

iTeos Therapeutics, Inc.
321 Arsenal Street, Building 3, Suite 301
Watertown, MA 02472
www.iTeosTherapeutics.com

VIA EDGAR

August 12, 2022

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

> Re: iTeos Therapeutics, Inc. Form 10-K for the Fiscal Year Ended December 31, 2021 Filed March 23, 2022 File No. 001-39401

On behalf of iTeos Therapeutics, Inc. (the "<u>Company</u>" or "<u>iTeos</u>"), we are submitting this letter in response to comments received from the Division of Corporate Finance (the "<u>Staff</u>") of the Securities and Exchange Commission ("<u>SEC</u>") by letter dated July 13, 2022 with respect to the above-captioned filing. For ease of reference, the Company's response is keyed to the Staff's comments.

1.1 We note that Section 3.1.3 of the GSK Collaboration and License Agreement as filed in exhibit 10.13 refers to a narrowly defined Phase 1 definition under "iTeos Phase 1 Clinical Study". Please clarify what the iTeos Phase 1 Clinical Study entails and if there is a Phase 1 clinical study that is outside the "iTeos Phase 1 Clinical Study". In addition, clarify whether Phase 2 and 3 is equivalent in scope to the "Global Development Plan".

Response: The Company respectfully acknowledges the Staff's comments and provides the following information in response:

As defined in Section 1.152 of the Collaboration and License Agreement between iTeos Belgium S.A and GlaxoSmithKline Intellectual Property (No. 4) Limited ("GSK") dated June 11, 2021 (the "Agreement"), the iTeos Phase 1 Clinical Study means the Company's study IO-002, which is a multicenter, open-label, dose-escalation Phase 1/2a clinical study to evaluate the safety and tolerability, PK, PD, and antitumor activity of EOS-448 in participants with advanced cancers. The Company initiated the iTeos Phase 1 Clinical Study in February 2020. Since the enrollment of the iTeos Phase 1 Clinical Study was almost completed when iTeos and GSK (the "Parties") negotiated the terms of the Agreement, the Parties agreed, for operational and cost reasons, to exclude the iTeos Phase 1 Clinical Study from the Global Development Plan. In accordance with Section 3.1.3 of the Agreement, iTeos conducted the iTeos Phase 1 Clinical Study at its sole cost and expense.

No other studies are included within the term "iTeos Phase 1 Clinical Study." The Global Development Plan includes other Phase 1 clinical studies, as well as Phase 2 and Phase 3 studies.

1.2 You also state on page 1 that "In partnership with GSK, iTeos has dosed the first patients in a clinical trial assessing the doublet of GSK's anti-PD-1 (dostarlimab) with EOS-448." and that "We and GSK also are initiating Phase 1b trials with novel triplets, including dostarlimab with EOS-448 and inupadenant as well as EOS-448 with dostarlimab and GSK's anti-CD96 antibody, GSK'608." For each of the clinical trials discussed here please explain to us (1) whether they fall under the scope

of "iTeos Phase 1 Clinical Study" or the "Global Development Plan", (2) which party is responsible for performing the work and which party is responsible for the related costs and expenses, and (3) timing and the status of the trial as of December 31, 2021 and March 31, 2022.

Response: The Company respectfully acknowledges the Staff's comments and provides the following information in response:

As noted in the response to Comment 1.1, only study IO-002 falls under the definition "iTeos Phase 1 Clinical Study." All other referenced studies are governed by other terms of the Agreement and certain of these studies will be performed under the Global Development Plan, including the clinical trial assessing the doublet of GSK's anti-PD-1 (dostarlimab) with EOS-448, and the Phase 1b trials with novel triplets. Pursuant to the terms of the Agreement, the parties share the responsibility and costs for all shared global development activities under the Global Development Plan that are undertaken to obtain or maintain regulatory approval in both the United States and Europe. While the Parties' specific operational responsibilities vary from study to study, GSK is responsible for 60% of the cost and the Company is responsible for the remaining 40% of the cost of all studies included in the Global Development Plan.

