

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

December 20, 2024

Paul Hickey
President and Chief Executive Officer
ReShape Lifesciences Inc.
18 Technology Dr., Suite 110
Irvine, CA 92618

Re: ReShape Lifesciences Inc.
Amendment No. 1 to Registration Statement on Form S-4
Filed December 6, 2024
File No. 333-282459

Dear Paul Hickey:

We have reviewed your amended 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. Unless we note otherwise, any references to prior comments are to comments in our October 31, 2024 letter.

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

### Cover Page

1. We refer to prior comment 2. With reference to the disclosure on page 14, please revise the prospectus coverpage to highlight the equity percentage range (between 88.9% and 92.31%).

#### Q:What is the proposed Asset Sale?, page 1

2. We note your response to prior comment 16. Please revise the Q&A to explain that ReShape expects to use substantially all of the proceeds it received from the Asset Sale to pay transaction expenses related to the Merger and Asset Sale and ordinary course accounts payable. Similarly, revise the disclosure on page 118 concerning Maxim's valuation analysis to clarify why ReShape expects to only having \$1.5

million in cash as opposed to \$5.16 million or more at closing.

# Q. What are the put-call option agreements to be entered into with certain stockholders of Vyome and Vyome India..., page 2

3. We note your revised disclosure in response to prior comment 3. Revise the disclosure at the bottom of page 2 to explain the "certain price" relating to the combined company's call option. We also note that your beneficial ownership table on page 267 indicates that the two affiliated Navam entities hold approximately half of the entitled shares (751,147). Please tell us whether any other Directors, Officers or 5% holders beneficially own entitled shares that are subject to the put-call option agreement, including shares underlying options.

### The Merger

# Background of Merger, page 105

4. We note your response to prior comment 12. Please revise the January 23 entry to disclose the merger consideration and the plans for ReShape's business assets.

## Opinion of ReShape's Financial Advisor - Maxim Group LLC, page 115

5. We note your response to prior comment 15. We also note that your disclosure continues to state that the Maxim opinion "was not prepared for ReShape's stockholders or any other person or entity, nor will it grant them any rights or remedies." Please remove this statement or disclose the basis for Maxim's belief that shareholders cannot rely on the opinion to support any claims against Maxim arising under applicable state law (e.g., the inclusion of an express disclaimer in Maxim's engagement letter with the company). Describe any applicable state-law authority regarding the availability of such a potential defense. In the absence of applicable state-law authority, disclose that the availability of such a defense will be resolved by a court of competent jurisdiction. Also disclose that resolution of the question of the availability of such a defense will have no effect on the rights and responsibilities of the board of directors under applicable state law. Further disclose that the availability of such a state-law defense to Maxim would have no effect on the rights and responsibilities of either Maxim or the board of directors under the federal securities laws.

### Certain U.S. Federal Income Tax Consequences, page 126

6. With reference to prior comment 21, we note the revised disclosure on page 126 stating that there are no U.S. federal income tax consequences of the Merger or Asset Sale to U.S. Holders of ReShape Shares. Please revise to provide a tax opinion regarding these tax matters and consequences to the ReShape shareholders. Refer to Regulation S-K, Item 601(b)(8).

# <u>U.S. Federal Income Tax Consequences of the Merger to U.S. Holders of Vyome Shares, page 128</u>

7. With reference to Exhibit 8.1, please revise to disclose that the disclosure in the section constitutes the opinion of Sichenzia Ross Ference Carmel LLP, or advise.

### Our Programs, page 171

- 8. We note your statement that the active agent in VT-1953 is approved by the US-FDA (NDA#22-308) as an eye drop for the treatment of bacterial conjunctivitis. We note that NDA#22-308 approved the drug Besivance for the treatment of bacterial conjunctivitis. An FDA approval is for the drug as a whole for a specific indication and not for a specific ingredient used in the formulation. As such, please revise the statement that the active agent in VT-1953 is approved by the US-FDA.
- 9. We note your revised disclosure in response to prior comment 24. Please remove the disclosure indicating that mycophenolate has been reported to be "clinically effective in unveitis." To the extent that you include the quotations from the published third party studies, please provide context by disclosing in the same paragraph, if true, that FDA has not approved mycophenolate or mycophenolate sodium to treat patients with uveitis and that FDA would need to review clinical trial data in order to determine that these drugs were safe and effective to treat uveitis.

### Our Strategy, page 173

10. We note your response to prior comment 25. Please also include a discussion here and on page 175 stating that, to date, you have not had any meetings with the FDA regarding Phase 3 trial protocols or regarding obtaining orphan drug designation, as you do on page 62, and that although you plan to receive orphan drug designation, there is no guarantee that such designation will be granted.

### Vyome's differentiated development engine, page 174

11. In your response letter, in response to prior comment 26 you state that you have revised disclosure on page 174. We do not note any changes on page 174, as such we reissue the comment. Please revise the last paragraph on page 174 to avoid the implication that the FDA provides general approval for use of a molecule.

#### Vyome's Product Portfolio, page 176

- 12. We note that in response to prior comment 22 you state that you plan to use approximately \$2.75 million for continued research and development towards regulatory work and pivotal trial of VT-1953. Please clarify if this plan is for one or both indications of VT-1053.
- 13. We note your response to prior comment 29. Please remove the MRT Platform from the pipeline table because its inclusion indicates that the platform has undergone clinical trials and received FDA approval. We would not object to a separate table for OTC products provided it is clear that these OTC products are out-licensed for sales in India.

## Pre-Clinical Toxicity Studies, page 180

- 14. We note your response to prior comment 31. Please revise to discuss the significance of each Cmax, AUC, and Tmax value. Further, define CDLQI at first use.
- 15. In response to prior comment 32 you state that Phase 1 studies are typically performed on healthy volunteers and do not need to be performed on patients with specific

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diseases for which it will be studied in pivotal studies. Please revise to clarify whether the Phase 1 open-label, safety, tolerability and pharmacokinetics study conducted on 12 patients with moderate to severe facial acne vulgaris will serve as the Phase 1 data for your future NDA applications pertaining to the MFW indication and the Inflammatory acne indication.

### Commercialization, page 199

16. In response to prior comment 39 you discuss the Development and Licensing Agreement with Sun Pharma. We note that Vyome is entitled to "additional sales linked milestone payments upon launch of the product based upon the outcome of a clinical." Please quantify the additional milestone payments and discuss the outcome of the clinical trial referenced.

### 4. Share Issuances, page 279

17. You disclose that the \$28,562 in the table on page 281 represents the equity portion of the purchase price. Please provide a table breaking out the components of the entire purchase price and clarify, if such is the case, that the \$28,562 is presented in thousands.

<u>Unaudited Pro Forma Condensed Combined Financial Statements</u>
5. Notes to Unaudited Pro Forma Condensed Combined Balance Sheet-Pro Forma Adjustments, page 281

18. Please separately disclose the amount of each adjustment included in adjustment C on page 282.

Please contact Gary Newberry at 202-551-3761 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Doris Stacey Gama at 202-551-3188 or Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Brett Hanson, Esq.