



DIVISION OF
CORPORATION FINANCE

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

September 18, 2023

Donna Cochener, Esq.
Interim Chief Executive Officer, General Counsel
Neoleukin Therapeutics, Inc.
188 East Blaine Street, Suite 450
Seattle, Washington 98102

Re: Neoleukin Therapeutics, Inc.
Registration Statement on Form S-4
Filed August 21, 2023
File No. 333-274095

Dear Donna Cochener:

We have reviewed your registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply 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 these comments, we may have additional comments.

Registration Statement on Form S-4

Cover Page

1. We note your disclosure that the closing of the Neurogene pre-closing financing is conditioned upon the satisfaction or waiver of the conditions to the closing of the merger. Please also clarify if the merger is conditioned upon the Neurogene pre-closing financing.

Questions and Answers About the Merger

Why are the two companies proposing to merge?, page 2

2. We note the disclosure that NGN-401 is a potentially "best-in-class" gene therapy for the treatment of Rett syndrome. Please revise references to "best-in-class" as this could imply an expectation of regulatory approval and appears to be speculative given the length of time and uncertainty with respect to securing marketing approval. If your intention is to

convey your belief that Neurogene's platform or product candidates utilize a novel technology or approach, you may discuss how the technology differs from technology used by competitors.

3. If appropriate, please revise to explain that if the merger is completed, the combined company will focus on developing Neurogene's product candidates, and it is anticipated that the combined company will not continue to develop Neoleukin's legacy product candidates.

What proposals will be voted on at the Neoleukin special meeting...?, page 3

4. You state that pursuant to the terms of the Merger Agreement, the following proposals must be approved in order for the merger to close and proceed to list Proposal Nos. 1, 2, and 4. In the same section you also state that the approval of Proposal No. 1 is a condition to completion of merger and approval of either or both Proposal Nos. 2 and 4 will be required to complete the merger. Please revise for consistency.

What are contingent value rights ("CVRs")?, page 4

5. We note from your disclosure on page 222 that you entered into an exclusive license agreement with the University of Washington where you were granted exclusive licenses and that you have also licensed rights to patents and own certain patents. Please clarify whether any of those assets are covered by the CVR Agreement.

Will the common stock of the combined company trade on an exchange?, page 7

6. We note your disclosure that the shares of the combined company are expected to be listed on Nasdaq. 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 the combined company 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 shares of the combined company.

Prospectus Summary

Neoleukin's Reasons for the Merger, page 13

7. Please balance your discussion here, as you do on page 117, to provide summary disclosure of the risks and other countervailing factors associated with your merger agreement that were considered by the board of directors of Neoleukin when it voted to approve the merger agreement.

Lock-Up Agreements, page 23

8. You state that certain of Neurogene's executive officers, directors, and stockholders have entered into lock-up agreements. Please revise to disclose when the lock-up agreements

will terminate as you do on page 176.

The Merger

Background of the Merger, page 105

9. You disclose that the transaction committee considered an initial 59 pharmaceutical companies and contacted 56 of those parties to determine their interest in a potential strategic transaction with Neoleukin. Please describe the criteria evaluated that helped the transaction committee determine which parties to contact to determine interest.
10. We note that at the meeting on March 5, 2023, representatives of Leerink Partners provided an update on the status of the outreach to the 16 potential reverse merger counterparties selected by the transaction committee to prioritize. Please include a description of the update provided.
11. We note that on March 9, 2023 the transaction committee identified Neurogene as a potential reverse merger counterparty. Please state how the transaction committee identified and initiated contact with Neurogene.
12. We note that on April 6, 2023 the Neoleukin's board of directors determined to proceed with detailed due diligence on three potential counterparties. Please discuss how the board of directors selected Neurogene, Party A, and Party B.

Financial Forecasts, page 122

13. We note from your chart on page 123 that Neurogene expects to receive total adjusted net revenues revenue in 2030, peaking in 2036, and beginning to decline thereafter. Please make clear what assumptions underlie these financial projections.

Opinion of Leerink Partners to the Neoleukin Board of Directors

Valuation Analysis - Discounted Cash Flow, page 128

14. We note the disclosure on page 129 that Leerink Partners' analysis resulted in an implied exchange ratio of approximately 2.6214x to 3.2989x. Please revise to state any conclusions Leerink Partners reached regarding the exchange ratio of 1.7378x used for purposes of the merger agreement based on the results of the discounted cash flow analysis.

Additional Factors Observed by Leerink Partners..., page 129

15. We note the disclosure on page 130 that Leerink Partners compared the resulting implied exchange ratio range from selected public companies of 1.0184x to 2.4707x to the estimated exchange ratio of 1.7378x. Please revise to state any conclusions Leerink Partners reached regarding the exchange ratio used for purposes of the merger agreement based on the results of the comparative public companies.

