

Golenbock Eiseman Assor Bell & Peskoe, LLP
711 Third Avenue – 17th Floor
New York, New York 10017
212-907-7300

Andrew D. Hudders
212-907-7349
ahudders@golenbock.com

September __, 2021

Securities and Exchange Commission
100 F Street N.E.
Washington, D.C. 20549
Attn: Jordan Nimitz, Esq.

Re: TC BioPharm (Holdings) Ltd.
Draft Registration Statement on Form F-1
Submitted July 26, 2021
CIK: No. 0001872812
Office of Life Sciences

Dear Ms. Nimitz:

On behalf of TC BioPharm (Holdings) Ltd. (the “Company”), we are responding to the letter, dated August 23, 2021 (the “Comment Letter”), regarding the Company’s initial submission of a Confidential Registration Statement on Form F-1 submitted July 27, 2021 (the “Registration Statement”). In response to the Comment Letter and to update certain information in the Registration Statement, the Company is submitting an Amendment No. 1 to Registration Statement on Form F-1 with the Securities and Exchange Commission (the “First Confidential Amendment”). For ease of reference, set forth below are the comments of the Staff as reflected in the Comment Letter. The Company’s response is set forth below each comment. Capitalized terms used herein have the meanings set forth in the First Confidential Amendment unless defined herein.

The Company has authorized us to respond to the Comment Letter as follows:

Draft Registration Statement Filed on July 26, 2021

Prospectus Summary
The Company, page 5

1. We note your statement here and on page 68 that you are a “leader in the field of cell-based immuno-oncology,” as well as your statement on page 78 that you are “leaders in the commercialization of GDTs.” Please explain to us to basis for this claim; we note that your most advanced product candidate has just finished a Phase 1/2 clinical trial and that you have not yet obtained a regulatory approval for a product candidate.

RESPONSE: The Company has amended the wording in the document to clarify that they are referencing their position as a leader in GD-T based immuno-oncology.

The Company believes it is appropriate to refer to themselves as leaders in GD-T based immuno-oncology as their closest competitors have only recently initiated Phase 1 studies, whereas the Company has formally completed a Phase 1 study and is about to commence a Phase 2 pivotal trial.

In addition, on page 78, the Company has amended the wording to note that they are leaders in the path towards the commercialization.

2. We note on page 7 your statement that one of your strengths is your “Ability to treat of patients under the ‘Specials’ regulatory framework in Europe and the United States.” As references to the United States in the context of the Specials framework implies FDA approval, please revise to remove the United States from associations with the MHRA Specials framework.

RESPONSE: The Company has removed the reference to the United States.

3. We note that you plan to conduct clinical trials for your first oncology product in the United States in 2022 following a planned application to the FDA. Please revise to clearly state which product you are planning you test in your United States clinical trials and when you plan to submit an IND for this product.

RESPONSE: The Company has revised the disclosure in the prospectus summary to indicate the product it plans on testing.

Implications of Being an “Emerging Growth Company”, page 7

4. 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.

RESPONSE: To date, neither the underwriter on behalf of the Company or itself nor the Company has contacted any potential investors or distributed any communications to investors in connection with the proposed offering pursuant to Section 5(d) of the Securities Act.

Risk Factors, page 13

5. Given the length of your risk factor section, please revise to comply with Regulation S-K Item 105(a) by relocating risks that could generically apply to any registrant or offering to the end of the section under the caption “General Risk Factors.” The below examples are illustrative only and not meant to be exhaustive.

- On page 15: “Exchange rate fluctuations may materially affect our results of operations and financial condition.”
- On page 21: “Collaborations, whether through joint ventures, licensing, development arrangements, and other forms of agreements, will be important to our overall business development.”

- On page 33: “Our internal computer systems, or those of our future collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a significant disruption of our product development programs and our ability to operate our business effectively”

RESPONSE: The Company has revised the risk factor section accordingly. The Company has reordered certain risk factors to segregate more generic risk factors into a new subsection within the risk factor section, and the Company reviewed all the risk factors with a view of eliminating and editing down some risk factors that are generic and not pertinent at this time.

