United States securities and exchange commission logo

March 25, 2021

Scott Requadt
Chief Executive Officer
Talaris Therapeutics, Inc.
570 S. Preston St.
Louisville, KY 40202

Re: Talaris Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted February 26, 2021
CIK No. 0001827506

Dear Mr. Requadt:

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

Prospectus Summary, page 1

1. Please clarify the meaning of scientific or technical terms the first time they are used in order to ensure that lay readers will understand the disclosure. For example, please briefly explain what you mean by chronic immunosuppression (as described on page 109), full myeloablative conditioning and nonmyeloablative conditioning.
2. Please revise the Summary to provide clear descriptions of the primary endpoints for each of the programs discussed, and, where applicable, whether the product candidate met such primary endpoints. Please also disclose any reported serious adverse events.

Overview, page 2

3. Please include disclosure of the open IND that permits you to move directly to Phase 2 for the FREEDOM-2 and FREEDOM-3 trials. In addition, please confirm that the open IND based on existing FCR001 safety data also applies to FREEDOM-3 patients with a severe form of scleroderma and who do not receive living donor kidney

transplantations.
Our Pipeline, page 3

4. We note that the first row in your pipeline table under the heading "Living Donor Kidney
Transplant (LDKT)" shows a bar in the middle of Phase 3. We also note your disclosure
that you have initiated and are currently enrolling patients in a Phase 3 trial of FCR001.
Please shorten the bar in this row to show that you have recently initiated the Phase 3 trial,
rather than implying further progress.
5. We refer to the fourth row of your pipeline table under the heading "Scleroderma."
We note the disclosure that the FREEDOM-3 s Phase 2 trial will soon be initiated under
the registrant s open IND. Please disclose whether your open IND for FRC001 applies to
patients with a severe form of scleroderma who do not receive a living donor kidney
transplant or if you have filed an original IND for this program.
We face substantial competition, which may result in others discovering..., page 21

6. We note your disclosure that your Facilitated Allo-HSCT Therapy using
nonmyeloablative conditioning is novel and mitigates the toxicities, morbidities and
extended hospital stays associated with the fully myeloablative conditioning typically
required by both allogeneic and autologous HSCT therapies. Please disclose whether any
of your competitors are developing HSCT therapy using nonmyeloablative conditioning.
We are dependent on a limited number of suppliers, and in some cases sole suppliers..., page 51

7. We note your risk factor disclosure that certain of your raw materials are available only
from a single supplier or a limited number of suppliers. Please expand your disclosure
here to discuss your sources and availability of raw materials and the names of any
principal suppliers. See Item 101(h)(4)(v) of Regulation S-K.
Capitalization, page 82

8. Please revise the table to exclude the amount of your cash, cash equivalents, and
marketable securities from your total capitalization.
Dilution, page 84

9. Please revise your historical and pro forma net tangible book value (deficit) to exclude
your intangible assets.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Estimates

Determination of the Fair Value of Common Stock, page 99

10. Please explain to us how you determined the fair value of the common stock underlying
your recent equity issuances and the reasons for any differences between recent sales of
equity and the fair value of the common stock. This information will help facilitate our
review of your accounting for equity issuances, including stock compensation and
beneficial conversion features.
Withdrawal of Chronic Immunosuppresion Irrespective of HLA Mismatch, page 120

11. Please revise the graphics on page 121 and 135 to include labels for both axes where

applicable.

License Agreement with University of Louisville Research Foundation, Inc., page 139

12. Please revise your disclosure regarding the above license agreement to disclose the total amount paid to date pursuant to the agreement.

Product Interest Rights Agreement, page 186

13. We note your disclosure surrounding the Product Interest Rights Agreement and the units that have been issued to date, both here and in the notes to the Financial Statements. Please clarify the total number of outstanding product interest rights and describe how the formula for payment was determined. To the extent the company believes the payments owed pursuant to the outstanding rights will be material in the event of the commercial sale of FCR001, please so state.

Financial Statements
Note 9. Convertible Preferred Stock
Product Interest Rights, page F-17

14. Please provide us with your analysis of the accounting for the Series A convertible preferred stock, particularly the units including the product interest rights.

Item 16. Exhibits and Financial Statement Schedules, page II-3

15. Please revise the footnote to the exhibit index regarding the omission of information from certain filed exhibits to specify the rule relied upon.

General

16. Please provide us with supplemental 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, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.

You may contact Ibolya Ignat at 202-551-3636 or Kate Tillan at 202-551-3604 if you have questions regarding comments on the financial statements and related matters. Please contact Jane Park at 202-551-7439 or Laura Crotter at 202-551-7614 with any other questions.

Sincerely,

FirstName LastNameScott Requadt

Division of Corporation Finance

Comapany NameTalaris Therapeutics, Inc.

Office of Life Sciences

cc: Gabriela Morales-Rivera, Esq.