



DIVISION OF
CORPORATION FINANCE

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

September 26, 2024

David D. Halbert
Chairman, Founder & Chief Executive Officer
Caris Life Sciences, Inc.
750 W. John Carpenter Freeway
Suite 800
Irving, TX 75039

**Re: Caris Life Sciences, Inc.
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted September 12, 2024
CIK No. 0002019410**

Dear David D. Halbert:

We have reviewed your amended draft registration statement and have the following comments.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to this letter and your amended draft registration statement or filed registration statement, we may have additional comments. Unless we note otherwise, any references to prior comments are to comments in our July 5, 2024 letter.

Amendment No. 1 to Draft Registration Statement on Form S-1
Letter from Chairman, Founder, and CEO, page iii

1. We note your revised disclosure in response to prior comment 1 and reissue in part. Please revise to explain the connection between AdvancePCS's sale in 2004 and this offering, and include balancing disclosure that prior performance is not indicative of your future results.
2. You disclose that you believe you were the first to offer comprehensive molecular profiling for "every patient when we launched whole transcriptome sequencing in 2019" and "the first to offer whole exome sequencing for every patient when we introduced our whole exome sequencing solution in 2020." Please revise to provide context for the

disclosure by explaining your reference to "every patient" and describe how this distinguishes you from your competitors, as appropriate.

Prospectus Summary, page 1

3. We note your response to comment 11, and your disclosure on page 2 that samples are provided by ordering physicians that contain sufficient genetic material for profiling. As your disclosure highlights your profiling solutions, please revise, either here or elsewhere in the registration statement, to clarify how you determine the eligibility of patient samples.

Management's Discussion And Analysis Of Financial Condition And Results Of Operations
Our Business Model, page 103

4. We note your response to comment 13. We also note your revised disclosure that "[u]nder the strategic partnerships, targets discovered and validated by [you] can be pursued by [y]our biopharma partners to conduct their own preclinical and clinical research, as well as the eventual development and commercialization of drug candidates. [Yo]ur biopharma partners are also able to combine their relevant technology and/or engineering capabilities to design and manufacture therapies for the treatment of cancer." Please revise to briefly explain how you determine which targets are shared with your biopharma partners and elaborate further on how they combine their technology and engineering capabilities to design and manufacture therapies for the treatment of cancer.

Molecular Profiling Services Revenue, page 109

5. We have reviewed your revised disclosure in response to comment 15. Please also revise your disclosure to discuss and analyze the increase in clinical cases associated with MI Profile and provide any other information that would be material to an understanding of the increase in cases and revenue. Refer to Item 303 of Regulation S-K.
6. In addition, in tabular form, please separately quantify the impact from the decline in selling prices and the increase in volume to your increase in revenue. Refer to Item 303(b)(2)(iii) of Regulation S-K.

Business
Overview, page 121

7. We note your response to comment 16. Please revise to discuss the timetable for Caris Assure's application to MCED, MRD tracking, and treatment monitoring. Please also clarify why you are planning to submit a PMA for Caris Assure for therapy selection.
8. We note your response to comment 17. Please revise to address the following points regarding each of the clinical and biopharma settings comprising the \$150 billion total addressable market:
 - We note your disclosure on page 130 that "[b]ased on U.S. Census Bureau data, the 45 to 75 years-old cohort who would be eligible for screening for cervical, breast, colon, lung, and prostate cancers represents approximately 112 million people in the United States." Please revise to discuss how you determined eligibility for screening for these cancers.

- Please revise your disclosures on pages 130 through 132 to explain the assumptions underlying the number of tests that could be administered annually to patients. For example, we note your disclosure on page 131 that "there is increasing evidence that patients could be eligible for at least two tests a year during therapy." We also note your disclosure on page 131 assuming "a range of two to three tests annually for each patient" and "five tests (one therapy selection test and four monitoring tests) for each trial participant."
- We note your disclosure on page 131 that "based on these newly- diagnosed patient, recurrent patient, and repeat testing patient cohorts, we estimate the total addressable U.S. market for therapy selection is comprised of approximately two million unique patient profiles annually and...amounts to approximately \$8 billion." Please disclose the number of diagnosed patient, recurrent patient and repeat testing patients.
- We note your disclosure on page 132 assuming that "approximately 25 Phase 1b trials progress to Phase 2 each year, with each trial having two partners (a specialty lab and a distributable kit)" and "a rate of rare mutation of 4.0% within the population of newly-diagnosed cancer patients in the United States with advanced-stage solid tumor cancers". We also note your disclosure on page 132 that you "estimate that approximately \$70 billion of the \$262 billion spent in 2023 represented R&D investments in discovery, pre- trial costs, and real-world evidence, areas where matched genomic data has demonstrated use cases for biopharma applications". Please revise to discuss the basis for each of these assumptions and estimates.
- We note your disclosures on pages 130 through 132 regarding assumed pricing for your solutions, tests, and average reimbursement rates. Please revise to briefly discuss the basis for each of these assumed amounts.
- Finally, please clarify whether your access to such markets would depend in part upon FDA clearance or approval.

Our Solutions, page 138

9. We note your response to comment 20. Please revise your disclosures to further discuss the parties conducting the studies, including whether the parties are affiliates or partners of Caris.
10. We note your response to comment 22, including your disclosure on page 147 that analytical validation for GPSai and FOLFIRSTai enabled you to offer the solutions as LDTs. Please revise to briefly discuss the importance of analytical validation in connection with the marketing of LDTs.

Consolidated Financial Statements

Molecular Profiling Services, page F-10

11. We note your revised disclosure in response to comment 31 as it relates to how you estimate variable consideration under a portfolio approach for third-party payers and patients with similar reimbursement characteristics. Please describe to us in further detail how you determined your disclosure meets the requirements of Topic 606. Specifically, please address ASC 606-10-50-1 which sets forth, in part, that an entity shall disclose quantitative and qualitative information about the significant judgments and changes in judgments made in applying the guidance in the Topic. As part of your response, please

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identify the significant judgments, and the quantitative and qualitative information about these judgments, as it relates to you estimating variable consideration and assessing whether an estimate of variable consideration is constrained. Also refer to ASC 606-10-50-17 and 50-20.

12. In addition, please clarify your disclosure to address whether there are any types of warranties, as set forth in ASC 606-10-50-12(e).

General

13. We note your response to comment 33. Please revise your gatefold graphics to identify the laboratories, technologies and people, and briefly explain how these images are representative of your business.

Please contact Tayyaba Shafique at 202-551-2110 or Michael Fay at 202-551-3812 if you have questions regarding comments on the financial statements and related matters. Please contact Juan Grana at 202-551-6034 or Lauren Nguyen at 202-551-3642 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Industrial Applications and
Services

cc: Alison Haggerty, Esq.