Below is the timing and the status of the studies referred to in question 1.2:

	As of Dec. 31, 2021	As of March 31, 2022
Clinical trial assessing the doublet of dostarlimab with EOS-448	Enrollment	On-going (first patients were dosed in early 2022)
Phase 1b trial assessing the triplet of dostarlimab with EOS-448 and inupadenant	Planning phase	Start-up activities
Phase 1b trial assessing the triplet of dostarlimab with EOS-448 and GSK'608	Start-up activities	Start-up activities

1.3 Explain to us why the entire \$625.0 million upfront payment was allocated to the components accounted for under ASC 606 and why some of the amount was not required to be allocated to the other material components of the agreement. In this regard, clarify why you believe the Phase 2 and 3 goods and services are distinct from the Phase 1 goods and services under ASC 808-10-15-5B.

Response: The Company respectfully acknowledges the Staff's comment and provides the following information in response:

The Agreement is not bifurcated into the "Phase 1 goods and services" and "Phases 2 and 3 goods and services". The bifurcation, instead, is between the iTeos Phase 1 Clinical Study, as defined by Section 1.152, and all other studies subject to the Agreement, including studies under the Global Development

Plan. The identified goods and services promised in the Agreement (including the Phase 1 Clinical Study) and the activities related to the other studies subject to the Agreement are distinct due to the differing levels of GSK's involvement with the studies. The Company has not promised any goods or services, and consequently, is not obligated to perform the activities related to the other studies subject to the Agreement. The identified goods and services, including the Phase 1 Clinical Study, are solely the responsibility of the Company. The Parties share the responsibilities regarding the rest of the activities related to the other studies under the Agreement.

ASC 808-10-15-5B provides guidance on situations in which collaborative agreements are partially in scope of ASC 606:

808-10-15-5B A collaborative arrangement is partially within the scope of Topic 606 if a unit of account, identified as a promised good or service (or bundle of goods or services) that is distinct within the collaborative arrangement using the guidance in paragraphs 606-10-15-4 and 606-10-25-19 through 25-22, is with a customer. An entity shall apply the guidance in Topic 606 to a unit of account that is within the scope of that Topic, including the recognition, measurement, presentation, and disclosure requirements. If a portion of a distinct bundle of goods or services is not with a customer, the unit of account is not within the scope of Topic 606.

Per the above, a collaborative agreement is partially within the scope of ASC 606 if a distinct good or service is promised to a customer. A customer is defined under ASC 606 as follows:

606-10-20 A party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration.

As disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "10-K"), the identified goods and services promised in the Agreement include: (i) transfer of the license under certain of the Company's intellectual property related to EOS-448, (ii) completion of the iTeos Phase 1 Clinical Study, (iii) transfer of "Know How" under the EOS-448 intellectual property, and (iv) manufacturing until the "Know How" transfer is complete. These identified goods and services were determined not to be distinct in the context of the contract and thus a single unit of account due to the high degree of interrelationship with the value of the license. The Phase 1 Clinical Study was in process at the time of contract execution and could not be transferred to GSK. Further, GSK restarting or reperforming the study itself would require them to reincur costs iTeos already had incurred, delay the development timeline, and reduce the value of the license. GSK provided consideration in return for the identified goods and services, which renders GSK a customer within the context of these promises and creates a vendor-customer relationship with respect to the identified goods and services.

While the Company is transferring its license and intellectual property developed in connection with the Phase 1 Study to GSK for consideration under the GSK Agreement, the development of such property is normally conducted for its own use. As described in Note 1 of the 10-K, the primary nature of the Company's business is pioneering the discovery and development of a new generation of highly differentiated immuno-oncology therapeutics for people living with cancer.

The Global Development Plan, as defined by the Agreement, consists of two types of Development activities: (1) "Shared Global Development Activities", the performance of which both parties are jointly responsible, and (2) "GSK Sole Development Activities", for the performance of which GSK is solely responsible. The parties share all costs of Shared Global Development Activities under the Global Development Plan at fixed share rate regardless of which party sponsors a given activity. GSK is solely responsible for all costs of the GSK Sole Development Activities. A Joint Development Committee

("<u>JDC</u>") and a Joint Steering Committee ("<u>JSC</u>"), each of which seats an equal number of representatives from both companies, have been established to govern activities performed under the Global Development Plan. As a point of clarification, the iTeos Phase 1 Clinical Study and related activities fall outside the scope of the JDC and JSC. There are no such committees with respect to the iTeos Phase 1 Clinical Study and related activities as the completion of these activities is solely the responsibility of iTeos. ASC 808-10-20 defines a collaborative arrangement as follows:

ASC 808-10-20 A contractual arrangement that involves a joint operating activity (see paragraph 808-10-15-7). These arrangements involve two (or more) parties that meet both of the following requirements: --

- a. They are active participants in the activity (see paragraphs 808-10-15-8 through 15-9).
- b. They are exposed to significant risks and rewards dependent on the commercial success of the activity (see paragraphs 808-10-15-10 through 15-13).