Risks Related to Development, Clinical Testing and Commercialization of Our Investigational Therapies and Any Future Therapeutic Candidates Collaborations, whether through joint ventures, licensing, development arrangements, and other forms.... page 21

6. We note your statement that neither of the collaborative arrangements with Nipro Corp. or bluebird bio inc. involve you in any current clinical or development activity. However, your pipeline tables include preclinical programs for TCB003 and TCB004, conducted in partnership with Nipro and bluebird bio, inc. respectively. Please revise your statement to correct the discrepancy. To the extent that these collaboration agreements are material, please include a description of the material terms of these agreements in the prospectus, including rights and obligations, financial terms including amounts paid to date, aggregate milestone amounts to be paid or received, the royalty range and term, as applicable, term and termination provisions. Please also file these agreements as exhibits. To the extent that the agreements are not material, please remove the collaborative partners and their associated programs from the pipeline table.

RESPONSE: The Company has updated the pipeline tables to provide clarity and demonstrate consistency. In particular, the Company notes that the pipeline tables reflect both the historic and prospective clinical activity. An explanatory sentence has been added below the tables. The Company does not consider the agreements with the collaborative parties as material, as there are no current obligations to be performed by either party at this time.

Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all, page 26

7. We note your accompanying risk factor disclosure that certain of raw materials related to the manufacture of your products are only available from a single-source supplier. Please expand your disclosure here to discuss your sources, the availability of raw materials and the names of any principal suppliers. See Item 101(h)(4)(v) of Regulation S-K.

RESPONSE: The Company has expanded the risk factor to include the names of principal suppliers.

Risks Related to Intellectual Property, page 36

8. Please add a risk factor, or revise in the appropriate risk factor, to address the limitations of patents protecting the method of use as opposed to other types of patents, such as a composition of matter patent.

RESPONSE: The Company has added further detail to the discussion in the third risk factor within the section “Risks Related to Intellectual Property to indicate the limitations of patent protection.

If we fail to comply with our obligations in the agreements...., page 40

9. We note that you have license agreements with MEDINET Co., Ltd, Cell Science & Technology Institute (“CSTI”), and UCL Business plc (“UCLB”).

Please revise the descriptions of each of your agreements to disclose:

- each parties’ rights and obligations under the agreement;
- quantify all payment made to date;
- disclose separately the aggregate amount of all potential development, regulatory and commercial milestone payments;
- disclose the amount of option fees for additional targets;
- quantify the royalty rate, or a range no greater than 10 percentage points per tier;
- disclose when royalty provisions expire, if the expiration is based on a number of years following commercialization, disclose the number of years;
- disclose the expiration date; and
- describe any termination provisions.

RESPONSE: The Company has removed the disclosure with respect to CSTI as the agreement was limited to supply of materials and is not considered material. The Company has removed the disclosure with respect to MEDINET as the license agreement is not considered material to the business. The Company has added outline details of the salient provisions of the agreement with respect UCLB, including the nature of the agreements and sources of potential revenue..

Use of Proceeds, page 50

10. Please revise your disclosure to provide your best reasonable estimate of how far in the pre-clinical or clinical developmental process you expect the amount of proceeds from this offering will enable you to reach for each of your product candidates.

RESPONSE: The Company has added further information to the Use of Proceeds section providing such estimates.

Management Discussion and Analysis of Financial Condition and Results of Operations Research and Development Expenses, page 58

11. You state on page 58 that you track certain research and development costs on program- by-program basis. Please provide disaggregate disclosure of your research and development expenses by program for each period presented. In addition, quantify in our narrative discussion of the changes in Research and Development expenses on page 60 the changes due to each program, or if not known, the changes due to clinical vs non-clinical.

RESPONSE: The Company has added disclosure on research and development costs on a program- by-program basis, including quantifying changes in the narrative discussion.

Business Overview, page 67

12. You make several assertions regarding the safety and efficacy of your product candidates. Safety and efficacy determinations are solely within the authority of the FDA (or applicable foreign regulator). You may present clinical trial end points and objective data resulting from trials without concluding efficacy and you may state that your product candidates have been well tolerated, if accurate. Please revise or remove statements/inferences throughout your prospectus that your product candidates are safe and/or effective.

