retained certain key employees to conduct the winding down of research and development activities and to continue to support operational and business development activities.

For the three months ended March 31, 2024, the Company reported approximately $9.6 million of operating expenses associated with operating activities (i.e., research and development expenses and general and administrative expenses). The Company believes that these operating activities and operating expenses were not "nominal," as required under Rule 12b-2 in order for the Company to be deemed a shell company.

More than "nominal" assets

The Company believes that its total assets (other than cash and cash equivalents) and the Company's intellectual property portfolio are more than "nominal." As of March 31, 2024, the Company had approximately $1.8 million of total assets on its balance sheet (other than cash and cash equivalents). Additionally, OnKure's agreement to merge with the Company was based on a valuation that ascribed a non-cash enterprise value of $15 million to the Company, which amount included the Company's intellectual property portfolio and other assets. This also included the Company's license agreement with vTv Therapeutics LLC, under which the Company has an exclusive, worldwide, sublicensable license under certain vTv Therapeutics LLC intellectual property to develop, manufacture and commercialize PPARd agonists and products containing such PPARd agonists for therapeutic, prophylactic or diagnostic applications in humans.

In the 2024 Adopting Release, the SEC reiterated its previous position set forth in the 2005 Adopting Release that companies that structure transactions to avoid shell company status may nonetheless be shell companies, and noted that a reporting shell company that is made to appear to have, or has cloaked itself as having, more than "nominal" assets or operations would still be subject to the shell company limitations. The Company respectfully submits that the Mergers are not a scheme "undertaken with the intention of evading the definition of shell company" as described in Footnote 32 to the 2005 Adopting Release.

Footnote 32 describes the scenario of a promoter of a company who appears to place assets within an entity and then seeks a business combination transaction for the entity, with the expectation of a return of the assets in the future. Unlike the scenario in Footnote 32, the Company is not being used to evade the shell company rules. The Company was formed in 2014 as a pharmaceutical company and has historically focused on the development of therapies for patients with rare genetic mitochondrial diseases, as discussed above. The Company continued these business activities up until December 2023 when the decision was made to halt further internal program development efforts, and shortly thereafter the decision was made to explore strategic alternatives for its program. Here, there was no promoter who temporarily placed the legacy assets with the Company with the intent of evading shell company status, and there is no expectation of benefitting from the assets being returned. The Company respectfully submits that the scenario described in Footnote 32 does not apply to the Company's facts, and that the Company's agreement to merge with OnKure is not structured to "cloak" the Company with assets for the purpose of avoiding shell company status.

The example provided in footnote 943 of the 2024 Adopting Release indicates that shell company status should "*apply to any company **that sells or otherwise disposes of its historical assets or operations** in connection with or as part of a plan to combine with a non-shell private company in order to convert the private company into a public one. This is true regardless of whether such sale or disposal of the legacy assets or operations occurs prior to or after the consummation of the business combination.*" As disclosed in the Registration Statement, OnKure shall continue to hold, maintain and preserve the Company's legacy assets. There are no plans to dispose of the legacy assets before or after Closing. Therefore, applying the shell company rules to the Company today, and up until the Closing of the Mergers, would not serve the purpose of protecting investors from the fraud and abuse in the securities markets the shell company rules were designed to deter.

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If you have any questions regarding these matters, please do not hesitate to contact Jonn R. Beeson of Jones Day at (949) 553-7528 or at jbeeson@jonesday.com or Brad Brasser of Jones Day at (612) 217-8886 or bcbrasser@jonesday.com.

Sincerely yours,

/s/ Gregory J. Flesher
Gregory J. Flesher
President and Chief Executive Officer
Reneo Pharmaceuticals, Inc.

Copies to:

Jonn R. Beeson, Jones Day
Bradley C. Brasser, Jones Day