



DIVISION OF
CORPORATION FINANCE

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

August 6, 2024

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

**Re: Bicara Therapeutics Inc.
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted July 22, 2024
CIK No. 0002023658**

Dear Claire Mazumdar:

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

Prospectus Summary

Ficerafusp alfa clinical results, page 3

1. We note your response to prior comment 3 and reissue in part. Please revise where you discuss obtaining accelerated approval 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.
2. We note your response to prior comment 6 and reissue in part. Please revise this section to disclose, as indicated in your response, that you cannot derive statistical significance from this phase of your clinical trials.

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Risk Factors

Risks Related to Our Dependence on and Work with Third Parties, page 33

3. We note your revised disclosure in response to prior comment 21. Please revise your Risk Factors section to disclose the risks relating to the Biocon Agreement's termination provision permitting termination upon reasonable advance notification by either party, how it may disrupt the development of ficerafusp alfa, or otherwise advise.

Business

Ficerafusp alfa synergizes with anti-PD-1 therapies, with anti-tumor activity superior to other anti-EGFR therapies in preclinical models, page 110

4. We note your response to prior comment 15 and reissue. Please revise to disclose the design, data and results of the two preclinical cancer mouse models whose data were published in Cancer Research. Regarding design, revise to disclose the number of mice receiving each treatment and the number of mice in control groups, whether the tests were powered for statistical significance and if so, state whether the results were statistically significant. Provide the data relied on for your conclusion that "the relapse rate of tumors in ficerafusp alfa-treated mice were minimal compared with cetuximab-treated mice;" that "treatment with ficerafusp alfa led to an improved response as compared to cetuximab combination;" and that you "believe this data supports the ability of BCA101ficerafusp alfa to prevent TGF-B from inducing resistance to EGFR-directed therapy and TGF-B-driven immunosuppression."

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.