As a non-exhaustive list of illustrative examples only, we note the following:

- On page 67, you state: “In-house clinical studies have demonstrated that TCB’s unmodified allogeneic GDT products are (i) safe and (ii) able to reduce cancer burden and improve life-expectancy of patients with late-stage blood cancer, known as acute myeloid leukemia – AML” and that you “generated meaningful safety and efficacy data in [y]our TCB002 trials treating late-stage AML patients with no remaining treatment options . . .”
- On page 72, you state that your product has an “improved safety profile.”
- On page 74, you state: “In the clinic, allogeneic treatment in AML patients has shown a favorable safety and efficacy profile,” that the TCB001 trial “did not raise any safety concerns,” and that TCB002 has a “promising medical plausibility.”
- On page 78, you state that your clinical trials “provided very strong evidence of safety and preliminary evidence of clinical benefit”, that “[d]ata from TCB002 suggests an excellent safety profile, with no observed Host versus Graft Disease (HvGD) and strong indication of clinical benefit,” and that you believe your products “will be demonstrably safer than the current generation of AB T cell CAR-T products.”
- On page 80, you state that the “[c]linical safety of the allogeneic vehicle [was] demonstrated at high does level.”

RESPONSE: The Company has reviewed the assertions made in the document and amended the wording to reflect the objective data and current clinical outcomes.

Progress CAR-modified GDTs into Phase 1 clinical trials for treatment of solid CNS tumors (B7-H3), page 68

13. We note that you plan to progress your CAR-modified GDT into Phase 1 clinical trials for treatment of solid CNS tumors (B7-H3) in 2022/2023. Please revise your disclosure to state whether you have or have not applied for an IND for CAR-modified GDTs and to clarify that Phase 1/2 trials for CAR-modified GDTs will not begin until an IND has been granted.

RESPONSE: The Company has revised the disclosure to state the expected position for the planned CAR-modified GD-T trial.

Our Pipeline, page 73

14. We note your statement on page 73 that your strategy for developing an allogeneic solution for CAR-T has a “clear route to commercialization in terms of manufacturing, clinical and regulatory execution”, your statement on page 77 that you have “[a] clear route to marketing authorization of allogeneic products which manage both safety and loss of graft (durability),” and your statement on page 80 that your allogeneic banks have a “[c]lear clinical and regulatory path to commercialization.” As “clear route to commercialization” and “clear route to marketing authorization” imply FDA approval, please delete these and similar references.

RESPONSE: The Company has amended the references to commercialization and marketing authorization.

Clinical Outcomes, page 74

15. We note that you have completed a Phase 1 clinical trial for TCB002. Please revise your disclosure to clearly identify all primary and secondary endpoints and the results related to all primary and secondary endpoints in the trial. Additionally, please revise the disclosure to provide p-values and conclusions as to statistical significance of all primary and secondary endpoints discussed. If no statistical analysis was performed please disclose that also. The first time you use the term p-value please explain what it measures and the p-value that you have to achieve in order to conclude a statistically significant result. Additionally, please expand the discussion to explain the significance and meaning of “PRA1” from the chart.

RESPONSE: The Company has added further details with respect to primary and secondary endpoints. In addition, further narrative is included with respect to statistical analysis.

16. We note that the Phase 1 unmodified allogeneic trial studied the clinical effects of TCB002, but you attributed that Phase 1 trial to TCB008-001 within the pipeline table. Please revise the disclosure to clarify the relationship between TCB002 and TCB008-001. Further, please explain how the conclusions of the Phase 1 trial completed using TCB002 can be attributed to TCB008-001.

RESPONSE: The Company has added narrative to the Pipeline and Plan section to clarify the relationship between TCB002 and TCB008-001.

Clinical studies - unmodified GDTs in blood cancer, page 74

17. Please revise the disclosure to define the acronyms GvHD, CR, and CRi. Please ensure that all acronyms are defined in the disclosure.

RESPONSE: The Company has amended the document to include definitions where acronyms have been used.

