United States securities and exchange commission logo

August 16, 2023

Mary Kay Fenton
Chief Financial Officer
Talaris Therapeutics, Inc.
93 Worcester St.
Wellesley, MA 02481

Re: Talaris Therapeutics, Inc.
Registration Statement on Form S-4
Filed July 20, 2023
File No. 333-273335

Dear Mary Kay Fenton:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Registration Statement on Form S-4

What is the Tourmaline pre-closing financing?, page 2

1. Please clarify if the merger is conditioned upon the consummation of the pre-closing financing.

What will Talaris stockholders receive in the Merger?, page 4

2. Briefly explain how the record date and ex-dividend date will impact which Talaris stockholders will be entitled to receive any special cash dividend declared by Talaris.

Will the common stock of the combined company trade on an exchange?, page 5

3. We note your disclosure that the shares of the combined company are expected to be listed

on Nasdaq. Please revise to disclose if the terms of the merger agreement permit that the Nasdaq listing closing condition could be waived without recirculation or resolicitation. If so, please revise your risk factors to reflect the risks associated with any such waiver and revise to indicate that shareholders may not have certainty at the time of the vote that the shares of the combined company will be listed on Nasdaq following the merger or revise your disclosure in a pre-effective amendment as appropriate if and when there is more certainty regarding the Nasdaq listing of the shares of the combined

company.
Prospectus Summary
Tourmaline, page 10

4. You state that Tourmaline is a late-stage clinical biotechnology company. Please revise references to late-stage given that Tourmaline's leading product candidate, TOUR006, has recently submitted its IND application to the FDA and has not begun clinical trials.
5. We note your disclosure here and throughout your prospectus regarding TOUR006 having the potential to be "best-in-class." Please remove references to "best-in-class" as this implies an expectation of regulatory approval and is inappropriate given the length of time and uncertainty with respect to securing marketing approval. If your intention is to convey your belief that your platform or your programs utilize a novel technology or approach, you may discuss how your technology differs from technology used by competitors. Statements such as these should be accompanied by cautionary language that the statements are not intended to give any indication that your technology or any potential product candidates have been proven effective or will receive regulatory approval.
The Merger
Background of the Merger, page 151

6. We note that Talaris management and representatives from Leerink Partners developed a list of 43 potential counterparties for the potential reverse merger transaction that was approved by the S&T Committee and that of the 43 potential counterparties, Leerink Partners distributed process letters on behalf of Talaris to 28 companies that the S&T Committee determined to be the most viable counterparties. Please describe the criteria the S&T Committee used in determining which counterparties should receive the process letters and which should not.
7. We note that on March 15, 2023 Tourmaline management shared a non-confidential corporate presentation with Leerink Partners who then shared it with the S&T Committee. Please discuss the contents of the presentation that would be material to Talaris' stockholders.
8. You state that on March 31, 2023 members of the S&T Committee discussed outreach they had received from certain potential counterparties. Please discuss who the parties were and what was the context of the outreach.

9. We note that on April 11, 2023 the S&T Committee decided to not advance with Party N. Please include a description for the reasons the S&T Committee decided to not move forward with Party N.
10. You state that on April 14, 2023 the S&T Committee selected to prioritize the indications of interest from Tourmaline, Party B, Party C, and Party H and that the S&T Committee decided to not move forward with the other 10 participants. We note that only 15 potential counterparties submitted indications of interest and that on March 16, 2023 the S&T Committee communicated to Parties F, G, I, J, and L that they were not invited to

move forward with the reverse merger process. Please clarify who the other 10
participants that were not invited to move forward on April 14, 2023 are.
11. We note that on April 14, 2023 the S&T Committee proposed certain revisions to
Tourmaline's transaction proposal. Please clarify if there were any other proposed
revisions or counterproposals presented to other potential counterparties.
12. On April 19, 2023 you state that the S&T Committee provided feedback to be
incorporated in Talaris' next counterproposal to Tourmaline. Please discuss such
feedback.

Opinion of Talaris' Financial Advisor, page 171

13. We note the disclosure on page 174 that for purposes of its analysis, Leerink Partners
utilized the estimated exchange ratio of 0.7403 shares of Talaris common stock for each
share of Tourmaline, based on Talaris' and Tourmaline's respective capitalization as of
June 22, 2023. However, this estimated exchange ratio does not appear to be within the
range of the exchange ratios disclosed on the cover page which range from 0.7553 to
0.7721. Please enhance the disclosure so that it is clear to investors how Leerink
concluded that the exchange ratio proposed to be paid by Talaris pursuant to the terms of
the Merger Agreement was fair, from a financial point of view, to Talaris using the
estimated exchange ratio of 0.7403. We also note the disclosure on page 175 that
Leerink s analysis resulted in an implied exchange ratio of approximately 1.2235x to
1.5454x. Please revise to state any conclusions Leerink reached regarding the exchange
ratio used for purposes of the merger agreement based on the results of the discounted
cash flow analysis.

