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

DIVISION OF
CORPORATION FINANCE

July 5, 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.
Draft Registration Statement on Form S-1
Submitted June 10, 2024
CIK No. 0002019410

Dear David D. Halbert:

We have reviewed your draft registration statement and have the following comment(s).

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.

Draft Registration Statement on Form S-1

Letter from Chairman, Founder, and CEO, page iii

1. Please revise or 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.

Prospectus Summary, page 1

2. We note that you make various statements throughout the registration statement regarding your leadership in your field and the efficacy of your products including, but not limited to, the following:

   - Page iii: "We were both the first comprehensive molecular profiling service and the first to offer whole exome and whole transcriptome sequencing for every patient for

both tissue- and blood-based profiling."

- Page iii: "[W]e were first to offer an AI-based drug response predictor for metastatic colorectal cancer patients as well as the first to offer biomarker-driven clinical trials matching and right-in-time clinical trial service."
- Page 1: "We are a leading, patient-centric, next-generation AI TechBio company and precision medicine pioneer."
- Page 1: "We have spent the last 16 years developing and building our portfolio of comprehensive, proprietary molecular profiling solutions and generating one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology."
- Page 2: "We sequence at sector-leading depth of coverage, which directly correlates with increased accuracy and detection of low frequency molecular markers of relevance."
- Page 2: "As the leader in the transition to WES/WTS sequencing, we believe we have more molecular data and information than any other company and are well-positioned to make precision medicine widely accessible."
- Page 2: "The Caris Precision Oncology Alliance (“Caris POA”), which we established in 2015, is now one of the leading research and data organizations in precision medicine in the United States and is comprised of over 90 members, including over 40 leading National Cancer Institute (“NCI”)-designated comprehensive cancer centers."

Please revise your disclosure throughout the prospectus to provide the basis for any statements, including those above, related to leadership in your field and the efficacy of your products. Please also ensure you disclose any relevant metrics on which these statements are based and any material assumptions.

3. We note the disclosure that your current commercial product portfolio is focused on oncology and consists of MI Profile, your tissue-based molecular profiling solution, and Caris Assure, your blood-based molecular profiling solution for therapy selection. Please revise to clarify that the majority of your current revenues is generated from your tissue-based molecular profiling solution.

4. Please revise to explain and substantiate how your Caris platform drives "superior" clinical outcomes for patients and benefits from a virtuous cycle that enables continued innovation and impact.

5. Please balance your summary disclosures by including a discussion of your substantial indebtedness and current sources of liquidity. Please also expand your discussion of your net losses for the years ended December 31, 2023 and 2022 to briefly discuss your costs and operating expenses.

The Caris Platform, page 3

6. Please revise to provide additional context for your business description by clarifying that you have not yet obtained FDA marketing authorization for any of your solutions, including MI Cancer Seek and Caris Assure. We note your disclosure on page 54.

Risk Factors
Our billing, collections, and claims processing activities are complex and time-consuming, and any delay in transmitting ..., page 27

7. We note your disclosure that you "are currently in litigation that [you] initiated with United Healthcare, regarding United Healthcare's ability to recoup payments made for MI Profile, relating to the use of allegedly incorrect billing codes." To provide additional context for the risk factor disclosure, please revise to disclose the amounts of the payments that United Healthcare is seeking to recoup.

If our facilities or those of our third-party collaborators are insufficient or become inoperable, our ability to provide our solutions ..., page 30

8. We note your disclosure that "[i]n 2020, [you] began the process of constructing a new laboratory facility in Irving, Texas to increase product development and operational capacity." Please revise to discuss the timeline for completion of the facility and obtaining, if applicable, CLIA accreditation. We also note your disclosure on page 58 that "[b]oth of the Phoenix laboratory facilities hold independent CLIA Certificates of Accreditation" while your "laboratory facility in Irving, Texas holds a CLIA Certificate of Registration." Please revise to explain the difference between CLIA accreditation and registration.

Our amended and restated certificate of formation will provide that the Business Court in the First Business Court Division ..., page 85

9. We note your disclosure that the forum selection provision in your amended and restated certificate of formation may have the effect of discouraging lawsuits against you and your directors, officers or other employees. Please revise this risk factor to disclose that there is also a risk that your forum selection provision may result in increased costs for investors to bring a claim.

Use of Proceeds, page 93

10. We note the disclosure that you "have no specific plan for the net proceeds from this offering, or any significant portion thereof. However, we intend to use the net proceeds from this offering for general corporate purposes, including working capital, operating expenses, and capital expenditures." You also disclose on page 110 that you believe your existing cash and cash equivalents and anticipated cash flows from operations, "together with the net proceeds from this offering," will provide sufficient capital and liquidity to fund your operating expenses and capital expenditure requirements for at least the next 12 months after the completion of this offering. As applicable, please provide further detail regarding the use of the proceeds towards your indebtedness. Please refer to Instruction 4 to Item 504 of Regulation S-K.