ASC 808-10-15-8 provides examples of situations that evidence active participation in a collaborative arrangement:

ASC 808-10-15-8 Whether the parties in a collaborative arrangement are active participants will depend on the facts and circumstances specific to the arrangement. Examples of situations that may evidence active participation of the parties in a collaborative arrangement include, but are not limited to, the following:

- a. Directing and carrying out the activities of the joint operating activity
- b. Participating on a steering committee or other oversight or governance mechanism
- c. Holding a contractual or other legal right to the underlying intellectual property.

The Company and GSK are both considered active participants in the Global Development Plan as each is responsible for carrying out joint activities through the fixed rate cost share arrangement, and with the joint participation on the JDC and JSC. With respect to ASC 808-10-15-10, both parties are exposed to significant risks and rewards associated with the Shared Global Development Activities. Both parties are bound to risk through the cost-share arrangement as there is the potential that each company could spend a significant amount of money without ever achieving commercial success. Conversely, each party stands to benefit greatly in the case that commercial success is attained. GSK will benefit from direct sales of a commercial product, and the Company will benefit from the milestone and royalty payment structure.

The activities under the iTeos Phase 1 Clinical Study are distinct from the activities under the Global Development Plan given that the Company is solely responsible for the iTeos Phase 1 Clinical Study activities, whereas both parties share the responsibility and costs of joint activities outside of the iTeos Phase 1 Clinical Study (e.g., the Shared Global Development Activities conducted under the Global Development Plan). Accordingly, GSK does not meet the definition of a customer with respect to the shared activities falling under the Global Development Plan. Under none of the Shared Global Development Activities has or will the Company receive consideration for providing goods or services to GSK. The Company may also make payments to GSK depending on the allocation of activities by the JSC and the costs incurred by each party in the respective period. This conclusion is also consistent with ASC 808-10-15-6, which states that a collaborative arrangement can begin at any point in the life cycle of an endeavor. The Agreement became a collaborative arrangement after the completion of the iTeos Phase 1 Clinical Study, the transfer of the license, the transfer of "Know How", and the manufacturing until the

completion of the "Know How" transfer. Accordingly, the Company allocated the \$625 million upfront payment to the identified goods and services described above, which are referred to as the performance obligation in the Company's Form 10-K for the Fiscal Year Ended December 31, 2021. The Shared Global Development Activities fall fully under the scope of ASC 808 and are not under the scope of ASC 606. As a result, GSK did not meet the definition of a customer under ASC 606 with respect to the Shared Global Development Activities.

1.4 You state on page F-20 under "Collaboration" that GSK is not a customer in the context of the Phase 2 and 3 and co-commercialization activities whereas you state on page F-21 under "Revenue Recognition" that GSK is a customer. Please clarify on page F-21 in what context GSK is a customer.

Response: The Company respectfully acknowledges the Staff's comment and provides the following explanation in response:

The determination for the context in which GSK is a customer and is not a customer follows the same fact pattern described in the prior response. A customer as defined by ASC 606-10-20 as a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration. GSK meets this definition in the context of the iTeos Phase 1 Clinical Study, the transfer of the license, the transfer of "Know How", and the manufacturing until the completion of the "Know How" transfer. GSK is not a customer in the context of the joint collaboration activities under the Agreement's Global Development Plan. Both parties actively participate in the Shared Global Development Activities under the Global Development Plan's cost-share arrangement, and both parties also have exposure to significant risks and rewards through that cost-share arrangement. The Shared Global Development Activities, therefore, meet the criteria for a collaborative arrangement under ASC 808-10-20. Additionally, GSK has not or will not receive goods or services in exchange for consideration from the Company in connection with any of the Shared Global Development Activities and, therefore, does not meet the definition of a customer with respect to this section of the Agreement. ASC 808-10-15-5B allows for a counterparty being recognized as a customer under one part of an agreement but not meeting the definition of a customer under other sections of the same agreement. ASC 808-10-15-6 further reinforces that a counterparty can be recognized as a customer in certain points of an arrangement but could fail to meet that definition at other points, as this section of the guidance affirms that a collaborative arrangement can begin at any point in the life cycle of an endeavor, and therefore does not need to be the case for the entirety of the agreement.