Financial Projections, page 179

14. If true, please make clear that the Financial Projections reflect the assumption that
appropriate patents would be granted for TOUR006 and, if granted, would not expire until
2043. Please also explain why the Financial Projections were modeled to reflect the
estimated impact of loss of market exclusivity for the TED indication in 2039.

Tax Characterization of the Merger, page 192

15. We note your representation that Talaris and Tourmaline "intend" for the merger to

qualify as a reorganization within the meaning of Section 368(a) of the U.S. Internal
Revenue Code of 1986, as amended (the "Code"). Please revise your disclosure here and
throughout to provide counsel s firm opinion for each material tax consequence, including
whether the merger will qualify as a reorganization, or to explain why such opinion cannot
be given. If the opinion is subject to uncertainty, please (1) provide an opinion that
reflects the degree of uncertainty (e.g., "should" or "more likely than not") and explains
the facts or circumstances giving rise to the uncertainty, and (2) provide disclosure of the
possible alternative tax consequences including risk factor and/or other appropriate

disclosure setting forth the risks of uncertain tax treatment to investors. Please refer to
Item 601(b)(8) of Regulation S-K and Section III.A of Staff Legal Bulletin 19, Legality
and Tax Opinions in Registered Offerings for guidance.
Securities Purchase Agreement, page 222

16. We note your description of the Securities Purchase Agreement. Please identify each
shareholder who, as a result of purchasing securities pursuant to such agreement, is
expected to be a beneficial owner of 5% or more of the outstanding shares of the
combined company following the financing and the merger.
Proposal No. 4-The Incentive Plan Proposal, page 245

17. We note your disclosure on page 245 that under the 2023 Plan that the stockholders are
being asked to approve, the combined company s board of directors will generally have
the authority to effect, without the approval of stockholders, (1) the reduction of the
exercise, purchase, or strike price of any outstanding option or stock appreciation right;
(2) the cancellation of any outstanding option or stock appreciation right and the grant in
substitution therefore of other awards, cash, or other consideration; or (3) any other action
that is treated as a repricing under generally accepted accounting principles. Please
include appropriate disclosure regarding these repricing provisions which could occur
without stockholder approval, including whether proxy advisory firms could find any such
repricings without stockholder approval contrary to a performance-based pay philosophy.
Talaris' Business
Overview, page 260

18. We note in February 2023 Talaris announced the discontinuation of its FREEDOM-1 and
FREEDOM-2 clinical trials and in March 2023 Talaris voluntarily paused its FREEDOM-
3 trials. We also note that on page 36 you discuss the risks concerning if Talaris were to
resume development of its product candidates. Please clarify here whether Talaris has had
discussions with Tourmaline on continuing these trials.
Talaris' Product Candidates and Historical Business, page 261

19. You state that the degree of immune mismatch between the donor and recipient did not
appear to impact the safety and efficacy of Talris' therapy candidate.
Safety and efficacy

determinations are solely within the authority of the FDA or applicable foreign regulator.
Please revise or remove this statement and similar statements throughout your prospectus.
Note that you may state your product candidate has been well tolerated, if accurate.
Phase 2 Clinical Trial Results as of March 1, 2023
Indication of Durable Chimerism and Withdrawal of Immunosuppression, page 270

20. You make references to a "figure above" that denotes patients achieving durable donor
chimerism and weaning off their chronic immunosuppressants without rejecting the
transplanted organ and refining Talaris' Phase 2 protocol to exclude female donors to
unrelated male recipients. Please include the referenced figure or remove such references.
Talaris' Phase 2 Results - Quality of Life ("QoL"), page 276

21. You state that the General Health Component of SF-36 and the EQ-5D-5L questionnaires
reported statistically significant rates. Please provide p-values and define the term and the

significance of the p-value results shown.
HSCT as Potential Treatment for dcSSc, page 281

22. Please define TBI at first use.
Tourmaline's Business
Overview, page 304

23. You disclose that Tourmaline has submitted its IND in the U.S. to support initiation of its Phase 2b trial of TOUR006 in first-line TED and plans to submit an IND to support initiation of a Phase 2 ASCVD trial in 2024. In an appropriate location, briefly indicate why you believe Tourmaline would not need to conduct Phase 1 trials for these indications. Include risk factor disclosure if appropriate.
Tourmaline's Pipeline, page 304

24. Your pipeline table includes Thyroid Eye Disease Expansion Cohorts that, according to your disclosure under "TOUR006 for the Treatment of Additional TED Populations" on page 315, appears to be in the study or pre-clinical phase at this time. Please limit your table to product candidates that are sufficiently material to your business to warrant inclusion and, if sufficiently material, tell us whether this indication should be shown as pre-clinical in Tourmaline's pipeline table.

25. Based on the disclosure, it does not appear that Tourmaline has received IND approval at this time for the clinical trials indicated in the pipeline table. Since the pipeline table read as showing that Tourmaline Inc. is currently in clinical trials, please revise your table as appropriate to more clearly show the current status of the programs.

