



FOIA Confidential Treatment Requested Pursuant to 17 C.F.R. §200.83

The entity requesting confidential treatment is:

**Tarsus Pharmaceuticals, Inc.
15440 Laguna Canyon Road,
Suite 160
Irvine, CA 92618
Attention: Leonard Greenstein, Chief Financial Officer**

CERTAIN PORTIONS OF THIS LETTER HAVE BEEN OMITTED FROM THE VERSION FILED VIA EDGAR. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS. INFORMATION THAT WAS OMITTED IN THE EDGAR VERSION HAS BEEN NOTED IN THIS LETTER WITH A PLACEHOLDER IDENTIFIED BY THE MARK “[*].”**

April 13, 2023

VIA EDGAR

United States Securities and Exchange Commission
Division of Corporation Finance
100 F. Street, N.E.
Washington, D.C. 20549
Attention: Li Xiao
Mary Mast

**Re: Tarsus Pharmaceuticals, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2022
Filed March 17, 2023
File No. 001-39614**

Ladies and Gentlemen:

On behalf of Tarsus Pharmaceuticals, Inc., (the “Company”), this letter responds to the comments set forth in the letter to the Company dated March 30, 2023 from the staff of the Securities and Exchange Commission (the “Staff”). For your convenience, we have repeated and numbered the comments from the March 30, 2023 letter in italicized print, and the Company’s responses are provided below each comment.

Form 10-K for the Fiscal Year Ended December 31, 2022

Management’s Discussion and Analysis of Financial Condition and Results of Operations

Components of our Results of Operations

Research and Development Expenses, page 93

www.tarsusrx.com



1. ***Please provide more disaggregated disclosures for your research and development expenses by each significant program. In this regard, we note that you disclosed at page 94 that you track your external research and development expenses on a program-by program basis.***

RESPONSE TO COMMENT 1:

The Company respectfully acknowledges the Staff's comment and confirms that it will provide disaggregated disclosure for significant external research and development costs by program in its future annual and quarter filings under the Securities Exchange Act of 1934, as amended, beginning with the Company's upcoming filing on Form 10-Q for the quarter ended March 31, 2023.

Financial Statements

Note 9. Out-License Agreement, page 126

2. ***Please address the following comments with regard to your accounting and disclosures for your Out-License of TP-03 Commercial Rights in Greater China with LianBio Ophthalmology Limited.***

RESPONSE TO COMMENT 2:

- ***Describe all material terms of the agreement, including the material rights and obligations of each party.***

On March 26, 2021, the Company entered into a development and license agreement (the "LianBio Agreement") with LianBio Ophthalmology Limited ("LianBio"), pursuant to which, the Company licensed the product rights for the development and commercialization of TP-03 (lotilaner ophthalmic solution, 0.25%) in the People's Republic of China, Hong Kong, Macau, and Taiwan (the "Territory") for the treatment of Demodex blepharitis and Meibomian Gland Disease ("MGD"). Under the terms of the LianBio Agreement, the Company is entitled to (i) aggregate upfront payments of \$25.0 million by June 2021, (ii) development and commercial milestone payments of up to an aggregate of \$75.0 million and \$100.0 million, respectively, (iii) tiered low-to-high teen royalties on the sale of TP-03 in the Territory; and an equity warrant exercisable for the purchase of LianBio ordinary shares, the receipt of which are discussed below, as applicable.

The LianBio Agreement established a Joint Steering Committee with an equal number of representatives from the Company and LianBio to serve as a forum for communication with regards to (a) the overall state of the alliance; (b) progress of the Company and LianBio's development and commercialization activities; (c) the Territory-specific development plan; and (d) clinical trials for Demodex blepharitis or MGD that support development or regulatory approval of any compound or licensed product inside or outside the Territory (this excludes Saturn-1 and Saturn-2 trials, as described further below).

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Pursuant to the terms of the LianBio Agreement, LianBio may extend the Phase 3 Milestone by an additional 12 months by paying the Company \$[***] creditable against the amount payable for a specified development milestone payment, if such development milestone payment becomes due. LianBio may also extend the regulatory approval milestone by an additional 12 months by paying the Company \$[***], creditable against the amount payable for a specified development milestone payment, if such development milestone payment becomes due.

The Company's responsibility pursuant to the LianBio Agreement included completion of clinical study data for TP-03 Phase 2b/3 (Saturn-1) and Phase 3 (Saturn-2) trials. At any point during the clinical trial activity through completion, LianBio is able to request and access the clinical trial data. Pursuant to the LianBio Agreement, LianBio is contractually responsible for all clinical development and commercialization activities and costs incurred within the Territory.

