

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

November 21, 2018

Irene P. McCarthy
Chief Executive Officer
Stealth BioTherapeutics Corp
c/o Intertrust Corporate Services (Cayman) Limited
190 Elgin Avenue, George Town
Grand Cayman
KY1-9005 Cayman Islands

Re: Stealth BioTherapeutics Corp Draft Registration Statement on Form F-1 Submitted October 26, 2018 CIK No. 0001696396

Dear Ms. McCarthy:

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 F-1 submitted October 26, 2018

# **Prospectus Summary**

# Overview, page 1

- 1. Please delete your reference to "first-in-class therapy" throughout your registration statement as it implies the product candidate's approval.
- 2. Please expand your discussion of LHON in the summary and throughout your registration statement to disclose that the Phase 2 clinical trial did not meet its primary endpoint. To the extent that your plans to expand the open-label portion of your Phase 2 trial is to

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assess whether the prior Phase 2 trial results were skewed by the unexpected variability in the placebo group, then please provide that additional information. Additionally, clarify in your risk factor titled, "We are dependent on the success of elamipretide..." that the phase 2 clinical trial failed to meet the primary endpoint. Additionally, expand other risk factor discussions to which these circumstances are applicable.

#### Our Pipeline, page 2

- 3. We note you completed a Phase 1 clinical trial of elamipretide for Dry Age-Related Macular Degeneration and expect to initiate a Phase 2b clinical trial in the first quarter of 2019. Unless you have conducted other Phase 2 trials related to Dry Age-Related Macular Degeneration, please revise your pipeline table to depict the current status for this indication at the end of Phase 1 or on the line between Phase 1 and 2, rather than in the middle of the Phase 2 column.
- 4. With respect to SBT-20 and SBT-272, if you have identified specific disease indications related to the development of these product candidates, please disclose them in the table. We note that your use of proceeds does not allocate any proceeds for preclinical development of SBT-20. Please tell us why you believe this product candidate constitutes a material program or delete it from your table.
- 5. Additionally, it appears that you have not yet begun preclinical development of SBT-20. Please revise the table to indicate the current status of your development in the indication you plan to pursue by moving the line depicting your progress to the beginning of the preclinical column, rather than the middle of the column.
- 6. Given SBT-20's current stage of development, please clarify in this section the circumstances under which 75 people were exposed to it systemically.

Explore potential strategic partnerships and alliances to maximize the value of our development programs, page 5

7. We note your statement that you hold worldwide exclusive rights for elamipretide and SBT-20 and have full ownership of your compound library, including SBT-272. These statements appear contradictory. Please explain how an investor can distinguish something from your compound library from something you license if SBT-272 is the only compound from your library referenced in your registration statement.

#### Implications of Being an Emerging Growth Company, page 6

8. 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.

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# Use of Proceeds, page 60

- 9. Please revise to clarify whether you expect the proceeds, together with existing cash, will be sufficient to fund each of the referenced trials through completion. If you do not, please indicate how far the proceeds of the offering, together with your existing cash, will allow you to proceed. Please also disclose the sources of other funds needed to reach regulatory approval and commercialization for elamipretide. Refer to Item 3.C.1 of Form 20-F.
- 10. We note that as of September 30, 2018, you had \$20 million of outstanding principal under your term loan facility with Hercules. Please advise if any net proceeds will be used to retire any debt. If applicable, please revise to disclose the aggregate amount of indebtedness that will be repaid, including the interest rate and maturity date of the indebtedness. Refer to Item 3.C.4 of Form 20-F.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Determination of the Fair Value of common Stock on Grant Dates, page 77

11. 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.

#### Our Product Candidates, page 88

12. The tables on pages on page 93 and 101 include a scale indicating "Favors Placebo" "Favors Elamipretide." The scale appears to indicate your conclusions about the trial results. Please note that statements regarding efficacy are within the sole authority of the applicable regulator, the FDA, EMA or NMPA. We will not object to presentation of the trial endpoints, the extent to which the end points were met or were not met or the aggregate or summary data collected from your trials, but you should not make statements indicating your conclusions about the efficacy of the trials. Please revise these tables to show the results of the two groups separately without indicating which group of participants experienced better results.

Index to Consolidated Financial StatementsNotes to Consolidated Financial Statements8. Convertible Preferred Shares, page F-16, page F-16

13. With respect to the automatic conversion feature afforded to the shareholders of the Series A preferred shares, please revise your disclosure to clarify the stipulations of a "qualified IPO".

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### Signatures, page II-7

14. Please revise your signature page to include a signature line for the principal financial officer and controller or principal accounting officer. To the extent that someone has signed in more than one capacity, indicate each capacity in which he or she has signed. Refer to Instructions for Signatures on Form F-1.

## General

15. Please provide us proofs of all graphics, visual, or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus.

You may contact Tabatha Mccullom at 202-551-3658 or Sharon Blume at 202-551-3474 if you have questions regarding comments on the financial statements and related matters. Please contact Irene Paik at 202-551-6553 or Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance Office of Healthcare & Insurance

cc: Rosemary G. Reilly, Esq.