United States securities and exchange commission logo

September 3, 2020

Bobak Azamian
Chief Executive Officer
Tarsus Pharmaceuticals, Inc.
15440 Laguna Canyon Road
Irvine, CA 92618

Re: Tarsus Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted August 7, 2020
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted August 14, 2020
CIK No.: 0001819790

Dear Dr. Azamian:

We have reviewed your draft offering 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 offering statement or publicly filing your offering statement on EDGAR. Please refer to Rule 252(d) regarding the public filing requirements for non-public submissions, amendments and correspondence. 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 your amended draft offering statement or filed offering statement and the information you provide in response to these comments, we may have additional comments.

Draft Registration Statement on Form S-1, submitted August 7, 2020

Cover Page

1. Please revise the table on the cover page and on page 185 to also take into account underwriting commissions. We note your disclosures elsewhere in the prospectus reflecting information after deducting estimated underwriting discounts and commissions.

Prospectus Summary
Overview, page 1

2. We note your references to your product candidates as "first-in-class" on page 1 and throughout the registration statement. This term suggests that the product candidates are effective and likely to be approved. Please delete these references throughout your registration statement. If your use of these terms was intended to convey your belief that the products are based on a novel technology or approach and/or is further along in the

development process, you may discuss how your technology differs from technology used
by competitors and, if applicable, that you are not aware of competing products that are
further along in the development process. Statements such as these should be
accompanied by cautionary language that the statements are not intended to give any
indication that the product candidates have been proven effective or that they will receive
regulatory approval. Additionally, with respect to TP-03, there are existing FDA
approved treatments for rosacea.

3. We note your statement that you estimate that the number of Demodex blepharitis cases
may be as high as approximately 25 million based on your internal studies, and your other
references to your research and surveys in the Summary. Please remove discussions of
your surveys from the Summary, and in the Business section, provide additional details
regarding the surveys so that an investor may understand their significance, including
which types of ECPs were included in the survey, how the surveyed ECPs and patients in
eye care clinics were selected, whether there was any ECP education that took place
between May 2019 and May 2020 that may have led to a rise in the number of
diagnoses, and what information regarding the indication and product candidates were
provided to those surveyed. Please also revise to provide balancing disclosure regarding
the small number of ECPs and patients surveyed. Also explain the basis for why you
believe there may be 25 million Demodex blepharitis patients when you state on page 2
that your research also indicates 58% of patients presenting to ECP offices have
collarettes indicative of Demodex blepharitis and that there are 20 million patients who
suffer from blepharitis.

4. Please revise the pipeline table on page 2, which also appears on page 108, so that it
reflects the current status of your product candidates. As such, please remove the grayed
out portion of the arrow for TP-04, and also shorten the length of the arrows for
the preclinical studies that are not yet completed. For example, we note your disclosure on
page 133 that you are conducting pre-clinical studies for TP-04. Please also expand your
disclosure on page 133 to state that you will need to obtain an IND for TP-04 prior to
commencing trials in the U.S., which you explain on page 19.

Blepharitis: A Significant, Underserved & Underdiagnosed Market , page 2

5. Please include a statement citing the number of people with collarettes that do not have
Demodex blepharitis.

6. Please remove the comparisons of the blepharitis market to the dry eye market and your
TP-03 product to Allergen's Restasis in your Summary section. Additionally, tell us why
you believe it is appropriate to make such comparisons when there are numerous

differences, including but not limited to the intended indication, regulatory approval status
and company operating history.

Our Approach: TP-03 , page 3

7. We note your statements on page 4 and elsewhere that your results are

highly statistically
significant. Please limit your discussions of trial results in the Summary section to
statements regarding the primary endpoints and whether they were met, or that the trials
and endpoints were exploratory, as applicable. The discussion of specific p-values and
whether they are statistically significant should be in the Business section, where you
should also explain how statistical significance relates to FDA approval and what you
mean by "highly" statistically significant.
8. We note your statement on page 4 regarding the robust and consistent clinical efficacy
of TP-03 that you observed in your Phase 2 clinical trials, as well as "meaningful and
consistent clinical efficacy and safety results" from your Phase 2 program. You also refer
on page 6 to "[c]ompelling efficacy and safety data" from your Phase 2 program, on page
7 that you observed in Phase 2 trials that TP-03 "results in collarette cure and mite
eradication," and your Figure 15 advertises a key advantage of TP-03 as its "Efficacy and
Efficiency." Please revise these and all similar statements throughout your prospectus that
state or imply that your product candidates are safe or effective as these determinations
are solely within the authority of the FDA and comparable regulatory bodies.
9. Please explain the basis for the amounts set forth in the following statement on page 5: "In
the United States, MGD prevalence has been found to be approximately two-thirds of that
of the estimated 34 million dry eye patient population." We note that on page 3,
you state the diagnosed population for dry eye was over 6 million in 2015 and similar
levels have been maintained since.
10. The footnotes to the graphic on page 5 indicate the Saturn trials are pending FDA
feedback. Please disclose this in your discussions of the Saturn trials and describe this
process and expected timeline. Please also increase the font size of the footnotes to the
graphic to make them more legible.
11. Please describe how the formulation of TP-03 that is expected to support your NDA
submission for Demodex blepharitis is different than the formulation of TP-03 used in
certain of your prior trials.

