

April 1, 2021

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Jane Park  
Kate Tillan  
Laura Cropper  
Division of Corporation Finance  
Office of Life Sciences  
Securities and Exchange Commission  
100 F Street, N.E.  
Washington, D.C. 20549

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

Dear Ms. Park:

On behalf of our client, Talaris Therapeutics, Inc. (the “**Company**”), we are responding to the comments from the Staff (the “**Staff**”) of the Securities and Exchange Commission (the “**Commission**”) relating to the Company’s confidential Draft Registration Statement on Form S-1 (the “**Draft Registration Statement**”) contained in the Staff’s letter dated March 25, 2021 (the “**Comment Letter**”). In response to the comments set forth in the Comment Letter, the Company has revised the Draft Registration Statement and is confidentially filing Amendment No. 1 to the Draft Registration Statement (the “**Amended DRS**”) together with this response letter. The Amended DRS also contains certain additional updates and revisions.

Set forth below are the Company’s responses to the Staff’s comments in the Comment Letter. The responses and information below are based on information provided to us by the Company. For convenience, the Staff’s comments are repeated below in italics, followed by the Company’s response to the comments as well as a summary of the responsive actions taken. We have included page numbers to refer to the location in the Amended DRS submitted herewith where the revised language addressing a particular comment appears. Capitalized terms used but not defined herein are used herein as defined in the Amended DRS.

**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.*

**RESPONSE:** The Company respectfully advises the Staff that it has clarified certain scientific or technical terms throughout the Amended DRS in response to the Staff's comment (e.g. pages 1, 2, and 109).

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.*

**RESPONSE:** The Company respectfully advises the Staff that it has revised the disclosure on pages 1 and 2 of the Amended DRS to provide descriptions of the primary endpoints for each program and the 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.*

**RESPONSE:** The Company respectfully advises the Staff that it has included disclosure that open INDs permit the Company to move directly to Phase 2 for the FREEDOM-2 and FREEDOM-3 trials on pages 2 and 3 of the Amended DRS. In addition, the Company also respectfully advises the Staff that a separate open IND based on existing FCR001 safety data applies to FREEDOM-3 patients with a severe form of scleroderma and who do not receive living donor kidney transplantations and has also included disclosure in the Amended DRS to clarify this.

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.*

**RESPONSE:** The Company respectfully advises the Staff that it has revised the pipeline table and corresponding disclosure on pages 3 and 4 of the Amended DRS in response to the Staff's comment.

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.*

**RESPONSE:** The Company respectfully advises the Staff that it has expanded its disclosure on page 3 of the Amended DRS in response to the Staff's comment to disclose whether its open IND for FCR001 applies to patients with a severe form of scleroderma who do not receive a living donor kidney transplant or if it has filed an original IND for this program. As noted under our response to Item 3 above, the FDA has cleared a separate IND for this program based on existing FCR001 safety data, and the disclosure has been revised to clarify that open INDs permit the initiation of the FREEDOM-2 and FREEDOM-3 trials.

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.*

**RESPONSE:** The Company respectfully advises the Staff that it has revised its disclosure on page 22 of the Amended DRS to clarify that a number of third parties are seeking to develop conditioning regimens that have lower toxicities or otherwise already offer non-myeloablative conditioning regimens for other treatments.

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.*

**RESPONSE:** The Company respectfully advises the Staff that it has expanded its disclosure on page 51 of the Amended DRS in response to the Staff's comment to discuss its sources and availability of raw materials and the names of any principal suppliers.

Capitalization, page 82

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

**RESPONSE:** The Company respectfully advises the Staff that it has revised the disclosure on page 82 of the Amended DRS in response to the Staff's comment.

Dilution, page 84

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

**RESPONSE:** The Company respectfully advises the Staff that it does not have any intangible assets as of December 31, 2020 and has revised the disclosure on page 84 of the Amended DRS in response to the Staff's comment.

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.*

**RESPONSE:** The Company respectfully acknowledges the Staff’s comment and will supplementally provide the requested information once the estimated offering price or range has been determined.