Management's Discussion And Analysis Of Financial Condition And Results Of Operations
Overview, page 100

11. We note your disclosure that you "remain the only genomic profiling company to consistently utilize WES and WTS as standard practice on every eligible patient sample." Please revise, either here or elsewhere in the registration statement, to explain how you

determine the eligibility of patient samples. Please also discuss how the patient samples are sourced.

Our Business Model, page 101

12. We note your disclosure that you "have robust Medicare and broad commercial reimbursement for MI Profile, with over 255 million covered lives in the United States". Please revise to explain what you mean by "broad commercial reimbursement".

13. We note your disclosure that you "also generate revenue utilizing [y]our Caris Platform to provide R&D services for biopharma partners, who [you] partner with to help improve the efficiency and success of their therapeutic development and clinical programs." Please revise to discuss the specific services offered to your biopharma partners. Please also disclose the terms of any material contracts with your biopharma partners, including your research partnerships with Moderna, AbbVie, Xencor, and Merck KGaA, and file any such contracts as exhibits to this registration statement or provide your analysis as to why such contracts are not required to be filed. Refer to Item 601(b)(10) of Regulation S-K.

Cost of Services, page 107

14. We note as part of your discussions of costs and operating expenses you sometimes quantify the components of an increase or decrease without providing further quantification or insight. For example, as part of your discussion of the cost of molecular profiling services you set forth, in part, the MI Profile tissue laboratory contributed a $15.6 million increase in materials, $10.4 million increase in laboratory labor costs, $5.4 million related to equipment leases and maintenance, and $1.8 million in other costs, including costs related to freight and third-party laboratory software. Please revise your discussion to provide additional quantitative and qualitative information related to the significant costs and expenses you identify, including quantifying the related underlying amount and providing any related discussion and analysis to enhance an investor's understanding of your results of operations, consistent Item 303 of Regulation S-K.

Management's Discussion And Analysis Of Financial Condition And Results Of Operations
Molecular Profiling Services Revenue, page 107

15. We note your 16.9% increase in revenue was primarily due to the increase in clinical cases associated with MI Profile and Caris Assure for therapy selection from 97,039 and 223 cases to 128,168 and 663 cases, a total increase of 31,569 cases or 32.5%. Please revise your disclosure to provide additional information to better allow investors to view the registrant from management’s perspective, as set forth in Item 303(a) of Regulation S-K. Please:

- revise your discussion to describe the underlying reasons for 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;
- discuss in further detail why revenue increased 16.9% when cases increased 32.5%, and any known trends related to the decline in average selling price and change in payer mix. Quantify the impact from the decline in selling prices; and
- Discuss the reasons why international revenue declined, as set forth on page F-40.

Business
Overview, page 118

16. Please revise to clearly disclose the current stage of development and/or commercialization of each of your products and product candidates. In particular, please disclose which products are currently being sold, when they commenced sales, and in which markets the products are being sold. Consider providing this information in narrative and tabular format for ease of reference. We also note your disclosure that MI Profile is your "market-leading tissue-based molecular profiling solution" and that Caris Assure is your "novel, universal blood-based molecular profiling solution". Please revise to explain by what metric MI Profile is "market-leading". Please also discuss the timetable for Caris Assure's application to MCED, MRD tracking, and treatment monitoring.

17. Please revise your disclosure regarding your estimated total addressable U.S. market to discuss the assumptions underlying each of the elements comprising the $150 Billion TAM. As an example only, we note your disclosure on page 128 that you "expect biopharma companies to keep increasing the allocation of their total research and development (“R&D”) investment, which totaled $262 billion in 2023" and that you "estimate the total addressable U.S. market for this opportunity is approximately $10 billion." Please explain the basis for your total addressable market opportunity estimate. As applicable, please also revise the disclosure on page 5.

Caris Assure - Our Universal Blood-Based Profiling Solution, page 134

18. Please revise to further explain how many of your competitors’ offerings are "siloed" and "require continued investment for the development of new products and generate disparate datasets across the patient journey for patients, oncologists, and researchers."

Our Solutions, page 134

19. Please revise to more clearly explain the use of Caris Assure vis-a-vis MI Profile for molecular profiling. We note your disclosure that MI Profile is a tissue-based molecular profiling solution including WES/WTS NGS assay and IHC protein expression testing, and that Caris Assure is a universal blood-based solution providing WES and WTS for every eligible patient sample. In particular, please explain if there is any overlap between Caris Assure and MI Profile regarding commercial use, and further discuss the advantages or disadvantages to blood-based versus tissue-based molecular profiling. For example, we note your disclosure on page 134 that "Caris Assure has many more opportunities for testing relative to tissue profiling."

20. Please revise your disclosures on pages 136-138 to further discuss the studies cited. In particular, please disclose the date of the studies and the parties conducting the studies, including whether the parties are affiliates or partners of Caris.

21. We note your disclosure on page 142 that you "use IHC testing to complement [y]our WES/WTS profiling both to inform decisions regarding therapy selection as well as to act as confirmatory testing in circumstances where [y]our GPSai algorithm indicates a different diagnosis than that indicated in the patient record prior to [y]our profiling." Please revise to further discuss how IHC testing is employed.