Our Strengths and Differentiation, page 6

12. Please balance your first bullet to explain that based on FDA feedback, your Phase 3 trials
will be using primary endpoints that are more stringent than the ones used in your Mars
and Jupiter trials and involve longer durations. Also explain that you expect to enroll 700
patients in your two Phase 3 trials as compared to your largest trial to date with 54
patients, that all your other trials were conducted outside of the U.S., and that the FDA has
not yet approved your trial designs.

Our Strategy, page 7

13. Please revise the last bullet on page 7 regarding the rights you retained, and similar
references elsewhere, to explain that you are dependent on intellectual property licensed
from Elanco Tiergesundheit AG for both TP-03 and TP-04.

Risks Related to our Business, page 7

14. Please revise your risk factor discussion so that they are of the same prominence as the discussion of your strategies. Please add bullets to discuss the risks associated with the significant concentration of share ownership by your principal shareholders, officers and directors, as referenced on pages 77-78, and that you are dependent on a license agreement for the intellectual property underlying your lead product candidate.

Implications of Being an Emerging Growth Company, page 9

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.

Risks Related to Intellectual Property, page 48

16. In the first risk factor on page 48 please include your obligation to grant Elanco a license to your patents and know-how if Elanco terminates the agreement for failure to meet a development milestone, which is mentioned on page 137.

Market, Industry and Other Data, page 85

17. It is not appropriate to directly or indirectly disclaim liability for statements in your registration statement. Accordingly, please delete the statements that the sources of the data cannot guarantee the accuracy or completeness of the information, and that your internal assumptions have not been verified by any independent source. Alternatively, specifically state that you take liability for these statements. We also note you state that you have conducted or sponsored surveys and studies set forth in this prospectus. Please expand your Business discussion to clarify which surveys were conducted by a third party, identify the party, and whether you commissioned the study for use in the registration statement. Please also tell us what consideration you gave with respect to filing a consent for such third party pursuant to Securities Act Rule 436.

Use of Proceeds, page 86

18. Please revise to disclose how far you expect to proceed in your Phase 3 trials of TP-03 for the treatment Demodex blepharitis and in the development of your other product candidates. Also, to the extent material amounts of other funds are necessary to accomplish your specified purposes, state the amounts of such other funds and the sources

thereof.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Fair Value of Common Stock, page 105

19. 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.
Business
Blepharitis Overview, page 113

20. On page 116, please clarify which of your clinical studies is referenced, or otherwise
disclose information regarding the trial, including the number of participants and the
results. In particular, you state only 7% of patients without collarettes had Demodex
and you also state [e]ven for those subjects without collarettes, but who were performing
daily lid scrubs with shampoo for a full year, 50% had Demodex infestation . Please
clarify how the 50% relates to the 7% in the description and Figure 7.
Market Opportunity in Blepharitis, page 116

21. On page 117, please revise the disclosure to state why a comparison to dry eye is being
presented in a study that you state was conducted to determine ECP awareness of the
connection between collarettes and Demodex infestation. With respect to the graphic,
please revise as necessary to clarify if any of these patients had overlapping diagnoses, in
particular with respect to MGD and dry eye.
22. On page 120 please explicitly state the basis for your comparison to dry eye and why that
comparison is meaningful. Please note whether there was any overlap between patients
that had both collarettes and were on a prescription therapeutic for dry eye disease and
explain how the survey results relate to your stated belief that there is a significant
population for Demodex blepharitis.
Our Approach: Treating Demodex Mites, a Root Cause of Disease, page 121

23. In the graphic on page 121 please clarify what you mean by "near complete resolution on
mean reduction of collarettes and mites" and either here or on page 114 include a
statement describing the basis for which you feel TP-03 may meaningfully improve
patient satisfaction with cataract and refractive surgery.
Clinical Development Program, page 122

24. On page 124 you state your study treated 15 people through day 28 and three did not

continue after day 28. The results on pages 125 and 126 show a total of 13 subjects on
days 7 and 14, and 14 subjects on day 28. A similar disconnect appears in connection
with the Io phase 2a trial discussion on page 127 with respect to Day 14. Please reconcile.
Our Additional Product Candidates - TP-04 Topical Formulation for the Treatment of Rosacea,
page 132

25. We note you indicate that TP-04 is in a preclinical stage. Please explain why you expect to
move TP-04 directly to a Phase 2a trial.
26. On page 133, please describe in more detail how you feel your TP-04 treatment for
rosacea would address the unmet medical need in the rosacea market and be more
effective than existing treatments that also target Demodex. For example, please expand
upon the following parenthetical "(longer half-life, more lipophilic, greater therapeutic
window)."
Intellectual Property, page 135

27. Please revise your discussion to clarify which patents (and their corresponding
jurisdictions and expiration dates) are licensed, and which ones are owned by you, and

whether your treatment and composition of matter claims are covered by issued patents or pending patent applications.

License Agreements, page 136

28. Please state the duration of the Elanco license agreement and the term of the royalty due thereunder. Please also provide the time period for the diligence and dermatology milestones or a range. We note that the earliest milestones were within a number of months after the agreement date per Exhibit 10.10. If you have missed any deadlines thus far please so state, and also note whether they were COVID-19 related or not.

You may contact Ameen Hamady at 202-551-3891 or Kate Tillan at 202-551-3604 if you have questions regarding comments on the financial statements and related matters. Please contact Margaret Schwartz at 202-551-7153 or Dorrie Yale at 202-551-8776 with any other questions.

Sincerely,

Division of Corporation Finance

Office of Life Sciences