Withdrawal of Chronic Immunosuppression Irrespective of HLA Mismatch, page 120

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

**RESPONSE:** The Company respectfully advises the Staff that it has revised the graphics on pages 123 and 137 of the Amended DRS 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.*

**RESPONSE:** The Company respectfully advises the Staff that it has revised the disclosure on pages 90 and 141 of the Amended DRS to disclose the total amount paid to date pursuant to the license agreement with the University of Louisville Research Foundation, Inc.

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.*

**RESPONSE:** The Company respectfully advises the Staff that it has revised the disclosure on page 188 of the Amended DRS to clarify the total number of outstanding product interest rights and describe how the formula for payment was determined. On March 12, 2021, the Company entered into a Termination Agreement with the holders of the product interest rights, terminating the Product Interest Rights Agreement and the rights and obligations thereunder subject to the consummation of the initial public offering.

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.*

**RESPONSE:** As described in Note 9 to the Financial Statements of the Amended DRS (“**Note 9**”), the Company entered into the Preferred Stock and Unit Purchase Agreement (the “**PSUPA**” and as subsequently amended for each of three closings, collectively the “**PSUPA Agreements**”) which consisted of Series A and Series A-1 preferred stock along with Product Interest Rights, with investors and their respective funds (the “**purchasers**”). From November 2018 through August 2020, the following tranches were closed under the PSUPA Agreements:

Tranche(s):	Series A Preferred Stock	Series A-1 Preferred Stock	Product Interest Rights	Purchase Price-Series A	Purchase Price A-1/PIR Unit	Total Proceeds
Tranche 1	22,500,000			\$22,500,000		\$22,500,000
Tranche 2	17,500,000	16,000,000	16,000,000	\$17,500,000	\$20,000,000	\$37,500,000
Tranche 3		12,000,000	12,000,000		\$15,000,000	\$15,000,000
Tranche 4	Terminated in connection with issuance of Series B preferred stock					
Total	40,000,000	28,000,000	28,000,000	\$40,000,000	\$35,000,000	\$75,000,000

Note 9 outlines the accounting for each closing of the transaction. In evaluating the accounting treatment of the instruments issued under the PSUPA Agreements, the Company particularly examined the treatment of the Series A-1 preferred stock and the product interest rights which together were issued as one unit. The Company's analysis focused on determining whether any of the features embedded in the Series A-1 preferred stock might represent a free-standing financial instrument or require bifurcation as a derivative.

The Company evaluated the following features to determine whether any were required to be accounted for separately from the Series A preferred stock and Series A-1 preferred stock (together, the "**preferred stock**") that were issued:

- *Conversion Features* – Each preferred stock converts into common shares under certain conversion scenarios as disclosed in Note 9. The economic characteristics and risk of the conversion features are considered clearly and closely related to the economic characteristics and risks of the equity host instrument (which is the preferred stock) as the conversion option provides for the conversion into common stock and, therefore, possess equity economic characteristics and risks. As such, the conversion feature does not meet the criteria within ASC 815-15-25-1(a) and, therefore, is not required to be separated.
- *Beneficial Conversion Feature* –The conversion formula of the preferred stock is disclosed in Note 9. The effective conversion price of the preferred stock, calculated in accordance with ASC 470-20-30-5, was greater than the fair value of the common stock at the issuance date and, accordingly, the conversion feature was not in-the-money at the issuance date. As a result, the preferred stock does not contain a beneficial conversion feature. The down-round price protection feature contained in the preferred stock is a beneficial conversion feature, however, it represents a contingency that would only be required to be recognized if the conversion price of the preferred stock is reduced and is less than the commitment date price of the common stock. This contingency has not been met as of any period presented in the financial statements.
- *Redemption Feature* – As described within Note 9 under "Liquidation preference," redemption can only occur upon a deemed liquidation event. The deemed liquidation feature is not separately transferrable from the preferred stock and, therefore, the embedded deemed liquidation feature is not a free-standing financial instrument. Further, the deemed redemption feature, which relates to a deemed liquidation event, does not meet the definition of a derivative as there is no ability for the deemed liquidation feature to be net settled as it must be settled by delivering gross shares. Therefore, the deemed redemption feature should not be bifurcated from the preferred stock and accounted for separately.

