



DIVISION OF
CORPORATION FINANCE

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

June 9, 2023

Robert Cobuzzi, Jr., Ph.D.
President and Chief Executive Officer
Diffusion Pharmaceuticals Inc.
300 East Main Street, Suite 201
Charlottesville, Virginia 22902

**Re: Diffusion Pharmaceuticals Inc.
Registration Statement on Form S-4
Filed May 11, 2023
File No. 333-271823**

Dear Robert Cobuzzi:

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

Questions and Answers About Diffusion's Special Stockholder Meeting And The Merger
What is the Merger, page 12

1. Please briefly discuss Diffusion's \$12.0 million net cash Merger closing condition and the potential impact of this condition on the merger. Additionally, given the Exchange Ratio is subject to adjustment based on Diffusion's net cash at the time of the Merger's closing, please disclose Diffusion's current amount of net cash, as calculated pursuant to the terms of the Merger Agreement.

As a holder of Diffusion Common Stock, what happens if I do not return a proxy card or otherwise provide proxy instructions, as applicable?, page 17

2. Please revise to explain what happens if shareholders of Diffusion Common Stock do not return their proxy card. As currently drafted, this Q&A only explains what happens if shareholders return a signed proxy card without marking any selections or do not give instruction to their brokers.

Risk Factors

Risks Related to Diffusion, page 47

3. Please include a risk factor addressing any material risks associated with the pending legal proceeding by Paul Feller, the former Chief Executive Officer of Diffusion's legal predecessor, which you mention on page 195. Alternatively, tell us why you believe risk factor disclosure is not required.

Background of the Merger, page 106

4. Please revise to more specifically describe the criteria proposed to assess potential counterparties. For example, if you were looking for parties with a candidate that had achieved a specific stage of development, what stage was that? What were you looking for with respect to the depth of the pipeline table? Additionally, please discuss whether the criteria and/or the prioritization of the criteria changed over time. We note that the counterparty's willingness to commit to continuing to develop TSC following the consummation of the transaction is included in the list of criteria, but we also note your statement on page 21 that you will continue to look for opportunities to sell or out-license TSC in newly diagnosed GMB patients. Please clarify when it was determined that the combined company would not continue to develop TSC.
5. Please clarify how you narrowed the 16 companies that submitted non-binding indications of interest between November 14, 2022 and November 18, 2022 to the five companies that Diffusion's board of directors, members of management, representatives of CG and Dechert identified on November 21, 2022. To the extent that you used the Criteria to eliminate the other nine, please explain how the Criteria was used in the selection process.

EIP Reasons for the Merger, page 122

6. Please expand the bullet point indicating that the shares of Diffusion Common Stock issued to EIP equity holders will be registered on a Form S-4 registration statement to clarify that certain stockholders who have agreed to vote all of their shares of EIP capital stock in favor of the merger will also not have their shares registered on the Form S-4.

The Merger

Opinion of Diffusion's Financial Advisor, page 123

7. We note disclosure on page 124 that, in connection with Canaccord Genuity's review of the Merger and developing of its opinion, it reviewed certain information, "among other things." Please revise to include all material information reviewed by Canaccord Genuity.

Summary of Financial Analyses, page 125

8. Please revise the discussions of the "Diffusion Selected Reverse Mergers Analysis," "EIP Selected Public Companies Analysis," and "EIP Selected Initial Public Offering Precedent Analysis" to describe the factors CG used in determining they were "relevant to consider," including classifications of industry sector(s) and key product development stage(s) used. To the extent CG determined that they shared "similar business characteristics," describe these characteristics and any other factors that warranted inclusion in the analyses. To the extent there were other companies or transactions that met the selection criteria that were not included in the analyses, please disclose this information and explain why they were excluded from the analyses.
9. Please explain the statement, "[b]ased on its analysis and other considerations that CG deemed relevant in its experience and professional judgement, CG derived a range of implied total enterprise values for Diffusion based on the first quartile and third quartile enterprise values of the companies in the selected reverse mergers of (\$15.8) million and \$2.6 million, respectively." Please explain what other considerations CG deemed relevant and how they impacted CG's analysis.
10. For each of the analysis presented, please disclose the values calculated for each company or transaction and clarify what value(s) were used to calculate the implied value for Diffusion post-merger. For example, did CG use the mean, median, high or low value from the calculations of the comparable companies/transactions?

Certain Unaudited Long-Range Financial Projections of EIP, page 131

11. Please revise to:
 - explain why you chose to use a 14-year time period for the Financial Projections;
 - explain how you arrived at the probability of regulatory approval for neflamapimod;
 - disclose the date you assumed that neflamapimod will be granted regulatory approval;
 - discuss whether the Financial Projections factored in the possibility of FDA approval of new competitive products.Additionally, confirm that all information that Canaccord Genuity considered in reaching its fairness determination, including any of these assumptions, is disclosed in this filing, or revise the filing accordingly.

Diffusion Business, page 177

12. Please clarify that the combined company's business following the merger will not include continuing to develop TSC.

TSC's Demonstrated Clinical Safety Profile, page 178

13. Please revise this heading and paragraph to remove any implication that TSC, which has not been approved by the FDA, is safe or effective. Safety and efficacy determinations are in the exclusive purview of the FDA or other comparable foreign regulators. In this regard, please similarly revise your disclosures on this page that "TSC has been observed to be safe" and that your clinical trials have demonstrated "TSC's safety and effects on oxygenation[.]"

EIP Business

Overview, page 196

14. We note the pipeline table on page 197. Please define the term "WW."
15. Please include a description of the Vertex agreement, including amounts paid to date, aggregate potential development milestone payment obligations, aggregate potential sales milestone payment obligations, the royalty percentage (or a range no greater than 10 points), minimum annual expenditures, diligence requirements and when your royalty obligation expires.

Our Strengths, page 198

16. Given your phase 2b trial of neflamapimod is still ongoing, your disclosure that "approval for neflamapimod could be obtained with the conduct of a single 24-week treatment duration Phase 3 study involving a few hundred subjects, that would have to simply replicate the results of the planned Phase 2b trial" is speculative. Moreover, it does not align with your risk factor disclosure on page 73 that there has never been an approval of a drug in DLB which "could result in a longer than expected regulatory review process[.]" Please revise.

Efficacy Results in Phase 2a Trial of Neflamapimod in DLB, page 203

17. Please expand your discussion to explain how to interpret p-values.

Planned Phase 2b Clinical Study in DLB, page 209

18. We note disclosure on page 210 that EIP was awarded a \$21 million grant from the National Institutes of Health's National Institute on Aging in January 2023 that is estimated to fully fund development costs associated with the planned Phase 2b trial. We also note disclosure on page 66 that these funds will be disbursed over the course of the trial as costs are incurred and that the grant is "subject to certain conditions for funding in

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subsequent years." Please disclose what portion of these funds have been disbursed and any material conditions for future funding. If there is a written agreement underlying this grant, please file the agreement as an exhibit pursuant to Item 601(b)(10) of Regulation S-K.

Principal Stockholders of EIP, page 293

19. Please identify in a footnote to the table all natural persons who have voting and/or investment power over the shares held by AI New Holdings 12 LLC. Please make a corresponding revision to the footnote to the Principal Stockholders of the Combined Company table on page 296, as appropriate.

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 Gary Newberry at 202-551-3761 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Dillon Hagius at 202-551-7967 or Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: John Alessi