BEIJING BOSTON BRUSSELS DUBAI FRANKFURT
JOHANNESBURG LONDON LOS ANGELES NEW YORK
PALO ALTO SAN FRANCISCO SEGUL SHANGHAI WASHINGTON

Covington & Burling LLP One International Places Suite 1020 Boston, MA 02110-260 T +1 617 603 8800

September 9, 2024

#### VIA EDGAR

U.S. Securities and Exchange Commission Division of Corporation Finance Office of Life Sciences 100 F Street, N.E. Washington, D.C. 20549 Attn: Tracie Mariner

Kevin Vaughn Tyler Howes Tim Buchmiller

Re: Cartesian Therapeutics, Inc.

**Registration Statement on Form S-1** 

Filed August 2, 2024 File No. 333-281204

Dear Ms. Mariner, Mr. Vaughn, Mr. Howes and Mr. Buchmiller,

On behalf of Cartesian Therapeutics, Inc. ("<u>Cartesian</u>" or the "<u>Company</u>"), we are submitting this letter in response to a letter, dated August 29, 2024, from the staff (the "<u>Staff</u>") of the Securities and Exchange Commission (the "<u>Commission</u>") with respect to the Company's Registration Statement on Form S-1 filed with the Commission on August 2, 2024 (the "<u>Registration Statement</u>"). The Company is concurrently filing Amendment No. 1 to the Registration Statement (the "<u>Amended Registration Statement</u>"), which includes changes to reflect responses to the Staff's comments and other updates.

The numbering of the paragraphs below corresponds to the numbering of the comments in the letter from the Staff. For the Staff's convenience, we have incorporated the text of the Staff's comments into this response letter in italics. Unless otherwise indicated, page references in the responses correspond to the page numbers in the Amended Registration Statement, and page references otherwise correspond to the page numbers in the Registration Statement. Capitalized terms used in this letter but not otherwise defined herein shall have the meanings set forth in the Amended Registration Statement.

The responses provided herein are based on information provided to Covington & Burling LLP.

Registration Statement on Form S-1

Prospectus Summary

Company Overview, page 4

1. Please explain the term "durable clinical benefit" as used on page 4 to briefly describe the results of your Phase 2 clinical trial of Descartes-08 in patients with myasthenia gravis. Please also explain the term "clinically meaningful" as used on page 56, and throughout your business section, to describe results observed from your clinical trials.

#### Response to Comment No. 1:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosure on pages 58, 59 and 60 of the Amended Registration Statement in response to the Staff's comment.

#### Risk Factors

## Anti-takeover provisions in our charter documents and under Delaware law..., page 35

2. We note that your forum selection provision identifies the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation, including any "derivative action." Please disclose whether this provision applies to actions arising under the Securities Act or Exchange Act. In that regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and 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. If the provision applies to Securities Act claims, please also revise your prospectus to state that there is uncertainty as to whether a court would enforce such provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. If this provision does not apply to actions arising under the Securities Act or Exchange Act, please also ensure that the exclusive forum provision in your governing documents states this clearly, or tell us how you will inform investors in future filings that the provision does not apply to any actions arising under the Securities Act or Exchange Act. Please also expand your risk factor to indicate that the forum selection provision may increase costs for shareholders to bring a claim.

## Response to Comment No. 2:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosure on pages 34 and 139 of the Amended Registration Statement in response to the Staff's comment.

#### Management's Discussion of Financial Condition and Results of Operations

## Results of Operations

## Comparison of the Three Months Ended March 31, 2024 and 2023, page 41

- 3. Please revise to address the following regarding your disclosure on page 39 that you track your external research and development costs on a program-by-program basis:
  - Please expand your disclosure of the changes in research and development expenses for each period presented to separately quantify the
    costs incurred for each of your key research and development programs.
  - For the research and development expenses that you do not track by program, provide a breakdown by type or nature of expense.
  - Provide a background discussion of the "strategic reprioritization" that you reference on pages 41 and 42.
  - Confirm that you will provide similar disclosure in your future periodic filings.

#### Response to Comment No. 3:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosure on page 41 of the Amended Registration Statement to, among other things, clarify that the Company does not track its research and development expenses on a program-by-program basis because its research and development expenses are shared across multiple development programs.

The Company respectfully advises the Staff that the phrase "strategic reprioritization" on page 45 of the Amended Registration Statement (pages 41 and 42 of the Registration Statement) is being used to describe the shift in the Company's focus following the Merger to devote substantially all of its financial resources and efforts to developing its mRNA-based therapies for the treatment of autoimmune diseases.

The Company confirms that it will provide similar disclosure in its future periodic filings.

#### Comparison of the Years Ended December 31, 2023 and 2022, page 42

4. We note you included audited financial statements for the three fiscal years ended December 31, 2023 of Cartesian Therapeutics, Inc. in your filing. However, you have only included an annual discussion of the Company's results of operations and cash flows for the year ended December 31, 2023 compared to the year ended December 31, 2022. Please include a discussion of the results of operations and cash flows for the year ended December 31, 2022 compared to the year ended December 31, 2021, or expand your disclosure to provide a statement that identifies the location in a prior filing where the omitted discussion may be found. See Instruction (b) 1 to Item 303 of Regulation S-K.

## Response to Comment No. 4:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosures on page 39 of the Amended Registration Statement in response to the Staff's comment.