22. We note your disclosure on page 142 that you "clinically validated FOLFIRST using a

real-world evidence dataset collected from the Caris POA registry." We also note your disclosure that "GPSai was trained and validated through retrospective profiling data from over 250,000 clinical cases using the outside pathologist diagnosis as the baseline." Please revise to explain the significance of a clinical validation, and also disclose the regulatory body or entity that provided the validations.

23. We note your tabular disclosure on page 144 regarding the performance of MI Tumor Seek Hybrid. Please revise to discuss the relevance of the PPA, NPA and OPA percentages in the table.

Data for Biopharma, page 148

24. We note your disclosure that you "license deidentified data that [you] have generated from [y]our clinical profiling business to biopharma companies with the aim of generating insights directly responsible for superior clinical outcomes for patients." Please revise to briefly explain the process through which you deidentify your patient data.

Caris Molecular AI Launches & Signature Pipeline, page 152

25. Please revise to briefly discuss each of the products listed in the pipeline table. In particular, please disclose which products are currently being sold, when they commenced sales, and in which markets the products are being sold. Please also clarify the stages of development included in the pipeline, such as "development", "external validation" and "launch." Finally, please also describe the external validation and disclose if any regulatory approvals have been obtained, sought or are required for the products.

Intellectual Property, page 155

26. Please expand your disclosure relating to your patent portfolio and identify for each material patent and patent application, as applicable, the scope and technology of each such patent or patent application, the type of patent protection, jurisdiction, and expiration dates. Consider adding tabular disclosure in addition to the narrative for ease of use.

Government Regulation, page 157

27. Please revise this section to clearly state the regulatory approvals that you have applied for, obtained, or will apply for, with regards to each of your products and product candidates, including but not limited to Caris Assure, MI Profile, MI Tumor Seek Hybrid, MI Cancer Seek, FOLFIRST, GPSai and your IHC tests. Please also explain the regulatory approvals required to bring each product to market and provide a timetable of when such regulatory approvals were obtained and/or are expected to be applied for and/or obtained. Consider providing this information in narrative and tabular format for ease of reference.

28. We note your disclosure on page 157 that you have "submitted a PMA seeking regulatory approval from the FDA for a companion diagnostic and tumor profiling designation for MI Cancer Seek, a WES/WTS NGS panel that [you] anticipate transitioning to using as the WES/WTS NGS component of MI Profile if approved by the FDA." Please revise to explain why a PMA is required for MI Cancer Seek. Please also explain the difference between MI Cancer Seek and MI Tumor Seek Hybrid, including why you plan to transition from MI Tumor Seek Hybrid to MI Cancer Seek if the latter receives

regulatory approval from the FDA.

Certain Relationships And Related Party Transactions, page 191

29. We note your disclosure that you have entered into "consulting and expert advisory agreements with George H. Poste and Jonathan Knowles, members of [y]our board of directors, pursuant to which Dr. Poste and Dr. Knowles provide certain consulting services to [you] as independent contractors and serve on [u]our Scientific Advisory Board." Please disclose the amounts that were paid to Messrs. Poste and Knowles for their consulting services, and file the agreements as exhibits to your registration statement.

Description of Capital Stock, page 197

30. Please revise to describe the terms of the Series A, B, C and D preferred stock in this section of your prospectus. We note your disclosures on page F-27.

Consolidated Financial Statements
Molecular Profiling Services, page F-10

31. Please revise your disclosure to describe the following:

- Your significant payment terms, including when payment typically is due, as set forth in ASC 606-10-50-12(b);
- Any obligations for returns, refunds, and other similar obligations, as set forth in ASC 606-10-50-12(d);
- Any types of warranties and related obligations, as set forth in ASC 606-10-50-12(e); and
- Greater detail about the inputs and assumptions, as set forth in ASC 606-10-50-20(a), (b) and (c). Also refer to ASC 606-10-50-1 which sets forth, in part, that an entity shall disclose **quantitative and qualitative information** about the the significant judgments, and changes in the judgments, made in applying ASC 606.

Exhibit Index, page II-4

32. Please file your term loan agreement with OrbiMed Royalty & Credit Opportunities III, LP, OrbiMed Royalty & Credit Opportunities IV, LP, and Braidwell Transaction Holdings LLC as an exhibit to the registration statement. Refer to Item 601(b)(10) of Regulation S-K.

General

33. We note the gatefold graphics with photos of laboratories and buildings and the caption, "Caris Life Sciences . . . Where Molecular Science Meets Artificial Intelligence." Please clarify whether these photographs identify your current operations, employees and equipment, and explain how they are representative of your business. We also note the graphic illustrating case volume growth. Please revise the graphic to substantiate the suggestion implied by the arrow pointing upwards, that your case volume will grow both for clinical cases and biopharma and external research cases in the future. Finally, please revise your "By the Numbers" graphic to further explain the terms included in relation to

the numerical values.

34. We note the use of various industry terms in the prospectus. Please consider including a glossary or defining the industry terms in the first instance of their use in the prospectus.

35. Please provide us with supplemental copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.

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.