



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

August 23, 2021

Michael Leek  
Chief Executive Officer  
TC BioPharm (Holdings) Ltd  
Maxim 1, 2 Parklands Way  
Holytown, Motherwell, ML1 4WR  
Scotland, United Kingdom

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

Dear Dr. Leek:

We have reviewed your draft 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 providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. 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 the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

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.
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.

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.

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.

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"

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.

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.

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.

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.

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.

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 a program-

by-program basis. Please provide disaggregate disclosure of your research and development expenses by program for each period presented. In addition, quantify in your 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.

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 dose level."

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.

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.

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.
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.

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.

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.
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.

### Competition

#### Our Strengths, page 78

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.

#### 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.
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.

#### 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

Michael Leek  
TC BioPharm (Holdings) Ltd  
August 23, 2021  
Page 7

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.

You may contact Christie Wong at 202-551-3684 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Jordan Nimitz at 202-551-6001 or Celeste Murphy at 202-551-3257 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Andrew Hudders