Under the terms of the LianBio Agreement, the specific development and commercial milestone events and related payments are as follows:

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<u>Milestone Event</u>	<u>Payment Amount (000's)</u>
Development Milestones:	
(i) [***]	\$ [***]
(ii) [***]	[***]
(iii) [***]	[***]
(iv) [***]	[***]
(v) [***]	[***]
(vi) [***]	[***]
Total Development Milestones	<u>75,000</u>
Commercial Milestones:	
(i) [***]	[***]
(ii) [***]	[***]
(iii) [***]	[***]
(iv) [***]	[***]
(v) [***]	[***]
(vi) [***]	[***]
Total Commercial Milestones	<u>100,000</u>
Total Milestones	<u>\$175,000</u>

The warrant to purchase ordinary shares of LianBio represents a minority interest in LianBio upon issuance, which vests upon the achievement of certain development and regulatory milestones. The warrant will be exercisable at the fair market value at the time of issuance. The warrant shall vest and be exercisable upon achievement of the following milestones: [***].

The LianBio Agreement includes conditions for supply agreements (collectively, the "Drug Supply Agreement") to be negotiated in good faith and executed between the Company and LianBio. The Company will supply Licensed Product, as defined in the LianBio Agreement, (the "Licensed Product"), to LianBio for development and commercialization purposes in the Territory, in accordance with separate written agreements, one for supply in clinical trials ("Clinical Supply Agreement") and another for commercialization ("Commercial Supply Agreement").

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In December 2021, the Company and LianBio entered into a binding term sheet outlining the principal terms and conditions and basis to negotiate the Drug Supply Agreement. The binding term sheet specified that the Company would be paid one-time payments of \$[***] upon execution of the respective Clinical Supply Agreement and Commercial Supply Agreement aggregating to a total of up to \$[***].

- ***Provide us an analysis of your revenue recognition under ASC 606, including your determination of the performance obligations, the transaction price, the amount allocated to each performance obligation, and your revenue recognition method (i.e. over time or point in time) for each performance obligation.***

The Company evaluated and concluded that the arrangement reflected a transaction with a customer. The Company is receiving consideration in exchange for delivering an out-license, in addition to access to clinical trial research and development activities and results. These activities fall within the scope and accounting of ASC 606 contracts with customers. The following summarized the Company's analysis of revenue recognition under ASC 606:

Determination of the performance obligations

In accordance with ASC 606-10-25-14 the Company identified the following performance obligations in the arrangement at contract inception: (1) an exclusive license to research, develop, manufacture, commercialize, make, offer for sale, sell and import the licensed products in the Territory; and (2) research and development services in the form of completed clinical study materials for the respective Saturn-1 and Saturn-2 trials. The promises to provide research and development services for Saturn-1 and Saturn-2 clinical trials were evaluated and determined to be distinct promises in the contract and each of the two clinical trials are separate performance obligations apart from the promise to provide the license.

The Company also considered whether the Joint Steering Committee represented a distinct performance obligation and determined that it was formed only as a governance activity to provide the Company protectionary rights that was not meant to be a separate service that would provide benefit to the customer. The Company further evaluated that the Joint Steering Committee is not material to the overall promises in the agreement.

Transaction Price

The transaction price includes nonrefundable upfront payments, development milestones, commercialization milestones, equity warrants, and royalties.

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Under ASC 606-10-32-8, the Company used the most likely amount method to determine the transaction price for development milestones. The Company evaluated at contract inception whether the achievement of the development milestones were within the control of the Company. Based on this evaluation, the Company included the \$10.0 million milestone amount in the transaction price related to milestones within the control of the Company. Given the high degree of inherent uncertainty around the occurrence of the remaining contingent development milestones, the Company determined these milestone amounts were outside of the control of the Company and milestone receipts were at-risk at contract inception. Therefore, the Company constrained the consideration associated with these milestones until resolution of the uncertainty associated with these payments. As the variability around the development milestones are resolved, the Company allocated the consideration to each of the performance obligations, as discussed further below. Subsequent to execution of the LianBio Agreement, the Company met certain development milestone performance obligations and at that time adjusted the transaction price and amount allocated to each of the performance obligations in accordance with ASC 606-10-32-43 at each reporting period.

The Company applied the accounting in ASC 606-10-55-65 to account for the commercial milestones and royalties. The Company evaluated that the license is the predominant promise in the contract as it is the provision that allows LianBio to generate future revenues. Therefore, under the sales-or-usage-based royalty exception, the Company recognizes revenue based on the contractual percentage of LianBio's sale of products to its customers at the later of (i) the occurrence of the related product sales or (ii) the date upon which the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. There have been no TP-03 product sales in the Territory and therefore, the commercial milestone and royalty amounts were not included in the transaction price at contract inception.