- *Rights to Future Stock Issuance (the “Tranche Rights”)* – The Tranche Rights were determined not to be separate free-standing financial instruments as the preferred stock are not legally detachable from the Tranche Rights. The holders of the preferred stock do not have the legal right to transfer their preferred stock without also transferring the Tranche Rights. The PSUPA Agreements state that such rights “are not separable from the ownership of Shares [...] and may only be transferred or assigned with the transfer or assignment of a like amount of Shares.” ASC 480-10-20 defines a free-standing financial instrument as:

“A financial instrument that meets either of the following conditions:

- a. It is entered into separately and apart from any of the entity’s other financial instruments or equity transactions.
- b. It is entered into in conjunction with some other transaction and is legally detachable and separately exercisable.”

The Tranche Rights do not meet either of the criteria for separation under ASC 480-10-20, as they were not entered into separately and apart from the preferred stock and they were not legally detachable.

The Company next considered whether the Tranche Rights should be bifurcated as an embedded derivative under ASC 815-15-25-1 and noted that, as there is no mechanism for net settlement under ASC 815-10-15-83(c), the Tranche Rights are not required to be separated.

The Tranche Rights associated with Tranche 4 were terminated in connection with issuance of Series B preferred stock in September 2020.

- *Product Interest Rights (the “PIRs”)* – The PIRs were determined not to be free-standing financial instruments as the Series A-1 preferred stock and the PIRs, which were issued together as a Unit, cannot be separately exercised. That is, the benefit from both the Series A-1 preferred stock and the PIR cannot be achieved simultaneously, as the transfer of a share of Series A-1 preferred stock results in the cancellation of a PIR. The fact that a share of Series A-1 preferred stock and the PIR originally issued with such share cannot be held by different parties indicates that they are not legally detachable from each other and, thus, the PIRs are not legally detachable instruments. The PIRs, therefore, meet neither the legal detachability nor the separate exercisability criteria of ASC 480 and, as a result, are not separate free-standing financial instruments.

The Company next considered whether the PIRs should be evaluated for separate recognition as an embedded derivative under ASC 815-15-25-1. In order to be within the scope, an instrument must meet the definition of a derivative under ASC 815-10-15-83. Although the PIRs may be a derivative under ASC 815-15-25-1, they are also subject to the derivative scope exception for non-exchange traded contracts with an underlying that is based on a specified volume of sales or service revenue of one of the parties to the contract. ASC 815-10-15-59 states:

“Contracts that are not exchange-traded are not subject to the requirements of this Subtopic if the underlying on which the settlement is based is any one of the following:

- ...(d) Specified volume of sales or service revenues of one of the parties to the contract. (This scope exception applies to contracts with settlements based on the volume of items sold or services rendered, for example, royalty agreements...)

As settlement of the PIRs is based on sales volume, the PIRs meet the definition of the scope exception and, therefore, are not required to be bifurcated.

As noted on page 188 of the Amended DRS, on March 12, 2021, we entered into a Termination Agreement with the purchasers of our Series A-1 preferred stock, terminating the Product Interest Rights Agreement and the rights and obligations thereunder subject to the consummation of the offering. The termination of the PIRs with no value exchanged supports the Company's analysis that the Unit share and the PIR were not separately detachable or exercisable.

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.*

**RESPONSE:** The Company respectfully advises the Staff that it has revised the footnote to the exhibit index on page II-4 of the Amended DRS to specify the rule relied on.

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.*

**RESPONSE:** The Company respectfully advises the Staff that it will provide the Staff, on a confidential basis under separate cover, copies of all written communications presented to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of such communications.

Sincerely,

/s/ Gabriela Morales-Rivera

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Gabriela Morales-Rivera

cc: Scott Requadt, *Talaris Therapeutics, Inc.*  
Mary Kay Fenton, *Talaris Therapeutics, Inc.*  
Arthur McGivern, *Goodwin Procter LLP*  
Sarah Ashfaq, *Goodwin Procter LLP*