

September 28, 2023

**VIA EDGAR**

U.S. Securities and Exchange Commission  
Division of Corporation Finance  
Office of Life Sciences  
100 F Street, N.E.  
Washington, DC 20549-3628  
Attention: Sasha Parikh, Angela Connell, Doris Stacey Gama, Tim Buchmiller

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

Ladies and Gentlemen:

We are submitting this letter on behalf of Neoleukin Therapeutics, Inc. (the “**Company**”) in response to the comments of the staff (the “**Staff**”) of the U.S. Securities and Exchange Commission (the “**Commission**”) contained in the Staff’s letter dated September 18, 2023 (the “**Letter**”), regarding the Company’s Registration Statement on Form S-4 (File No. 333-274095) initially filed on August 21, 2023 (the “**Registration Statement**”). Concurrently herewith, we are transmitting Amendment No. 1 to the Registration Statement (“**Amendment No. 1**”). The numbered paragraphs below correspond to the numbered comments in the Letter and the Staff’s comments are presented in bold.

In addition to addressing the comments raised by the Staff in the Letter, the Company has revised Amendment No. 1 to update certain other disclosures. Capital terms used and not otherwise defined herein have the same meanings as specified in the Registration Statement.

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.***

In response to the Staff’s comment, we have revised Amendment No. 1 on the cover page and on pages 3 and 31.

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.***

In response to the Staff’s comment, we have revised Amendment No. 1 on page 2.

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.***

In response to the Staff’s comment, we have revised Amendment No. 1 on page 2.

*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.***

In response to the Staff’s comment, we have revised Amendment No. 1 on page 3.

*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.***

In response to the Staff’s comment, we have revised Amendment No. 1 on page 226.

*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.***

In response to the Staff’s comment, we have revised Amendment No. 1 on pages 7, 27, 30 and 148.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 15.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 24.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 108.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on pages 109 to 110.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 110.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on pages 112 to 113.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 125.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 132.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 133.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 226.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 245. We respectfully advise the Staff that the legacy institutional advisors of Neurogene did not purchase their securities at a discount to the 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***

In response to the Staff's comment, we have revised Amendment No. 1 on page 247.

19. ***Please include a Phase 3 column in the pipeline table or otherwise advise.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 247. We supplementally advise the Staff that gene therapy products do not follow the traditional clinical development paradigm. Because of the nature of Neurogene's gene therapy programs, which are being developed for patients with rare neurological diseases with high unmet medical need, its product candidates begin clinical evaluation in Phase 1/2 trials. The initial data collected from these Phase 1/2 trials may allow adaptation to integrate a pivotal trial design within a single study as opposed to the conduct of a separate classic Phase 3 trial. This may ultimately accelerate the approval process and allow the collection of confirmatory efficacy data post-approval.

Accordingly, Neurogene intends to work with the regulators to eschew the conduct of separate Phase 3 trials for its product candidates, and may, after completion of a Phase 1/2 trial, in accordance with regulatory authority guidelines and guidance, evaluate its product candidates in a pivotal trial. As a result, Neurogene has added a "Pivotal" trial column instead of a "Phase 3" trial column to its pipeline table in response to the Staff's comment.

*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.***

In response to the Staff's comment, we have revised Amendment No. 1 on pages 13, 244, 251, 259 and 296.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 252.

*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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 255.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 257.

License Agreements, page 257

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

In response to the Staff's comment, we have revised Amendment No. 1 on pages 261 and 312.

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.***

In response to the Staff's comment, we have revised Amendment No. 1 on page 308.

Unaudited Pro Forma Condensed Combined Financial Information Notes to the Unaudited Pro Forma Condensed Combined Financial Information

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.

In response to the Staff's comment:

- The Company evaluated the guidance in ASC 805-10-55-3A through 55-9 to determine whether Neoleukin met the definition of a business. As a first step, the Company performed the screen test described in ASC 805-10-55-5A through 55-5C, with reference to Neoleukin's assets as of June 30, 2023 at fair value. The results of the screen test did not result in substantially all of the fair value being concentrated in a single asset or a group of similar assets. Accordingly, the screen test was not met.

Next, the Company considered the framework in ASC 805-10-55-3A through 55-9 to determine if the set of assets includes, at a minimum, an input and a substantive process that together significantly contributes to the ability create outputs. Neoleukin possesses inputs, in the form of intellectual property, some long-lived assets such as property and equipment, the rights to use assets associated with an office lease and the ability to obtain materials or rights. Neoleukin's remaining employees perform general and administrative functions, as all research and development employees were previously terminated in the two reduction-in-force actions publicly announced in November 2022 and March 2023. The Company noted the guidance in ASC 805-10-55-5D, which states that "When a set does not have outputs (for example, an early stage company that has not generated revenues), the set will have both an input and a substantive process that together significantly contribute to the ability to create outputs only if it includes employees that form an organized workforce and an input that the workforce could develop or convert into output." Neoleukin is an early stage research & development company that has not generated revenues, and following the two reduction-in-force actions publicly announced in November 2022 and March 2023, its only employees are general and administrative staff. Accordingly, the Company concluded that Neoleukin does not possess employees that form an organized workforce capable of developing or converting inputs into one or more outputs, and as a result, does not meet the definition of a business.