The Company proposes to include in the paragraph on page F-21 under the subtitle *Revenue Recognition* the following language to clarify in its disclosures the context in which GSK is a customer:

The Company also evaluated the elements of the GSK Collaboration Agreement in accordance with the provisions of ASC 606 and concluded that the contract counterparty, GSK, is a customer. The Company's arrangement with GSK contains the following material promises under the contract at inception: (i) transfer of the license under certain of the Company's intellectual property related to EOS-448, (ii) completion of the iTeos Phase 1 Clinical Study, as defined in the GSK Agreement, (iii) transfer of "Know How" under the EOS-448 intellectual property, and (iv) manufacturing until the "Know How" transfer is complete. The Company evaluated the above material promises under ASC 606 and determined that it has one combined performance obligation. These promises are considered to be outputs of the Company's ordinary activities and ongoing major operations. As GSK provided the Company consideration in exchange for these promises, GSK meets the definition of a customer under ASC 606-10-20 in the context of the combined performance obligation. These promises are distinct from the

co-development and co-commercialization activities in which the Company and GSK jointly participate. Accordingly, the context in which GSK is a customer is limited to the material promises described above.

2. Here and at page 67, you disclose that you recorded a \$17.0 million liability as of December 31, 2021, related to an uncertain tax position regarding your allocation of revenue between Belgium and the U.S. Also as disclosed on pages 14 and 23 of the Form 10-Q for the fiscal quarter ended March 31, 2022, you recorded an additional \$22.3 million liability as of March 31, 2022. Please tell us and disclose in more detail in future filings the reason for the significant increase in the liability, the uncertainties, as well as its potential impact, if recognized, to your effective tax rate. Refer to ASC 740-10-50-15. Please also ensure your response specifically addresses whether the change is the result of correcting an error under ASC 250, Accounting Changes and Error Corrections.

Response: The Company respectfully acknowledges the Staff's comment and provides the following explanation in response:

As discussed in Note 5 – License and Collaboration Agreements in the Form 10-K (page F-9), the Company recognizes revenue over time as the costs to complete its performance obligation relating to the iTeos Phase 1 Clinical Study and related activities are incurred. As of December 31, 2021, iTeos recognized approximately \$344.8 million of revenue related to the Agreement. Based on the Company's review of the revenue recognized in 2021 resulting from the Agreement, the Company recognized an accrual of \$17 million for an uncertain tax position that could result from the allocation of revenue between Belgium and the U.S tax jurisdictions. The resulting effective tax rate as disclosed for that period as per Note 9. Income Taxes (page F-26) was 16.4%.

The Company recognized an additional \$152.5 million of revenue from January 1, 2022 through March 31, 2022 related to the Agreement, as noted in the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2022 (the "10-Q"). As a result of the 2022 revenue recognized, the Company recorded an additional accrual of \$22.3 million for the uncertain tax provision. The resulting effective tax rate for the quarter ended March 31, 2022 was 41.8% as presented in the 10-Q (page 14). The effective tax rates calculated as of the respective year and quarter end reflect the inclusion of the uncertain tax position.

The increase in the accrual for the uncertain tax position noted in our 10-Q was not a result of correcting an error under ASC 250, *Accounting Changes and Error Corrections*, but the result of the continued recognition of the revenue from the performance obligation under the Agreement in 2022.

If you have any questions or comments about this letter or need any further information, please direct any communications to the undersigned at (339) 217 0161 or matthew.gall@iteostherapeutics.com.

Respectfully Submitted,

/s/ Matthew Gall
Matthew Gall
Chief Financial Officer
iTeos Therapeutics, Inc.