





August 22, 2024

### **VIA EDGAR AND FEDERAL EXPRESS**

United States Securities and Exchange Commission Division of Corporation Finance Office of Life Sciences 100 F. Street, N.E. Washington, D.C. 20549

Attention: Tara Harkins, Vanessa Robertson, Daniel Crawford and Tim Buchmiller

**Re:** Bicara Therapeutics Inc.

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

Submitted July 22, 2024 CIK No. 0002023658

Dear Ladies and Gentlemen:

This letter is submitted on behalf of Bicara Therapeutics Inc. (the "Company"), in response to the comments of the staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") with respect to the Company's Amendment No. 1 to Draft Registration Statement on Form S-1, confidentially submitted on July 22, 2024 (the "Amendment No. 1"), as set forth in the Staff's letter, dated August 6, 2024, addressed to Claire Mazumdar (the "Comment Letter"). The Company is concurrently publicly filing the Registration Statement on Form S-1 (the "Registration Statement"), which includes changes that reflect responses to the Staff's comments and other updates.

For reference purposes, the text of the Comment Letter has been reproduced herein with responses below each numbered comment. For your convenience, we have italicized the reproduced Staff comments from the Comment Letter. Unless otherwise indicated, page references in the descriptions of the Staff's comments refer to Amendment No. 1, and page references in the responses refer to the Registration Statement. All capitalized terms used and not otherwise defined herein shall have the meanings set forth in the Registration Statement.

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

<u>Prospectus Summary</u> <u>Ficerafusp alfa clinical results, page 3</u>



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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.

**RESPONSE**: The Company respectfully advises the Staff that it has revised its disclosure on page 4 of the Registration Statement in response to the Staff's comment.

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.

**RESPONSE**: The Company respectfully advises the Staff that it has revised its disclosure on pages 3, 118 and 119 of the Registration Statement in response to the Staff's comment.

## 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.

**RESPONSE**: The Company respectfully advises the Staff that it has revised its disclosure on pages 34 and 126 of the Registration Statement in response to the Staff's comment.

#### **Business**

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

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



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data supports the ability of BCA101ficerafusp alfa to prevent TGF-B from inducing resistance to EGFR-directed therapy and TGF-B-driven immunosuppression."

**RESPONSE**: The Company respectfully advises the Staff that it has revised its disclosure on page 114 of the Registration Statement in response to the Staff's comment to add additional disclosure regarding the design of the preclinical mouse model published in Cancer Research (the "**Model**"), including the number of mice in the test and control groups and the statistical significance of the Model. We have also indicated on page 114 that we have relied on the clinical data from this Model to support the statements made in this section around the improved anti-tumor activity of ficerafusp alfa in combination with pembrolizumab as compared to pembrolizumab alone. With respect to the statements referenced in the Staff's comment, the Company respectfully advises the Staff that it has removed these statements that draw comparisons to cetuximab and EGFR therapies as they are no longer the focus of this section.

If you should have any questions concerning the enclosed matters, please contact the undersigned at (617) 570-1329.



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Sincerely,

/s/ Gabriela Morales-Rivera

Gabriela Morales Rivera

## **Enclosures**

cc: Claire Mazumdar, Bicara Therapeutics Inc.

Ryan Cohlhepp, *Bicara Therapeutics, Inc.* Ivan Hyep, *Bicara Therapeutics, Inc.* Lara Meisner, Bicara Therapeutics, Inc. Kingsley L. Taft, Goodwin Procter LLP Christopher W. Huntsman, Goodwin Procter LLP