



DIVISION OF
CORPORATION FINANCE

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

February 18, 2021

Yat-Gai Au
Chief Executive Officer
Regencell Bioscience Holdings Ltd
11/F First Commercial Building
33-35 Leighton Road
Causeway Bay, Hong Kong

**Re: Regencell Bioscience Holdings Ltd
Amendment No. 1 to Draft Registration Statement on Form F-1
Submitted February 4, 2021
CIK No. 0001829667**

Dear Mr. Au:

We have reviewed your amended 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.

Amendment No. 1 to Draft Registration Statement on Form F-1

Prospectus Summary, page 1

1. As your product candidates are at a preliminary stage of development, please clearly qualify the timeline graphic on page 2 to note that the projected timeline is aspirational in nature and that there is no guarantee that any of the listed milestones will be met in the time noted or at all.
2. In line with our prior comment 3, we note that you have added the statement "the TCM Practitioner has prescribed the TCM base formula based on his TCM brain theory for over 30 years to treat ADHD, ASD and many neurological disorders and obtained satisfactory

clinical treatment results." As you have not provided clinical data to support this statement, we ask that you remove it in all places that it appears or appropriately qualify the statement by stating that such results are not supported by controlled clinical data or trials.

3. We note your response to our prior comment 5 and your disclosure that you are not currently developing the U.S. market. However, the prospectus continues to include detailed disclosure regarding the U.S. market, namely in the industry overview section, which does not appear relevant to the company at this time. Please remove these discussions, or, if you intend to continue to reference the U.S. market, include disclosure regarding the regulatory landscape and hurdles you will face once you seek to expand into the U.S.
4. We reissue our prior comment 6 as you have not removed all claims of safety and efficacy in the prospectus. We note, for example, disclosure on page 3 where you state that "TCM . . . provides progressive improvement over time," and disclosure on page 65 in the paragraph beginning "Our TCM Practitioner," where you state your products are effective and imply they are safe by contrasting them with the negative side effects of existing ADHD and ASD medications. We also note your continued claims of your TCM Practitioner's "established track record of treating children afflicted with ADHD and ASD and other patients suffering from a wide range of neurocognitive disorders and degeneration" on page 67 and elsewhere.

Use of Proceeds, page 36

5. We note your response to our prior comment 14 and reissue the comment. Please revise your disclosure to clarify whether you believe the proceeds from this offering will fund full "research and development of TCM formulae and products," and if not, how far along in the process you expect the proceeds to take you. Clarify whether you expect the proceeds from this offering to fund all of your "regulatory approvals, IP applications and working capital related needs" and if not all, to what extent.

Our Business

Our Products, page 53

6. We note your response to our prior comment 19 and reissue the comment. As patients were given different doses and measured by different individuals, the charts do not appear appropriate. Please remove the charts on pages 56-63, as requested in our prior comment.
7. We note your response to our prior comment 18 and reissue the comment, as your revised disclosure does not distinguish between the assessment tools, which you characterize as standardized, and those who utilized the assessment tools, who were the parents of the patients. Please revise to clarify.

Competition, page 64

8. We reissue our prior comment 21 as you continue to refer to your "exceptional track record" and "over one hundred ADHD and ASD patients" in this section (now on page 65) and elsewhere in this document. Your revised references to "long track record" "established track record" and "long-period track record" should be removed, as you have no clinical data to support your claims and have received no regulatory approvals to date.

Taxation, page 97

9. We note the tax opinion filed as Exhibit 8.1 in response to our prior comment 27. Please revise the tax disclosure starting on page 97 to state clearly that the disclosure in the tax consequences section is the opinion of the named counsel. In addition, please revise the disclosure to clearly identify and articulate the opinion being rendered. Please also describe the degree of uncertainty expressed in the opinion, including in relation to your PFIC status for the year ended June 30, 2020. See Sections III.B.2 and III.C.4. of Staff Legal Bulletin No. 19 for guidance.

You may contact Tara Harkins at 202-551-3639 or Al Pavot at 202-551-3738 if you have questions regarding comments on the financial statements and related matters. Please contact Abby Adams at 202-551-6902 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Joan Wu, Esq.