The warrant to purchase ordinary shares of LianBio represented noncash consideration under ASC 606. In accordance with ASC 606-10-32-21 through 32-24, the Company included the estimated fair value of the warrants in the transaction price at contract inception.

Allocation of the Transaction Price to each Performance Obligation

In accordance with ASC 606-10-32-29, to meet the allocation objective, an entity shall allocate the transaction price to each performance obligation identified in the contract on a relative standalone selling price basis in accordance with paragraphs 606-10-32-31 through 32-35, except as specified in paragraphs 606-10-32-36 through 32-38 (for allocating discounts) and paragraphs 606-10-32-39 through 32-41 (for allocating consideration that includes variable amounts).

- In order to estimate the standalone selling price for license performance obligation, the Company considered ASC 606-10-32-34 and utilized an adjusted market assessment approach. The Company determined the standalone selling price by using a discounted projected sales model that included estimated product sales attributable to the license and discounted the sales using a present value factor. The Company believes this approach approximates the standalone selling price of the license as it represents the present value of all expected benefit for LianBio, its customer.

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- In order to estimate the standalone selling price for the respective research and development service performance obligations for Saturn-1 and Saturn-2, the Company considered ASC 606-10-32-34 and utilized the adjusted market assessment approach. The Company analyzed costs expected to be incurred for each of the clinical trials through completion to estimate the price that a customer would be willing to pay for these services in order to benefit from the clinical trials.

Based on the Company's application of ASC 606, the Company determined that the amount of the transaction price allocated to each performance obligation is as follows:

<u>Performance Obligation</u>	<u>Allocated Transaction Price (000's)</u>
(i) License for exclusive development and commercialization of TP-03 in the Territory for the treatment of Demodex blepharitis and MGD	\$[***]
(ii) Research and development services related to Saturn-1, including delivery of the clinical trial results	[***]
(iii) Research and development services related to Saturn-2, including delivery of the clinical trial results	[***]
Total	\$ 36,233

Revenue Recognition Method

In accordance with ASC 606-10-55-62 through 55-63, the Company determined that the license provides the right to use intellectual property as it exists at the point in time at which the license is granted as the license was sufficiently developed for LianBio to benefit from it. Therefore, the amount initially allocated to the license performance obligation was recognized as revenue at contract inception, upon delivery of the license.

In accordance with ASC 606-10-25-27, the Company determined that LianBio simultaneously benefits from the research and development services that are satisfied over time, as they are able to request and access the clinical trial data at any point through the trial completion. Therefore, the Company recognized the amounts allocated to the respective research and development performance obligations for Saturn-1 and Saturn-2 over the expected period of time that each clinical trial is ongoing, based on an input method as the related costs are incurred. The Company monitored the expected completion dates for each clinical trial and updated its estimated time to completion at each reporting period, as necessary.

- Tell us who is responsible for the achievement of additional TP-03 events discussed on page 22 which may result in additional consideration and clarify that the additional consideration is not included in the transaction price, if such is the case. Confirm that you have no further performance obligations including any clinical work with respect to either TP-03 for the treatment of Demodex blepharitis or MGD.***

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The Company disclosed in its Form 10-K on page 22 that “We will be eligible to receive further consideration from LianBio upon the achievement of additional TP-03 events, including: (i) additional development milestone payments of up to an aggregate of \$25.0 million (includes \$2.5 million for a milestone triggered in February 2023), (ii) China-based TP-03 sales threshold milestone payments of up to an aggregate of \$100.0 million, (iii) tiered low-to-high-teen royalties for the Territory TP-03 product sales, and (iv) vesting of a LianBio equity warrant upon certain regulatory milestones.”

LianBio is responsible for the achievement of remaining development milestones, as well as the commercial milestones, Territory TP-03 product sale thresholds, and regulatory milestones. The additional consideration for these milestone events is not included in the transaction price at contract inception.

Apart from the promises in separately executed Clinical Supply Agreement in February 2023 and the Commercial Supply Agreement that is to be executed, as discussed below, the Company has no further performance obligations pursuant to the LianBio Agreement, including any clinical work with respect to TP-03 for the treatment of Demodex blepharitis. The Company is in control of the initiation and completion of any MGD clinical trial activities, and therefore, assessed that this is not a performance obligation in the LianBio Agreement. The Company will, however, deliver clinical data to LianBio if it completes a pivotal trial for MGD.

