United States securities and exchange commission logo

January 11, 2023

Frederic Guerard, Pharm.D.
President and Chief Executive Officer
Graybug Vision, Inc.
203 Redwood Shores Parkway, Suite 620
Redwood City, CA 94065

Re: Graybug Vision, Inc.
Preliminary Proxy Statement on Schedule 14A
Filed December 14, 2022
File No. 001-39538

Dear Frederic Guerard:

We have reviewed your filing 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 these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments.

Preliminary Proxy Statement on Schedule 14A filed December 14, 2022

CalciMedica, Inc., page 10

1. We note your disclosure that Auxora has demonstrated a favorable safety profile. Please note that determinations of safety and efficacy are solely within the authority of the FDA and comparable regulatory bodies; therefore, please revise your prospectus to remove all references and/or implications of safety and efficacy.

Summary
Private Placement, page 17

2. We note your description of the securities purchase agreement here and on page 156. In your description of the agreement, please identify each purchaser who is purchasing shares pursuant to such agreement and who is expected to be a beneficial owner of 5% or more of the outstanding shares of the combined company following the financing and merger.

Risks Related to the Merger, page 23

3. We note your disclosure on page 143 that the representations and warranties contained in the merger agreement will terminate at the effective time of the merger. Please include appropriate risk factor disclosure.

The bylaws of the combined company will provide that the Court of Chancery of the State of Delaware is the exclusive forum..., page 90

4. Please revise your risk factor to disclose that there is also a risk

that your
exclusive forum provision may result in increased costs for
stockholders to bring a claim.
Opinion of Graybug's Financial Advisor, page 106

5. Please supplementally provide us with copies of all materials prepared
by Piper Sandler
and shared with your board of directors and their representatives,
including any board
books, transcripts and summaries of oral presentations, that were
material to the board's
decision to approve the merger and the transactions contemplated
thereby.
Financial Analyses of CalciMedica, page 108

6. Please revise to disclose whether Piper Sandler excluded any companies
or transactions
meeting the selection criteria from its selected public companies
analysis and its selected
IPOs analysis. If so, revise to state why Piper Sandler excluded the
companies or
transactions. If Piper Sandler used additional factors in its
selection criteria other than
professional judgment and companies with small molecule drug
development that targeted
specialty indications (excluding oncology) with lead product
candidates in Phase 2 stage
clinical trials, discuss those factors. For example, without
limitation, describe whether
Piper Sandler considered the number of product candidates each company
was
developing, the clinical development of each product candidate for
each indication and
how Piper Sandler considered the addressable market (including the
expected dosing
period of Auxora) in the selection criteria since CalMedica appears to
be pursuing acute
indications.
Discounted Cash Flows Analysis, page 110

7. Please expand your disclosure here to provide the industry standards
published by BIO of
the statistical probability in achieving specified development
milestones by biotechnology
companies that Graybug used to adjust CalciMedica's estimates. Revise to
explain how
Graybug applied these statistical probabilities to adjust the
CalciMedica projections.
Revise to provide the CalciMedica projections provided to the Board and
the data and
FirstName LastNameFrederic Guerard, Pharm.D.
assumptions underlying those projections. Discuss why you considered
projections
Comapany NameGraybug
extending over a 16Vision, Inc. to be reasonable given CalciMedica
s current stage of
year period
Januarydevelopment.
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Page 3 11, 2023 Page 3
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Graybug-Adjusted CalciMedica Management Projections, page 117

8. Disclose and explain the bases for and the nature of the material
assumptions referenced
in the first full paragraph on page 118 that underlie the line items
presented in the
Financial Projections summary table. Please ensure that the level of
detail provided is
sufficient for a shareholder to evaluate and understand the
reasonableness of the
assumptions, uncertainties and/or contingencies underlying the
projections as well as the

inherent limitations on the reliability of projections in order to make informed decisions.

In regard to the total revenue and EBITDA projected amounts, please specifically address the growth rates as well as disclose your assumptions as to which product candidates were assumed to have received approvals and identify the jurisdictions in which such approvals were assumed to be received by period. Clearly disclose the limitation that regulatory approval is outside of your control.

