

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

December 9, 2020

John Celebi President and Chief Executive Officer Sensei Biotherapeutics, Inc. 620 Professional Drive Gaithersburg, MD 20879

Re: Sensei Biotherapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted November 12, 2020
CIK No. 0001829802

Dear Mr. Celebi:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

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 our comments apply 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 these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1 filed November 12, 2020

<u>Prospectus Summary</u> <u>Company Overview, page 1</u>

1. We note your statements throughout the prospectus that SNS-301 has been "well-tolerated and has shown promising anti-tumor activity" and you characterize the results received to date as positive. However, given that only nine patients have been evaluated to date, please revise your disclosure in the Summary to present a balanced view of the ongoing clinical trial and the meaning of the results. In addition, please include a risk factor discussing the limited nature of the data received to date and the potential for diverging data once the patient population is expanded.

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- 2. Please remove all references to "Phase 1/2" and "Phase 2/3" clinical trials throughout the prospectus and instead reference either phase 1, 2, or 3 distinctly or tell us the basis for your belief that have been approved to conduct a Phase1/2 trial and that you will be eligible to conduct a Phase 2/3 trials for your SNS3-1 product candidates and revise your disclosure as appropriate. Our concern is that the references as currently disclosed may be read to imply a shorter clinical trial process or further progress than has actually been made, and may skew a potential investor's understanding of the process applicable to the company's product candidates. Please ensure your references throughout the document are consistent with your disclosure regarding Government Regulation beginning on page 113.
- 3. We note the following statements on pages 1, 89 and 94: "ImmunoPhage is not only capable of driving T cell responses, but also generates strong B cell mediated antibody responses. We believe that the unique features of ImmunoPhage, including the flexibility of antigen design, the ease of platform engineering, its large antigenic capacity, the low cost of goods and the high speed of manufacturing, as well as the enduring stability of our product candidates, have the potential to lead to a paradigm shift in cancer immunotherapies." Given your early stage of development and limited clinical data received to date it does not appear these claims are supported. Please remove in each place in which they appear.
- 4. Please remove all references to "positive FDA feedback" received, as this may be read to imply approval by the FDA and assured progression in the clinical trial process which is not known or within the company's control.
- 5. We note your statement that you believe that the addition of SNS-301 has the "potential to generate and expand ASPH specific anti-tumor T cells and thereby enhance the efficacy of PD-1 blockade." Please remove all references to efficacy in relation to your product candidates, as the determination of both safety and efficacy is solely within the purview of the FDA, which has not yet determined SNS-301 to be safe or effective.

## Our Pipeline, page 3

6. Please revise your pipeline table to include a column for the discovery phase prior to the preclinical phase and separate the columns depicting clinical trials to distinctly show phases 1, 2 and 3. In addition, adjust your bar graph for each candidate to accurately show its progression in relation to each phase once the table has been revised. In this regard we note the pipeline table shown on your website.

Please also remove the rows relating to SNS-CoV2 and "multiple pathogens", as it does not appear from your disclosure elsewhere that these categories are material to the company's business at this time.

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Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Stock-Based Compensation
Fair Value of Common Stock, page 86

7. 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 IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features. Please discuss with the staff how to submit your response.

# Business, page 89

- 8. Where appropriate, please disclose any human capital measures or objectives that the company focuses on in managing its business. See Item 101(c)(2)(ii) of Regulation S-K.
- 9. We note your discussion of collaborations with AstraZeneca for future Phase 2 clinical trials for SNS-301 and the University of Washington for your SNS-401 program. As each of these product candidates appear material to the business, for each collaboration please disclose the company's rights and/or obligations, termination provisions and expiration terms, and quantify the amounts paid to date (including upfront payments and milestone payments already paid), the aggregate potential milestone payments to be paid or received, and any applicable royalty rates. Please also file each as an exhibit. Please also revise to disclose that status of any collaboration with the manufacturer of pembrolizumab or include risk factor disclosure as appropriate.

# Our Approach to Immunotherapy, page 94

10. Please revise your disclosure to provide support for the statements under the above heading relating to the functionality of your ImmunoPhage platform and its components. To the extent you have clinical data to support the statements please include a summary thereof. If you have no clinical data to support the statements, please clearly state this in the disclosure.

#### Targeting ASPH, page 101

11. Please clarify the purpose of the graphics on page 101 entitled "Tumors Stained Highly Positive for ASPH", namely what the four individual images are meant to convey (i.e., a progression of ASPH over time, four separate patient samples, etc.).

#### Intellectual Property, page 109

12. Please revise your intellectual property discussion to disclose on an individual basis the jurisdiction of each foreign patent and pending patent application.

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## License Agreement with Fred Hutch, page 112

13. Please revise your reference to the annual license maintenance fee due under the Fred Hutch Agreement from the mid-single digit thousands to "low six figures" to a more clearly defined range. Please also confirm that the 1,429,412 shares issued by Alvaxa to Fred Hutch (and subsequently exchanged for 2,191,514 shares of the company's stock) is the only payment that has been made to date under the agreement.

## Principal Stockholders, page 151

14. Please include footnotes to your table that disclose the natural persons who have beneficial ownership of the shares held by the entities listed in your table.

#### General

- 15. 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.
- 16. We note the statements on the company's website that SNS-301 has shown "excellent safety and clinical benefit in Phase 1 patient trials, and is currently in Phase 2 at multiple clinical sites across the USA", that SNS-301 has "successfully completed a Phase 1 clinical study", that ImmunoPhage has been "proven" "safe and tolerable in phase 1 and 2 clinical trials", and that it may solicit a "complete" immune response. Although we note that the information contained on your website is not incorporated by reference into the prospectus, the information cited above appears to be different from the disclosure in the prospectus. Please explain.
- 17. We note your disclosure throughout the prospectus that you are a smaller reporting company; however, you have not indicated this status by checking the box on the cover page of the registration statement. Please address this in your next filing.

You may contact Christine Torney at 202-551-3652 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Laura Crotty at 202-551-7614 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Michael E. Tenta, Esq.