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

DIVISION OF
CORPORATION FINANCE

July 5, 2024

Claire Mazumdar
Chief Executive Officer
Bicara Therapeutics Inc.
116 Huntington Avenue, Suite 703
Boston, MA 02116

Re: Bicara Therapeutics Inc.
Draft Registration Statement on Form S-1
Submitted June 10, 2024
CIK No. 0002023658

Dear Claire Mazumdar:

We have reviewed your 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.

Draft Registration Statement on Form S-1

Cover Page

1. Please revise your cover page to clarify whether the offering is contingent upon final approval of your Nasdaq listing. Please ensure that the disclosure is consistent with your underwriting agreement.

BCA101 Clinical results, page 3

2. We note your disclosure here and elsewhere throughout your Prospectus comparing data from your clinical trials with other therapeutics. To the extent that these comparisons were not the result of head-to-head clinical trials, revise to remove the comparisons. As a non-exhaustive list, we note the following:
   - "The CR rate we observed in this cohort appears to be significantly higher compared to those previously reported in investigator-sponsored trials, or ISTs, of cetuximab in combination with pembrolizumab or nivolumab, as well as the KEYNOTE-048 study

with pembrolizumab, of approximately 3%" on pages 3 and 113;

- "the mPFS in HPV-negative subjects was 9.8 months, a threefold increase in PFS benefit when compared to published historical data for pembrolizumab monotherapy, and superior to the data published for cetuximab and anti-PD-1 combination ISTs" on page 113; and
- "treatment-related adverse events, or TRAEs, leading to discontinuation of BCA101 and/or pembrolizumab was 12%, markedly lower than historical pembrolizumab combinations, including lenvatinib or chemotherapy, which showed TRAEs leading to discontinuation rates of 28% and 33%, respectively" on page 114.

3. Revise page 4 and where else you state you believe you may use the accelerated approval pathway for BCA101 to briefly describe the feedback received from the FDA that supports your belief. Please also revise to include balancing disclosure that an accelerated approval pathway may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that your product candidate will receive marketing approval.

4. Please revise to remove the statements appearing on pages 4 and 113 that you "believe BCA101 in combination with pembrolizumab could be established as the new chemotherapy-free standard of care for HPV-negative first-line R/M HNSCC" as it is speculative given your current stage of development.

5. Please revise pages 4, 112 and 113 to state what "PD" abbreviates in the graphics.

6. Discuss whether the results presented in this section were statistically significant. Include the associated p-values, if appropriate.

Our Team, page 6

7. We note you disclose the names of your investors on pages 6 and 101. Please limit the disclosure of specific investors to those identified in the Principal Stockholders table on page 174. Additionally, indicate that prospective investors should not rely on the named investors' investment decision, that these investors may have different risk tolerances and that the shares purchased in the referenced financings were conducted at a significant discount to the IPO price, if true.

Summary of Material Risks Associated with our Business, page 6

8. Please expand your summary of material risks to further provide balancing disclosure by discussing if you are substantially dependent on any license agreements for BCA101, that you have never generated revenue and never commercialized a product.

The Offering, page 9

9. Please revise pages 9 and 78 to clearly state for your Phase 2/3 trial whether proceeds are intended to fund some but not all of the clinical trial work that would be necessary for you to file a Biologics License Application. Disclose the additional head and neck squamous cell carcinoma patient populations you plan to expand your BCA101 program to using proceeds from this offering.

Risk Factors
The operations of our suppliers, many of which are located outside of the United States, are subject to additional risks . . ., page 37

10. Please revise to state why "[i]f approved, the BIOSECURE Act in its current form would not prevent [you] from sourcing drug product from WuXi Bio for clinical use."

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations
Research and Development Expenses (including Research and Development (Related Party), page 90

11. We note your disclosure that you have not reported program costs since your inception because you have not historically tracked or recorded your research and development expenses on a program-by-program basis. Please break out your external research and development costs separately and clarify if they relate to more than the BCA101 program.

Critical Accounting Policies and Estimates
Common Stock Valuation, page 95

12. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation. Please discuss with the staff how to submit your response.

Business
Overview, page 98

13. We note your disclosure on page 28 that you are currently conducting a clinical trial in Canada. Please revise your Business section where appropriate to disclose all the jurisdictions where you are currently conducting clinical trials.

Our Solution: BCA101, a Novel Bifunctional Antibody, page 105

14. Please revise your graphic on page 105 to remove "[i]mproved efficacy" as efficacy determinations are within the sole discretion of the FDA or similar foreign regulators.

BCA101 synergizes with anti-PD-1 therapies, with anti-tumor activity superior to other anti-EGFR therapies in preclinical models, page 108

15. Please revise to disclose the design, data and results of the two preclinical cancer mouse models whose data were published in *Cancer Research*.

Preclinical in vivo models demonstrate BCA101 may have an enhanced ability to prevent tumor relapse compared to cetuximab, page 108

16. Please revise to state whether your preclinical experiments in patient derived xenograft models of EGFR-expressing treatment-naïve HNSCC tumors were powered for statistical significance and if so, provide the p-values.

Ongoing Phase 1/1b Trial, page 111

17. Please revise your graphic on page 111 so all of the text is legible.

18. Please revise page 111 to state the number of patients you expect to enroll in the multiple dose expansion cohorts.

BCA101 has been generally well-tolerated with a favorable tolerability profile, page 114

19. Please disclose the number of patients that experienced treatment-related severe adverse events due to dermatitis acneiform and the number of patients with treatment-related adverse events that discontinued BCA101 and/or pembrolizumab. Also revise to clarify if the Grade 3 or 4 adverse events were considered treatment-related severe adverse events.

20. We note your disclosure in the second paragraph of this section of the EGFR-related adverse events and note that your first paragraph indicates that there may also be adverse events associated with TGF-B inhibition. Please revise to clarify if you have observed any adverse events related to TGF-B inhibition in your trials of BCA101 to date.

Contract Transfer And License Agreement with Biocon, page 117

21. Please revise to clarify how you use the technology licensed from Biocon. Revise to state how each party may terminate the Biocon Agreement, the aggregate amount paid to date, the aggregate amount of any future milestone payments, whether there is a royalty term and if so, disclose the royalty rate. Please also file the Assumed Contracts as exhibits, or tell us why they are not required to be filed, and disclose when the ownership of the Assumed Contracts will be transferred to you.

Intellectual Property, page 118

22. Please revise to disclose the jurisdictions for each patent family where you have pending patents. Revise to describe the patent family with "pending patent applications that, if issued, may provide additional intellectual property protection for BCA101."

Manufacturing, page 120

23. Please disclose the names of your principal suppliers. Refer to Item 101(h)(4)(v) of Regulation S-K.

Certain Relations and Related Party Transactions
Policies for approval of related party transactions, page 173

24. Please disclose the standards to be applied in deciding whether to approve or ratify any related party transaction. Refer to Regulation S-K Item 404(b)(1)(ii).

Exhibits

25. Please file the Director Engagement Letters, Scientific Advisory Board Letter with Dr. Hodi, Ivan Hyep Promissory Note, Syngene Master Manufacturing Services Agreement, and Syngene Master Contract Services Agreement as exhibits or otherwise advise.

General

26. Please supplementally provide us with 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,

present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Please contact Tara Harkins at 202-551-3639 or Vanessa Robertson at 202-551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Daniel Crawford at 202-551-7767 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Gabriela Morales-Rivera, Esq.