Pursuant to the LianBio Agreement, the Company and LianBio shall negotiate in good faith and enter into a Commercial Supply Agreement by which LianBio will source from the Company, and the Company will supply LianBio, the Licensed Product. The Company and LianBio are responsible for executing the mutually satisfactory Commercial Supply Agreement. The additional consideration for this achievement is not included in the transaction price at contract inception.

- ***Tell us if the license was determined to be distinct and your basis for it.***

The Company determined that the license is distinct from other promises in the arrangement. The Company assessed the LianBio Agreement in accordance with ASC 606-10-25-14 and ASC 606-10-25-19 and identified the following to be considered: (1) an exclusive license to research, develop, manufacture, commercialize, make, offer for sale, sell and import the licensed products in the Territory; and (2) research and development services in the form of completed clinical study materials for the respective Saturn-1 and Saturn-2 trials.

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The Saturn-1 and Saturn-2 trials were initiated to evaluate the safety and efficacy of the Licensed Product. The Company believes the nature of the research and development services, explicitly promised in the arrangement, indicate that the license is distinct within the context of the contract. In assessing that the license is capable of being distinct from other promises, the Company considered that LianBio has the research and development capabilities to benefit from the functional intellectual property given their robust pipeline of product candidates in therapeutic areas and the availability of the associated expertise in the general marketplace. In addition, the Company considered whether LianBio can benefit from a promise for its intended purpose without the receipt of the remaining promise, whether the value of the promise is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is separately identifiable from the remaining promise.

- **Clarify how you are accounting for the drug supply agreement discussed on page 93 and provide references within ASC 606 to support your accounting treatment.**

The Drug Supply Agreement on page 93 refers to the binding term sheet entered into in December 2021, as referred to above in the description of the material terms of the LianBio Agreement. The binding term sheet provides the basis to negotiate definitive agreements in good faith. As of December 31, 2022, no Clinical Supply Agreement or Commercial Supply Agreement had been executed. In accordance with ASC 606-10-25-2, the binding term sheet did not create an enforceable right beyond negotiating specific terms in definitive agreements.

In accordance with ASC 606-10-32-8, the Company utilized the most likely amount method to estimate the amount of consideration to which it will be entitled. Given the high degree of uncertainty around the occurrence of these events, the Company determined the amounts to be constrained at contract inception and until the uncertainty associated with these payments is resolved. [***].

- **Lastly, clarify what is included in the line item “collaboration revenue” in your statement of operations.**

Collaboration revenue in the statement of operations and comprehensive loss consists of the revenue recognized for research and development services performed pursuant to the LianBio Agreement. Specifically, this line item includes the proportion of allocated transaction price recognized over time, as the TP-03 Saturn-1 and Saturn-2 clinical trials are completed, and the associated clinical data and reports are delivered to LianBio. License revenue recognized from the LianBio Agreement was disclosed in the license fees line in the statement of operations and comprehensive loss.

The Company respectfully acknowledges the Staff’s comment and in response, advises the Staff that it will supplement its existing disclosures included in the notes to the financial statements to provide additional detail regarding its revenue recognition and related accounting policies for out-license arrangements. For the convenience of the Staff, we attach the relevant paragraphs from our footnotes as Appendix A.

[Remainder of page intentionally left blank.]

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BY TARSUS PHARMACEUTICALS, INC.**

* * * * *

Please do not hesitate to contact me at (949) 418-1780 if you have any questions or would like additional information regarding this matter.

Very truly yours,

/s/ Leonard M. Greenstein
Leonard M. Greenstein

cc: Bryan Wahl, General Counsel and Secretary, Tarsus Pharmaceuticals, Inc.
Ryan J. Gunderson, Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP

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Excerpt from Note 2. Summary of Significant Accounting Policies and use of Estimates of Tarsus Pharmaceuticals, Inc.'s
Form 10-Q for the Quarter Ended March 31, 2023

(vii) Revenue Recognition for Out-License Arrangements

Overview

The Company currently has no product revenue. Reported revenue in the accompanying Statements of Operations and Comprehensive Loss is associated with one out-license agreement (the “China Out-License”) that allows the third-party licensee to market the Company’s TP-03 product candidate (representing functional intellectual property) in the People’s Republic of China, Hong Kong, Macau, and Taiwan (the “China Territory”)—see Note 9. The accounting and reporting of revenue for out-license arrangements requires significant judgment for: (a) identification of the number of performance obligations within the contract, (b) the contract’s transaction price for allocation (including variable consideration), (c) the stand-alone selling price for each identified performance obligation, and (d) the timing and amount of revenue recognition in each period.