Neoleukin's Business

UW License Agreement, page 222

16. You state on page 223 that the Exclusive License Agreement with the University of Washington will expire upon the expiration of the last valid claim within the licensed patent rights. Please include the expected expiration date or otherwise advise.

Neurogene's Business

Neurogene's Team and Investors, page 242

17. You state that since inception, Neurogene has raised approximately \$245 million of capital from premier life science and mutual fund institutional investors, including funds and accounts managed by Blackrock, Cormorant Asset Management, EcoR1 Capital, Janus Henderson Investors, Redmile Group, Samsara BioCapital, and a healthcare investment fund. Please indicate that Neoleukin's stockholders should not rely on the named investors' investment decisions, that these investors may have different risk tolerances and, if true, that the securities purchased by those investors may have been conducted at a significant discount to price reflected in the merger agreement.

Neurogene's Pipeline, page 244

18. We note your pipeline table includes a row for a product candidate labeled "Early Discovery." Please limit your table to product candidates that are sufficiently material to Neurogene to warrant inclusion. If you believe such product candidate is sufficiently material, please explain why and identify the product candidate and indication.
19. Please include a Phase 3 column in the pipeline table or otherwise advise.

NGN-401 Phase 1/2 Clinical Trial, page 248

20. We note that Neurogene received clearance for its IND application from the FDA in January 2023 with enrollment advancing as planned in the second half of 2023. Please update your disclosure to clarify whether enrollment has begun or whether your timeline has been delayed.
21. You state that key pillars of your preclinical evidence demonstrated a "favorable safety profile." Since safety is a determination that is within the authority of the FDA, please revise or remove these statements and similar statements throughout your prospectus. Note that you may state your product candidate has been well tolerated, if accurate.

Bridging Sheep Study Comparing Ovine and Human CLN5 Transgene Administration, page 252

22. You state Neurogene plans to have a CMC meeting with the FDA in the second half of 2023. Please update your disclosure to clarify whether you have already met with the FDA, if you plan to meet towards the end of 2023, or whether your timeline has been delayed.

Intellectual Property, page 254

23. Please revise the disclosure in this section to more clearly describe the type of patent protection being sought (composition of matter, use, or process) in Neurogene's owned or in-licensed patent applications. Please also clearly distinguish between owned patents and licensed patents. For example, where you disclose that Neurogene owns 24 patent applications, please disclose the material product candidates, product groups or technologies to which those patent applications relate and when those patents would expire if the applications are granted.

License Agreements, page 257

24. Please revise to disclose the term and termination provisions for the license agreements described in this section.

Neurogene Management's Discussion and Analysis of Financial Condition and Results of Operations

Liquidity and Capital Resources, page 303

25. We note your disclosure that Neurogene expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances the clinical development of its product candidates, and that Neurogene expects that its costs will continue to increase significantly, including the costs associated with operating as a public company. We also note the disclosure concerning substantial doubt about Neurogene's ability to continue as a going concern. Please revise to disclose how the funds available to the post-merger company will be allocated. In particular, discuss whether the funds available to Neurogene after the merger and the pre-closing financing are expected to be sufficient for Neurogene to complete its current clinical trials. Also, clarify whether such funding is expected to be sufficient to operate the combined business for twelve months following the closing of the merger.

Unaudited Pro Forma Condensed Combined Financial Information

Notes to the Unaudited Pro Forma Condensed Combined Financial Information

5. Transaction Accounting Adjustments, page 333

26. Please address the following as it relates to your pro forma adjustments to reflect the reverse asset purchase, as illustrated by adjustment (d):
- Describe the analysis you performed in determining that Neoleukin does not meet the definition of a business. Refer to the guidance in ASC 805-10-55-3A to 55-9.
 - Explain your basis for determining that the purchase consideration should be based on the current estimated fair value of Neoleukin common stock. In this regard, ASC 805-50-30-2 states that in asset acquisitions where the consideration given is not in the form of cash, measurement is based on either the cost which shall be measured based on the fair value of the consideration given or the fair value of the assets (or net assets) acquired, *whichever is more clearly evident and, thus, more reliably*

measurable.

- Explain how you determined it was appropriate to record a contingent consideration liability related to the Contingent Value Rights (CVRs) given that you (a) determined the merger to be a reverse asset acquisition rather than a reverse business combination and (b) determined that the CVRs met the scope exception from derivative accounting. Cite the authoritative literature upon which you relied in your response.

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.

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.

You may contact Sasha Parikh at 202-551-3627 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Doris Stacey Gama at 202-551-3188 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Robert A. Freedman, Esq.