Pipeline and Plan, page 75

18. We note the inclusion of TCB008-002, TCB009, and TCB005/6 in the table on pages 6 and 75 indicating that those products are in the midst of preclinical development. Given their materiality, please revise your disclosure on page 75 to provide a more fulsome discussion of these programs, including preclinical studies or other development activities conducted. For each preclinical study and developmental activity, please provide material details such as type of study, number of participants, primary and secondary endpoints, if applicable, and anticipated completion date. Alternatively, remove any programs that are not material from your pipeline table.

RESPONSE: The Company has expanded the discussion with respect to TCB008-002, TCB009, and TCB005/6 within the document.

19. The arrows for TCB005/TCB006 and TCB009 are drawn to the end of the pre-clinical column. However, your disclosure in the Business section indicates that the pre-clinical portions of the clinical trials for each of these product candidates are still ongoing. Additionally, the green arrow for TCB008-001 is drawn to the end of the Phase 3 column, but your disclosure indicates that the Phase 2/3 trials do not start until H2 of 2021. Also, the green arrow for the TCB008-002 is drawn to the end of the Phase 1 column, but your disclosure indicates that the Phase 1/2 trials do not start until H2 2021. Please shorten the arrows in the pipeline chart to match the current status of each trial as described in Business.

RESPONSE: The Company has amended the pipeline chart to provide further clarity on the current status of each program.

20. We note you count your in-house manufacturing and clinical testing infrastructure as a strength and your statement that you do not rely on CMOs or CROs to manufacture your products or conduct your clinical studies. However, on page 25, you state that you depend upon collaborators such as CROs to conduct your clinical trials, and on page 26, you state that you “currently manufacture [your product candidates] through contract manufacturers.” Please revise the disclosure to resolve the discrepancy and to clarify the extent to which manufacturing is conducted in-house and the extent to which it is conducted by third-party suppliers.

RESPONSE: The Company has amended wording in both the ‘Our Strengths’ section and the risk factors to reflect the support currently provided by third parties.

Intellectual Property, page 80

21. In your Prospectus Summary on page 5, you state that you own “one granted patent and 47 patent applications in six families.” However, in your Intellectual Property disclosure on page 80, you state that you own “2 granted patents and 46 patent applications in 6 families.” In addition, you state in your Risks Related to Intellectual Property on page 37 that “[n]o patents have issued from our pending applications in the United States, and only two patents have issued from our pending applications in Europe.” However, you state in your Intellectual Property disclosure on page 80 that *WO 2016/166544* was granted a United States patent and you do not list any issued patents from Europe. Please revise the relevant sections to address these discrepancies. Additionally, please be sure to disclose all material patents.

RESPONSE: The Company has revised the relevant sections to provide consistent disclosure with respect to their patent portfolio.

22. Please disclose the jurisdictions in which patent applications for GB 2015543.8 and GB 2104070.4 have been filed and are pending. Please also expand your disclosure to clarify the type of patent protection afforded by your applications covering GB 2015543.8, GB 2104070.4, and GB 2569692 (e.g., composition of matter, method of use, etc.). Please revise to disclose the expiration dates for the US granted WO 2016/166544 patent, the WO 2016/174461 patent owned by UCL Business plc and for the WO 2016/005752 patent granted in Israel.

RESPONSE: The Company has provided additional narrative around the jurisdictions and types of patent protection afforded. The document has been updated to include details of expiration dates. We respectfully note that GB 2569692 was, as disclosed in the document, published in the UK, thereby establishing it as prior art against potential competitors, but was not progressed to examination and as such we have not included detail of patent protection afforded by that patent.

Description of Share Capital and Articles of Association , page 101

23. Once you have an estimated offering price range, please explain to us the reasons for any differences between recent valuations of your ordinary shares leading up to the planned initial public offering and the midpoint of your estimated offering price range. This information will help facilitate our review of your accounting for equity issuances.

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.

If there are any questions concerning the above, please contact either the Company representatives or the undersigned at ahudders@golenbock.com or 212-907-7349.

Very truly yours,

Andrew D. Hudders

cc: Martin Thorp, TC BioPharm Limited
Toby Rintoul, TC BioPharm Limited
Joseph Lucosky, Lucosky Brookman LLP