Corporate History and Tourmaline's Team, page 305

26. You state that Tourmaline's management team has been involved in the development of approved pharmaceutical products such as YERVOY, OPDIVO, KALBITOR, TAKHZYRO, and DALIRESP. Please clarify that although these products were approved, they are not an indication that your product candidates will be approved or receive orphan and/or large market designations.

27. You state that Tourmaline has raised money in private financing from leading biotechnology investors including Deep Track Capital, Cowen Healthcare Investments, QVT, Braidwell, Hydra, Petrichor, TCGX, KVP, RTW, Avego, Vivo, and Logos. Please limit the disclosure of specific investors to those identified in the Principal Shareholder table on page 398. Additionally, indicate that prospective investors should not rely on the named investors investment decisions, that these investors may have different risk tolerances and the securities purchased by those investors may have been conducted at a significant discount to price reflected in the merger agreement.
Our Product Candidate: TOUR006, page 309

28. We note your disclosure that TOUR006 was originally developed from a hybridoma cell

line using a transgenic mouse platform and that the IgG1 isotype of the original clone was
switched by Pfizer to IgG2 to reduce Fc receptor binding, thereby creating TOUR006.
Along with this disclosure, please add a brief discussion of how TOUR006 is considered a
fully human monoclonal antibody.
29. You state that TOUR006 was tested by Pfizer and across those studies TOUR006 has
demonstrated a safety profile consistent with the IL-6 class. Safety is a determination that
is within the authority of the FDA. Please revise or remove these statements and similar
statements throughout your prospectus. Note that you may state your product candidate
has been well tolerated, if accurate.
30. You disclose that TOUR006 has demonstrated low rates of anti-drug antibodies
(ADAs). Please disclose if the sample size of the data on which you base this disclosure
is sufficient to draw statistically meaningful conclusions in that regard.
31. In your table on page 310 you indicate that a black box warning is "N/A" for TOUR006.
Please tell us how you have determined at this time that such labelling would be not
applicable or revise your disclosure as appropriate.

Current Treatment Paradigm for TED, page 311

32. You state that the TEPEZZA had a proptosis response rate defined as a greater than or
equal to 2mm decrease in proptosis from baseline. Please explain the significance of the
result.

Clinical Experience in TED with IL-6 Inhibition, page 312

33. We note your disclosure that tocilizumab, an anti-IL-6R antibody, was reported to offer
meaningful improvement in efficacy outcomes. Since efficacy determinations are within
the authority of the FDA or other applicable regulators, please revise this statement as
appropriate. Please also disclose whether the studies presented in the table on page 313
were geared for statistical significance. In addition, if the inference to be made here is
that anti-IL-6 antibodies, such as TOUR006, would perform as well as anti-IL-6 receptor
antibodies, please include any cautionary disclosure that would be appropriate.

Clinical Experience with TOUR006, page 318

34. We note your disclosure of trials related to your product candidate throughout this
section. Please revise to clarify whether each trial was powered for statistical
significance. If a trial was powered for statistical significance, please provide p-values for
the results of each trial. If no statistical analysis was performed, please state so.

License Agreement with Pfizer, page 323

35. Please clarify if the transactions related to the merger agreement will constitute a
Significant Transaction under the License Agreement for purposes of the one-time
payment described at the top of page 324.

PD and Efficacy Data, page 323

36. We note your use of p-values for the CDAI-70 response rate. At first use, please provide
a brief explanation of the disclosed p-value and how it is used to

measure statistical
significance.
Patents, page 327

37. Please disclose the jurisdictions where Tourmaline's patent applications have been filed.
Please also disclose the specified indications the patent applications would cover if
granted.
Unaudited Pro Forma Condensed Combined Financial Information
Adjustments to the Unaudited Pro Forma Condensed Combined Financial Information
4. F, page 380

38. Please provide the calculation for how you determined that 150,997,662 shares of Talaris
shares will be received in exchange for 128,148,529 Tourmaline shares considering the
estimated exchange ratio of .7592.
Principal Stockholders of the Combined Company, page 401

39. Please revise your disclosure to identify the natural person or persons who have voting
and investment control of the shares held by the entities affiliated with Cowen Healthcare

Investments.
Exhibits

40. We note you intend to file the form of preliminary proxy card as Exhibit 99.1. Please note
that the form of proxy card should be filed as an appendix rather than as an exhibit to the
registration statement. Refer to the Note to paragraph (a)(3) of Exchange Act Rule 14a-4.
General

41. Please supplementally provide us with copies of all materials prepared by Leerink and
shared with Talaris board of directors and their representatives, including any board
books, transcripts and summaries of oral presentations, that were material to the board's
decision to approve the merger and the transactions contemplated thereby.
We remind you that the company and its management are responsible for the accuracy
and adequacy of their disclosures, notwithstanding any review, comments, action or absence of
action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate
time for us to review any amendment prior to the requested effective date of the registration
statement.

You may contact Christine Torney at 202-551-3652 or Daniel Gordon at 202-551-3486 if
you have questions regarding comments on the financial statements and related matters. Please
contact Doris Stacey Gama at 202-551-3188 or Tim Buchmiller at 202-551-3635 with any other
questions.

Sincerely,