

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

March 10, 2023

Jennifer J. Rhodes, Esq. General Counsel Angion Biomedica Corp. 51 Charles Lindbergh Boulevard Uniondale, New York 11553

Re: Angion Biomedica Corp.

Registration Statement on Form S-4

Filed February 13, 2023

File No. 333-269741

Dear Jennifer J. Rhodes:

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 the Merger, page 1

1. Please include a question and answer that addresses the material U.S. federal income tax consequences, if any, of the Merger to Angion stockholders.

What are the material U.S. federal income tax consequences of the Merger to U.S. holders of Elicio shares?, page 5

2. We note your representation on page 5, and beginning on page 123, that Angion and Elicio "intend" the merger to qualify as a reorganization within the meaning of Section 368(a) of the U.S. Internal Revenue Code of 1986, as amended (the "Code"). Please revise your disclosure here and throughout to provide counsel's firm opinion for each material tax consequence, including whether the Merger will qualify as a reorganization,

or to explain why such opinion cannot be given. If the opinion is subject to uncertainty, please (1) provide an opinion that reflects the degree of uncertainty (e.g., "should" or "more likely than not") and explains the facts or circumstances giving rise to the uncertainty, and (2) provide disclosure of the possible alternative tax consequences including risk factor and/or other appropriate disclosure setting forth the risks of uncertain tax treatment to investors. Please refer to Item 601(b)(8) of Regulation S-K and Section III.A. of Staff Legal Bulletin 19, Legality and Tax Opinions in Registered Offerings.

#### Nasdaq Stock Market Listing, page 17

3. Please disclose whether the merger is conditioned upon receiving Nasdaq listing approval to trade on the The Nasdaq Global Market. Also disclose whether the terms of the merger agreement permit this closing condition to be waived without recirculation or resolicitation. In this regard, we note that the disclosure on page 126 seems to indicate that this condition could be waivable.

#### **Risk Factors**

Elicio's success will depend upon intellectual property and proprietary technologies...., page 62

4. Please expand this risk disclosure to make it clear that Elicio does not currently own any patents. In this regard, we note your disclosure on page 203 that Elicio does not own any issued patents covering clinical product candidates and the patent portfolio owned by Elicio currently comprises only applications.

#### **Risk Factors**

The certificate of incorporation of the combined company will provide that the Court of Chancery..., page 84

5. We note your disclosure that the combined company's amended and restated certificate of incorporation and amended and restated bylaws will also provide the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against the combined company or any of its directors, officers, employees, or agents and arising under the Securities Act. Please disclose that there is uncertainty as to whether a court would enforce such a provision. Please also state that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. In that regard, we note that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Additionally, please revise to note that this provision may also make it more costly for a shareholder to bring a claim against you.

#### The Merger

Angion Reasons for the Merger, page 105

6. We note your disclosure in the fourth bullet point of the second paragraph. In an

appropriate location, please expand your disclosure to provide material information on the clinical and scientific diligence and analysis process that formed the basis for the Angion Board's belief as to the market opportunity for Elicio's product candidates.

## Opinion of Angion's Financial Advisor, page 109

- 7. For the disclosure under "Selected Public Companies Analysis" and "Selected Precedent Initial Public Offering Analysis," revise to describe in more detail the underlying methodology and selection criteria used for selecting the companies listed for comparison purposes, including the general characteristics of the selected companies such as the number of product candidates in the pipeline, stage of clinical development, total addressable market and how those companies compared to Elicio.
- 8. Please supplementally provide us with copies of all materials prepared by Oppenheimer 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.

# Certain Unaudited Financial Projections, page 114

- 9. With respect to the Financial Projections:
  - Disclose and explain the bases for and the nature of the material estimates and assumptions that underlie the line items presented in the Financial Projections summary table. Please ensure that the level of detail provided is sufficient for an investor to evaluate and understand the reasonableness of the estimates, assumptions, uncertainties and/or variables underlying the Financial Projections as well as the inherent limitations on the reliability of the Financial Projections in order to make informed voting and investment decisions. As to the Total Global Revenue line item, please specifically address the growth rates as well as identify the material product revenue streams underlying these projections and the date you assume Elicio will be granted regulatory approval for each indication for each significant market reflected in the Total Global Revenue forecast.
  - You note on page 115 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 straight line growth assumptions. Explain how management and the Angion 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 Elicio is a clinical stage company with no approved products to date and the uncertainty regarding regulatory approvals. Specifically, address the reliability of the projections related to the later years presented.

