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

DIVISION OF
CORPORATION FINANCE

January 10, 2025

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. 2 to Draft Registration Statement on Form S-1
Submitted December 20, 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 September 26, 2024 letter.

Amendment No. 2 to Draft Registration Statement on Form S-1

Prospectus Summary, page 1

1. We note your disclosure that FDA approval of MI Cancer Seek as a companion diagnostic was obtained in the fourth quarter of 2024. Please disclose when you intend to commercially launch MI Cancer Seek. Please also revise to clarify the timing of your submission of the Caris Assure for therapy application for approval from New York State's Clinical Laboratory Evaluation Program.

Risk Factors
Our solutions may not perform as expected, and the results of our validation studies or our clinical trials may not support the launch or..., page 20

2. We note your disclosure that the FDA included certain conditions of approval and limitations in the PMA approval letter for MI Cancer Seek. Please revise to discuss these conditions and limitations.

Management's Discussion And Analysis Of Financial Condition And Results Of Operations
Molecular Profiling Services Revenue, page 111

3. We note your response to prior comment 5 and your updated disclosure around increased adoption of MI Profile by ordering physicians. Please revise your discussion to describe whether the increase in clinical cases associated with MI Profile is a result of an increased effort by your sales team, or natural market acceptance. Your discussion should provide an investor with information on any known trends or uncertainties that would impact revenue from continuing operations. Refer to Item 303(b)(2)(ii) of Regulation S-K.
4. In addition, we note your sales team has grown from 185 employees at the end of 2020 to over 270. Please describe for us and in your filing, as appropriate, the extent to which any increase in your sales team contributed to the increase in clinical cases and revenue. Also, please describe for us the structure of your sales team and any metrics used to evaluate their performance and effectiveness related to clinical cases, and provide us this information.
5. We note from your website the Caris POA has working groups across 13 oncology specialties. Please describe to us the extent to which you quantify clinical cases or revenue across any oncology specialties or any other type of classifications and provide us this information for the periods presented. If there is any such information, please tell us whether there is any related material information that would be required to be provided under Item 303 of Regulation S-K.
6. In addition, we note on page F-13 the table of major payers. Please briefly clarify the facts and circumstances related to these payers and the corresponding revenue, and provide any other information pursuant to Item 303 of Regulation S-K.

Business
Our Market Opportunity and Vision for Leveraging Molecular Information, page 132

7. We note your response to comment 8, including your disclosure on page 134 that you've assumed five tests for each trial participant, including one therapy selection test per standard of care, and your disclosure that "[a]ssuming approximately 25 Phase 1b trials progress to Phase 2 each year...with each trial having two partners per customary industry practice (a specialty lab and a distributable kit) and an average contract price of $10 million based on third-party industry research...and an average reimbursement per patient of $10,000 based on third-party industry research, [you] estimate the addressable U.S. market for commercial services that include identification of patients for approved therapies is approximately $300 million." Please revise to clarify what you mean by "per standard of care" and disclose the "third-party industry research" referenced.

8. Please revise to balance your total addressable market presentation here by disclosing that your revenues to date are primarily derived from molecular profiling services. Please also make corresponding revisions to your Summary section.

Our Solutions, page 141

9. We note your response to comment 9. We also note your disclosure on page 148 that "[i]n a validation study [you] conducted in collaboration with leading cancer centers analyzing nearly 12,000 patients with advanced cancer across 48 tumor types, nearly four out of 10 patients had at least one pathogenic or likely pathogenic CH variant among reportable clinical genes. The study found a median rate of CH variant classification of 17% for patients ranged from 65 to 69, 29% for patients aged 70 to 74, 33% for patients aged 75 to 79, and 50% for patients 80 years of age and older. High CH rates were notably detected in BRCA2, BRCA1, CHEK2, and ATM." Please revise to disclose the date of the study and the leading cancer centers that you collaborated with to conduct the study.

HEME Assay, page 156

10. Please revise to disclose the material terms of your exclusive license arrangement with Washington University in St. Louis, and file the license agreement as an exhibit to this registration statement. Please also revise to provide the p-values for the results of the 2021 study published by WashU and clarify whether you plan to submit the licensed assay for FDA approval or whether you intend to commercialize the assay as an LDT.

Consolidated Financial Statements of Caris Life Sciences, Inc.
Note 2. Summary of Significant Accounting Policies and Estimates, page F-8

11. Please revise your disclosure to identify the legal structure of the Caris POA and to provide your accounting policies related to the Caris POA.

12. As it relates to each payer referred to on page F-13, please tell us:

- the type of business represented by the payer;
- whether the payer is the obligor of your services;
- whether you, including Caris POA, have multiple contracts with the payer and, if so, how you considered ASC 606-10-25-9; and
- whether the payer has access to your datasets and, if so, how you evaluated the existence of a performance obligation, as set forth in ASC 606-10-25-14 through 25-22.

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.