## **Business**

## Overview, page 54

5. We note the inclusion of Descartes-08 for the treatment of pediatric autoimmune diseases in your pipeline table. Given the limited disclosure related to this program in your business section, please explain why it is sufficiently material to your business to warrant inclusion in your pipeline table. If it is material, please expand your disclosure in the Business section to provide a more fulsome discussion of this program and shorten the corresponding bar in your pipeline table, as disclosure on page 60 indicates you have not yet filed an IND for this indication. Alternatively, remove any programs that are not currently material from your pipeline table on page 55.

### Response to Comment No. 5:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosures on pages 59 and 65 of the Amended Registration Statement in response to the Staff's comment.

6. Please remove the statements on page 55 and 56 and elsewhere claiming that Descartes-08 was observed to be "safe" and demonstrated a "favorable safety profile" as safety determinations are within the sole discretion of the FDA and comparable foreign regulators.

#### Response to Comment No. 6:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosures on pages 60, 62, 64 and 93 of the Amended Registration Statement in response to the Staff's comment.

#### **Our Product Candidates**

## Descartes-08, page 57

7. Please remove any references to your Descartes-8 product candidate being potentially "first-in-class" as this is speculative in light of your current regulatory status.

## Response to Comment No. 7:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosures on page 59 of the Amended Registration Statement in response to the Staff's comment. The Company has also included additional disclosure on page 61 of the Amended Registration Statement regarding its novel mRNA approach.

## Clinical Development, page 58

8. Please revise this section to disclose if any serious adverse events were observed in your clinical trials of Descartes-08 and quantify them, if applicable.

## Response to Comment No. 8:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosures on page 64 of the Amended Registration Statement in response to the Staff's comment.

### Descartes-15, page 60

9. Please provide narrative disclosure explaining what is depicted in the graphic appearing on page 61.

### Response to Comment No. 9:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosures on page 66 of the Amended Registration Statement in response to the Staff's comment.

# Intellectual Property, page 61

10. Please revise to disclose the types of patent protection for the material patents and patent applications disclosed in this section. Please also disclose the potential expiration dates, if granted, for the fourteen patent applications related to your mRNA CAR-T technology and other developments in your mRNA cell therapy pipeline.

#### Response to Comment No. 10:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosures on page 67 of the Amended Registration Statement in response to the Staff's comment.

#### Key Agreements, page 62

11. We note your disclosure that the Biogen Agreement will expire when all claims of all issued patents within the patents and patent applications licensed to you under the Biogen Agreement have expired and that the NCI License Agreement terminates upon the expiration of the last to expire of the patent rights licensed thereunder. Please revise to clarify when the patents and patent applications under the Biogen Agreement are expected to expire and when the patent rights licensed under the NCI License Agreement are expected to expire. Please also disclose the exclusivity provisions related to these agreements.

#### Response to Comment No. 11:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosures on pages 68 and 69 of the Amended Registration Statement in response to the Staff's comment. The Company also respectfully advises the Staff that each of the Biogen Agreement and the NCI Agreement is defined as being non-exclusive on page 47 of the Amended Registration Statement.

# Astellas License Agreement, page 63

12. Please revise your discussion of the Astellas License Agreement to disclose the current status of this agreement as of the latest practicable date. In this regard, we note your disclosure appearing on page 40 stating that you were notified by Astellas of their intention to terminate the Astellas Agreement effective June 6, 2024. If the agreement has been terminated, clearly disclose this and tell us why it is appropriate for you to discuss the agreement in this section. If the agreement remains in place, please file this agreement as exhibit to your registration statement. Refer to Item 601 of Regulation S-K for guidance.

## Response to Comment No. 12:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosures on pages 41, 44, 48, 69 and F-27 of the Amended Registration Statement in response to the Staff's comment.

#### General

13. We note your disclosure on page 126 that your Selling Stockholders may sell all or a portion of the Resale Shares to or through underwriters or purchases by a broker-dealer as principal and resale by the broker-dealer for its account. Please confirm your understanding that the retention by a selling stockholder of an underwriter would constitute a material change to your plan of distribution requiring a post-effective amendment. Refer to your undertaking provided pursuant to Item 512(a)(1)(iii) of Regulation S-K.

## Response to Comment No. 13:

The Company respectfully acknowledges the Staff's comment and confirms to the Staff that it understands that the retention by a selling stockholder of an underwriter would constitute a material change to the "Plan of Distribution" contained in the Amended Registration Statement would require a post-effective amendment.

14. The forepart of your prospectus should consist of the cover page, summary and risk factors sections. Please relocate the sections "About This Prospectus" and "Cautionary Note Concerning Forward-Looking Statements" appearing after the table of contents to a more appropriate location in the prospectus.

## Response to Comment No. 14:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised the disclosures in the Amended Registration Statement to move the section "About this Prospectus" to appear prior to the table of contents and to move the section "Cautionary Note Concerning Forward-Looking Statements" to appear following the "Risk Factors" section.

We thank the Staff for their review and comments on the Registration Statement. We acknowledge that it is the responsibility of the Company and its management to provide adequate and accurate disclosures in its filings.

We are committed to cooperating with the Staff and providing any additional information or clarification as needed. We respectfully request that the Staff inform us of any further comments or questions, or if the Staff is satisfied with our responses and has no further comments.

If you have any questions or need any additional information, please contact me at 617-603-8815 or sgriffiths@cov.com.

Sincerely,

/s/ Sarah C. Griffiths

Sarah C. Griffiths Covington & Burling LLP

cc: Carsten Brunn, Cartesian Therapeutics, Inc.
Blaine Davis, Cartesian Therapeutics, Inc.
Matthew Bartholomae, Cartesian Therapeutics, Inc.
Brian K. Rosenzweig, Covington & Burling LLP