# RENEO PHARMACEUTICALS, INC.

18575 Jamboree Road, Suite 275-S Irvine, CA 92612

August 19, 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.

Amendment No. 1 to Registration Statement on Form S-4

Filed July 29, 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 August 12, 2024 (the "Comment Letter") with respect to Amendment No. 1 to the Company's Registration Statement on Form S-4 filed with the Commission on July 29, 2024.

An amended Form S-4 is being filed with the Commission on August 19, 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.

# Amendment No. 1 to Registration Statement on Form S-4 filed July 29, 2024

# <u>Opinion of Leerink Partners LLC</u> <u>OnKure Forecasts, page 135</u>

1. We note your revised disclosure in response to prior comment 11. Please further revise to discuss why the projections utilized by Reneo assumed that commercialization for OKI-219 would be able to begin in 2032. Please also clarify here what milestones that will need to be satisfied in order for OKI-219 to achieve this timeline.

### Response:

In response to the Staff's comment, the Company has revised the disclosure on page 135 of the Amended Form S-4.

#### **OnKure Business**

# OKI-219, a Targeted Inhibitor of PI3Ka, page 222

2. We note your response to prior comment 19. Please further revise your discussion of the OnKure generated preclinical data supporting the selectivity of OKI-219 to clarify if these studies were powered for statistical significance.

# Response:

In response to the Staff's comment, the Company has revised the disclosure on page 230 of the Amended Form S-4.

# Phase 1 PIK-ture-01 Trial, page 230

3. We note your revised disclosure on page 232 stating the monotherapy portion of this trial will not be powered to assess efficacy. However, disclosure on page 230 continues to state your Phase 1 trial of OKI-219 will be powered to assess the "efficacy of OKI-219 as monotherapy." Please reconcile your disclosure or advise.

### Response:

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

### **Intellectual Property**

### PI3K Platform, page 235

4. We note your revised disclosure in response to prior comment 25. Please further revise to clarify if the current patent applications relate to OKI-209, including whether such patent applications include composition of matter claims for OKI-209.

### Response:

In response to the Staff's comment, the Company has revised the disclosure on page 240 of the Amended Form S-4.

# Unaudited Pro Forma Condensed Combined Financial Information, page 293

5. We note your response to prior comment 28 and the company's claim that it intends to retain Reneo's intellectual property portfolio. We continue to consider your response to comment 28. However, in order to clarify the treatment of this business combination, please provide us with your accounting analysis of all relevant factors supporting your conclusion that the merger should be accounted for as a reverse recapitalization. As part of your analysis, clearly identify the factors that are indicative that Reneo is a shell company versus the factors that are indicative that it meets the definition of a business at the time of the merger, specifically addressing your ongoing operating activities.

# Response:

After further consideration, including with respect to the accounting treatment of the Mergers, Reneo acknowledges that it will be deemed a shell company by the time of the closing of the Mergers. As stated on page 306 of the Amended Form S-4, for accounting purposes, the Mergers are expected to be accounted for as a reverse recapitalization of OnKure because on the closing date of the Mergers, the pre-combination assets of Reneo are expected to be primarily cash, cash equivalents, short-term investments and other non-operating assets.

Accordingly, the Company respectfully advises the Staff that it has revised the disclosures on pages 95-96 and 319 of the Amended Form S-4.

\* \* \* \* \* \* \* \* \*

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 Bradley C. 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