9. You note on page 118 that the Financial Projections cover multiple years, and that this information by its nature becomes subject to greater uncertainty with each successive year. With respect to the length of the projections, please disclose the basis for projections beyond year five, including if the forecasts reflect more than simple assumptions about growth rates. Explain how management and the board relied upon the Financial Projections and how they determined that they are reasonable, particularly in light of the extensive length of the forecasts and since CalciMedica is a clinical stage company with limited operations and no approved products. Specifically, address the reliability of the projections related to the later years presented.

Conditions to the Completion of the Merger, page 136

10. Please clarify whether the CalciMedica private placement for an aggregate purchase price of $10.3 million is a condition to closing and, if so, whether such condition is waivable.

Plan Administration, page 170

11. We note your disclosure that the combined company s board of directors generally has the authority, without the approval of stockholders, to reprice outstanding options or stock appreciation rights. Please include appropriate disclosure as to whether proxy advisory firms could find such repricing without stockholder approval contrary to a performance-based pay philosophy.

CalciMedica Business

Overview, page 183

12. Please revise to remove statements that CalciMedica is developing first-in-class therapeutics as such statement are speculative given CalciMedica s current stage of development.

13. We note CalciMedica states on pages 183, 188, and 244 that it believes it is the leading company in the discovery and development of CRAC channel inhibitors. Please revise to provide the basis for this statement.

14. We note the statement on page 183 and elsewhere regarding CalciMedica's CRSPA trial that "all patients who have received a full course of therapy have had rapid resolution of their symptoms." Please revise to provide the data supporting this claim, including the typical timeframe for symptom resolution using the current standard of care. Please also indicate whether the results of this trial for the first cohort were statistically significant.

15. We note your disclosure on page 183 and elsewhere that you intend to seek an accelerated approval designation from the FDA. Please revise to include balancing disclosure that an

accelerated approval pathway may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that your product candidate will receive marketing approval.

Our Pipeline, page 184

16. We note your disclosure on page 39 that you plan to conduct a significant portion of the ongoing CARPO trial in India. Please revise to disclose the regulatory status and any development and marketing plans for CalciMedica s product candidates for AP in India. To the extent that you are conducting your clinical trials in foreign jurisdictions and plan to seek FDA approval, please include risk factor disclosure indicating that the FDA may require you to conduct additional trials if it does not accept data from your trials or believes that additional data is necessary to supplement your trial data.

Auxora for the treatment of Acute Kidney Injury, page 186

17. Please disclose the basis for your disclosure that you may be in a position to initiate a Phase 2 trial for your acute kidney injury indication without having to conduct a phase 1 clinical trial.

Auxora, a Selective CRAC Channel Inhibitor, page 192

18. Please revise your disclosure on page 192 to remove the statement that Auxora is particularly well-suited for the treatment of acute critical illnesses because it creates an improper inference that Auxora is safe and effective and such determinations may only be made by the FDA or similar regulator.

Unaudited Pro Forma Condensed Combined Financial Statements, page 261

19. You disclose that while Graybug is planning to to sell its technology, such sale has not been finalized as of the date of your proxy statement, and is only expected to occur shortly after the consummation of the planned merger. Accordingly, the sale transaction is not reflected in the unaudited pro forma condensed combined financial statements. Please tell us why you believe the merger should be accounted for as a reverse recapitalization, and

your consideration of accounting for the transaction under ASC 805, given that Graybug Vision Inc. does not appear to be a public shell. Explain to us your consideration of the criteria in ASC 805-10-55-10 through 55-15 in establishing the accounting for the planned merger. In addition, please tell us why it was considered appropriate to not present pro forma adjustments for non-recurring items separately.

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.

You may contact Ibolya Ignat at 202-551-3636 or Daniel Gordon at 202-551-3486 if you have questions regarding comments on the financial statements and related matters. Please contact Daniel Crawford at 202-551-7767 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

FirstName LastNameFrederic Guerard, Pharm.D.

Division of