- To determine the value of purchase consideration in the merger, the Company considered the guidance in ASC 805-50-30-2 and also the guidance in ASC 805-40-30-2, which states that, "In a reverse acquisition, the accounting acquirer usually issues no consideration for the acquiree. Instead, the accounting acquiree usually issues its equity shares to the owners of the accounting acquirer. Accordingly, the acquisition-date fair value of the consideration transferred by the accounting acquirer for its interest in the accounting acquiree is based on the number of equity interests the legal subsidiary would have had to issue to give the owners of the legal parent the same percentage equity interest in the combined entity that results from the reverse acquisition."

As described above, the Company concluded that Neoleukin did not meet the definition of a business under ASC 805, and as such, the transaction is considered an asset purchase. In addition, Neurogene will become a wholly owned subsidiary of Neoleukin and the legal acquiree, but is deemed to be the acquirer for accounting purposes, which meets the definition of a reverse acquisition. Based on these conclusions, the Company concluded that the proposed merger between Neoleukin and Neurogene represents a reverse asset purchase, and that the fair value of Neoleukin's shares, as a publicly traded company, multiplied by a fixed number of shares at closing, is more reliably determinable than the fair value of Neurogene's shares, which are privately held, or the fair value of the assets acquired. The fair value of net assets acquired or Neurogene's shares would involve a third party valuation using Level 3 fair value inputs whereas the fair value of Neoleukin's shares are based on quoted prices in an active market. Therefore, we believe the fair value of the consideration given using the Neoleukin stock price is *more clearly evident and, thus, more reliably measurable*.

The Company has added disclosure to page 337 to clarify its position.

- As the CVRs qualify for scope exceptions under ASC 815 and the estimated fair value of the assets acquired exceeds the initial estimate of the consideration paid, the Company first allocated the cost to the net assets acquired based on their relative fair values and reduced the value of all non-monetary assets to zero in accordance with ASC 805-50-30-3. After this reduction of non-monetary assets to zero, a material difference (“bargain purchase gain”) between the estimated fair value of the net assets still exceeded the estimate of the consideration paid. Next, due to the lack of prescriptive guidance for bargain purchase gains in asset acquisitions, the Company looked to interpretative guidance.

With reference to Deloitte’s Life Sciences interpretive guide entitled, “Life Sciences Industry Accounting Guide — March 2023,” the Company considered Section 4.2.2, Asset Acquisitions which states in part:

ASC 805-50 states that any liabilities incurred by the acquiring entity are part of the cost of the asset acquisition, but it does not provide any specific guidance on accounting for contingent consideration in an asset acquisition. However, in EITF Issue 09-2, the Task Force addressed contingent consideration in an asset acquisition. While a final consensus was not reached, the minutes of the September 9–10, 2009, EITF meeting state that “the Task Force reached a consensus-for-exposure that contingent consideration in an asset acquisition shall be accounted for in accordance with existing U.S. GAAP.” The following examples (not all-inclusive) were provided:

- “[I]f the contingent consideration meets the definition of a derivative, Topic 815 (formerly Statement 133) would require that it be recognized at fair value.”
- “Topic 450 (formerly Statement 5) may require recognition of the contingent consideration if it is probable that a liability has been incurred and the amount of that liability can be reasonably estimated.”
- “Subtopic 323-10 (formerly Issue 08-6) may require the recognition of the contingent consideration if it relates to the acquisition of an investment that is accounted for under the equity method.”

In addition to the above interpretative guidance, the Company also considered KPMG’s publication entitled “Handbook to Asset Acquisitions — May 2023”, and reviewed the answer to question 4.6.30, “How does the acquirer measure a bargain purchase amount when contingent consideration is also included?” The interpretative guidance provided in the answer KPMG provided to this question is consistent with Deloitte’s interpretative guide above.

Given the lack of authoritative guidance, the Company analogized to the guidance in ASC 323-10-25-2A and ASC 323-10-30-2B and recognized contingent consideration in the acquisition of an equity method investment. That guidance states that if an entity acquires an equity method investment in which the fair value of its share of the investee’s net assets exceeds its initial cost and the agreement includes contingent consideration, the entity recognizes a liability equal to the lesser of:

- The maximum amount of contingent consideration.
- The excess of the fair value of the net assets acquired over the initial consideration paid.

Based on this guidance, the Company concluded that it was appropriate to record a contingent consideration liability equal to the maximum amount of contingent consideration payments that could be paid under the CVR. After the guidance was applied, a smaller bargain purchase gain still remained and was recorded as other income (expense) in the unaudited proforma condensed combined statements operations for the year ended December 31, 2022.

The Company has added disclosure to Note 1 — *Contingent Value Rights Agreement* to clarify its position.

## 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.***

In response to the Staff’s comment, we have revised Amendment No. 1 to file the form of preliminary proxy card as an appendix, which will be done in a future filing.

\* \* \*



Should the Staff have additional questions or comments regarding the foregoing, please do not hesitate to contact me at (206) 389-4524, or, in my absence, Julia Forbess at (415) 875-2420, or Chelsea Anderson at (206) 389-4516.

Sincerely,

FENWICK & WEST LLP

/s/ Robert A. Freedman

Robert A. Freedman, Esq.

cc: Julia Forbess, Esq.  
David Michaels, Esq.  
Chelsea Anderson, Esq.  
Fenwick & West LLP

Donna M. Cochener, Esq., Interim Chief Executive Officer  
Neoleukin Therapeutics, Inc.