The China Out-License was analyzed under GAAP to determine whether the promised goods or services are distinct or must be accounted for as part of a combined performance obligation. In making these assessments, the Company considers factors such as the stage of development of the underlying intellectual property and the capabilities of the customer to develop the intellectual property on their own, and/or whether the required expertise is readily available. If the license is not distinct, the license is combined with other promised goods or services as a combined performance obligation for revenue recognition.

The China Out-License arrangement included the following forms of consideration: (i) non-refundable upfront license payment, (ii) equity-based consideration, (iii) sales-based royalties, (iv) sales-based threshold milestones, (v) one-time payments for executing drug supply agreements, (vi) development milestone payments, and (vii) regulatory milestone payments. Revenue is recognized in proportion to the allocated transaction price when (or as) the respective performance obligation is satisfied. The Company evaluates the progress related to each milestone at each reporting period and, if necessary, adjusts the probability of achievement and related revenue recognition. The measure of progress, and thereby periods over which revenue is recognized, is subject to estimates by management and may change over the course of the agreement.

Collaboration revenue primarily consists of distinct research and development services for which revenue is recognized in proportion to the allocated transaction price as the performance obligations are satisfied.

Out-License of TP-03 Commercial Rights in Greater China in March 2021

On March 26, 2021, the Company entered into The China Out-License agreement with LianBio for its exclusive development and commercialization rights of TP-03 (lotilaner ophthalmic solution, 0.25%) in the China Territory, as defined in the agreement, for the treatment of Demodex blepharitis and Meibomian Gland Disease. LianBio is contractually responsible for all clinical development and commercialization activities and costs within the China Territory.

The Company assessed this arrangement in accordance with ASC 606 and identified the following material promises under the arrangement: (i) the exclusive license to research, develop, manufacture, commercialize, make, offer for sale, sell, and import TP-03 in the China Territory, and (ii) the research and development services in the form of clinical study materials for the respective Phase 2b/3 trial (Saturn-1) and Phase 3 (Saturn-2) TP-03 trials. The promises to provide research and development services for Saturn-1 and Saturn-2 clinical trials were evaluated and determined to be distinct promises in the contract and each of the two clinical trials are separate performance obligations apart from the promise to provide the license.

The assessment of the initial transaction price for the China Out-License agreement included an analysis of amounts the Company expected to receive, which at contract inception consisted of: (i) the upfront cash payment of \$15.0 million, (ii) a second cash payment of \$10.0 million, (iii) a \$10.0 million milestone that was determined to be within the control of the Company, and (iv) \$1.2 million representing the initial fair value of the equity warrant.

We accounted for each performance obligation as follows:

Out-License

The Company determined that this license was distinct based on an evaluation of the delivery of the functional license that was in the later stages of development, and it met the criteria for being distinct from the research and development services required under the China Out-License agreement. The Company determined the standalone selling price of this license using a discounted projected sales model and recognized as license fees revenue the total allocated transaction price at contract inception, upon delivery of the license.

Research and development services

The standalone selling price of these performance obligations was determined using the adjusted market assessment approach. The Company analyzed costs expected to be incurred for each of the clinical trials through completion to estimate the price that a customer would be willing to pay for these services in order to benefit from the clinical trials. The Company determined that LianBio simultaneously benefited from the research and development services that are satisfied over time, as they were able to request and access the clinical trial data at any point through the trial completion. Therefore, the Company recognized the amounts allocated to the respective research and development performance obligations for Saturn-1 and Saturn-2 as the research and development services were

provided using an input method, based on the costs incurred for each clinical trial and the total costs expected to be incurred to satisfy each performance obligation. The Company believes this method most faithfully depicted its performance in transferring the promised services during the expected period of time that each clinical trial was ongoing. The Company monitored the expected completion dates for each clinical trial and updated its estimated time to completion at each reporting period, as necessary.

Through March 31, 2023, the Company received payments from LianBio totaling [] comprised of an upfront payment of \$15.0 million and [] for the achievement of specified milestone events.

The Company is eligible to receive further consideration from LianBio upon the achievement of additional TP-03 events, including (i) additional regulatory milestone and one-time payments of up to an aggregate of [], (ii) China-based TP-03 sales threshold milestone payments of up to an aggregate of \$100.0 million, (iii) tiered low-to-high-teen royalties for China Territory TP-03 product sales, and (iv) vesting of a LianBio equity warrant upon certain regulatory milestones.

Revenue recognized in the accompanying Statements of Operations and Comprehensive Loss relates to the satisfaction of performance obligations including (i) the transfer of TP-03 license rights in the China Territory to LianBio and (ii) the completion of U.S. clinical activities and then providing LianBio with the related data to supplement its local pivotal trial package for TP-03 in the treatment of Demodex blepharitis.