- You disclose that "Elicio's management prepared a preliminary internal financial forecast for Elicio, which Angion's management adjusted to reflect certain assumptions applicable to Elicio's assets as well as to Elicio's expenses based on industry metrics consistent with the experience and judgment of Angion's management and the Angion Board." Please describe in more detail the process undertaken to formulate the forecasts and the parties who participated in the preparation of the forecasts. Explain and quantify the adjustments that Angion's management made to the initial forecasts provided by Elicio and the reasons for the adjustments, including how Angion's management and board were in a position to make adjustments to Elicio's preliminary internal financial forecasts given the different natures of Angion's and Elicio's businesses and product development efforts.
- Disclose your assumptions as to which product candidates were assumed to have received approvals and identify the assumed regulatory jurisdictions in which they received such approvals by period. Clearly disclose the limitation that regulatory approval is outside of your control.
- We note the Financial Projections cover a period through 2039. Please indicate the basis for why you believe that this period is a reasonable period to project. For example, if that period is tied to expected patent protections, please make the material assumptions underlying that basis clear.
- We note the risks described under the caption "Any future product candidates for which Elicio intends to seek approval as biologic products may face competition sooner than anticipated" on page 46. Since the Financial Projections cover a period through 2039, please disclose whether the Financial Projections factored in any of those risks.

#### Miscellaneous, page 114

10. We note your disclosure that "[a]s Angion was aware and as was disclosed to the Angion Board on January 13, 2023 in connection with rendering the opinion of Oppenheimer, Daniel Geffken, the Chief Financial Officer and a member of the Elicio Board, was also the Chief Financial Officer for OPY Acquisition Corp. I (OPY1), and the sponsor of OPY1 was an affiliate of Oppenheimer." If this relationship created a potential source for a conflict of interest, please explain the nature of the potential conflict in clearer terms and how Angion's board viewed that potential source of conflict. Also, we note that Mr. Geffken is referred to in this section as the Chief Financial Officer of Elicio but elsewhere as the Interim Chief Financial Officer. Please revise for consistency.

<u>Description of Angion's and Merger Sub's Business</u> <u>Angion's ROCK2 Inhibitor Program, page 177</u>

11. For each patent family, please specify the type of patents or pending patents (e.g.,

composition of matter, method of use or process) for Angion's Rock2 Inhibitor Program.

## Description of Elicio's Business

## Overview, page 181

- 12. Please revise your disclosure to clarify the meaning of any significant scientific or technical terms or acronyms the first time they are used in order to provide context for such terms and better ensure that lay readers will understand the disclosure. By way of example, we note the usage of "PDAC" and "CRC" on page 9 and 181.
- 13. We note the disclosure in the last full paragraph on page 181 that "Elicio is demonstrating its lymph node targeting technology can create effective therapeutics...." As safety and efficacy determinations are solely within the authority of the FDA and comparable regulatory bodies, it is too early to state or imply that product candidates are safe or effective. Please revise your disclosure as appropriate.
- 14. With respect to Elicio's scientific advisory board, if material, please include disclosure in an appropriate location that describes the role or function of the scientific advisory board, and indicates whether there are any rules or procedures governing this board. Please also disclose how members of the scientific advisory board are compensated.

## Elicio's Pipeline, page 182

- 15. Please revise Elicio's pipeline table to include a column for Phase 3. We also note that you have two programs that have undisclosed product candidates. Please explain to us why each of those programs is sufficiently material to Elicio's business to warrant inclusion in the pipeline table at this time or revise your table as appropriate.
- 16. We note your disclosure in the last full paragraph on page 181 that examples of mutant BRAF-driven and TP53-expressing cancers include melanoma, CRC, and NSCLC. Given that disclosure, please tell us why the indications for ELI-008 and ELI-007 are "Undisclosed" or revise the pipeline table to include the indications.
- 17. From your disclosure on page 190 under the heading "ELI-002 Clinical Development Program" it appears that Elicio has two trials underway: (1) the Phase 1 AMPLIFY-201 trial with a 2-peptide (2P) formulation, and (2) the Phase 1/2 AMPLIFY-7P, using the 7-peptide formulation of ELI-002. Please tell us whether presenting each of these trials in the pipeline table separately would be appropriate. We note in this regard that the arrow for ELI-002 in the current pipeline table could be interpreted as indicating Elicio is close to the end of Phase 1 rather that at the initial or middle stages of Phase 1 in these trials. Please ensure your arrows align with your disclosure.
- 18. We note your disclosure on page 194 that the combination trial of ELI-002 and cemiplimab, called "AMPLIFY-202," will be conducted by Elicio and is expected to begin after the Phase 1a safety evaluation portion of AMPLIFY-7P completes. Given this disclosure, please tell us why the arrow for ELI-002 + cemiplimab indicates that trial is

half way through Phase 1 or revise as appropriate. We also note your disclosure that this trial is conditioned upon the receipt of additional funding. Please disclose if the cash acquired in the proposed merger will be sufficient to commence this trial after the Phase 1a safety evaluation portion of AMPLIFY-7P completes or clarify that future funding beyond the merger may be required.

19. Please revise the pipeline table and footnotes to ensure that the text is readable.

The results of Elicio's preclinical studies have provided evidence of ELI-002 activity against KRAS mutations, page 188

20. We note your disclosure that when vaccinated mice were infused with mKRAS-pulsed target cells, only those who had received AMP vaccines were able to generate an mKRAS G12D-specific cytotoxic response and that in those animals, approximately 50% of mKRAS-target cells were eliminated over the course of 16 hours, while comparator vaccines were inactive. We also note your disclosure that one of the challenges of current immunotherapies is that the tumor environment is compounded by the difficulties of T cell infiltration into the tumor microenvironment and mechanisms by which tumor cells evade detection by the immune system. Please indicate whether you generated any preclinical data that indicated cytotoxic activity against solid tumors, or if the studies were limited to mKRAS-pulsed target cells, clarify the extent to which the results described in this section may not be applicable to solid tumors in humans and indicate whether immunosuppressive effects were studied or observed. Please also disclose the number of mice that were dosed and indicate whether the observed 50% elimination rate was statistically significant.

# AMPLIFY-7P: A Phase 1/2 clinical trial of ELI-002, page 192

21. We note your disclosure that the Phase 2 portion of this trial is conditioned upon the receipt of additional funding. Please disclose if the cash acquired in the proposed merger will be sufficient to commence the Phase 2 portion of this trial or clarify that future funding beyond the merger may be required.

## ELI-004: Elicio's Universal Adjuvant, page 197

22. We note your disclosure that "few serious adverse events have been observed." Please specify the number and the types of such serious adverse events.

## AMP Immune Cell Therapy AMP-lifiers, page 200

23. Please revise throughout to remove any inference regarding regulatory approval or the safety and efficacy of your product candidates or explain to us why these statements are appropriate given the stage of your product candidates. By way of example only, we note the disclosure on page 200 regarding preclinical trials that promoted therapeutic efficacy. Please remove these statements, and any similar statements, as conclusions of safety and efficacy are within the sole authority of the FDA and comparable foreign regulators.

# Future Cash Needs and Funding Requirements, page 236

24. We note your references in the third and sixth bullet points to ongoing clinical trials of ANG-3070. However, we note your disclosure on page 174 that Angion suspended the advancement of ANG-3070 in clinical studies. Please revise to reconcile your disclosure.

#### **Exhibits**

25. We note the statement in Exhibit 99.1 that Oppenheimer "disclaim[s] that we come within the category of persons whose consent is required under Section 7 of the Securities Act of 1933, as amended, or the rules and regulations of the Securities and Exchange Commission promulgated thereunder, nor do we admit that we are experts with respect to any part of the Registration Statement within the meaning of the term 'experts' as used in the Securities Act or the rules and regulations promulgated thereunder." Please have Oppenheimer revise the consent to remove this disclaimer, as it appears that Oppenheimer is required to provide a consent under Section 7 of the Securities Act because it provided an opinion that is summarized in and included in the registration statement and which is attributed to Oppenheimer.

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 Christine Torney at 202-551-3652 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Jimmy McNamara at 202-551-7349 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Brett D. White, Esq.