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

DIVISION OF
CORPORATION FINANCE

December 10, 2020

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
Draft Registration Statement on Form F-1
Submitted November 13, 2020
CIK No. 0001829667

Dear Mr. Au:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Form F-1 Submitted on November 13, 2020

Cover Page

1. You indicate that you have applied for listing on the Nasdaq Capital Market; however, you state throughout the prospectus that there is no assurance you will obtain a listing on Nasdaq. Please clarify whether you will go forward with the offering if you are not successful in obtaining the listing. If you do plan to move forward without a listing, please state this prominently on the cover page and throughout the prospectus and include a risk factor discussing the consequences of the lack of liquidity in the company's shares.

Our TCM Practitioner, page 1

2. We note that the TCM Brain Theory is a proprietary theory developed by the TCM

Practitioner. Please revise your disclosure to state whether the theory is recognized in traditional Chinese medicine or elsewhere, and if so, how. If the theory has not been recognized, please state this prominently throughout the prospectus where the theory is discussed.

3. Please remove the last sentence on page 2, that "[t]he TCM Practitioner has also treated patients afflicted with Alzheimer's disease, depression, arthritis, diabetes, SARS and COVID-19 with promising results," as you have not provided clinical data to support the statement and these areas of medicine do not appear sufficiently material to your business to be highlighted.

Prospectus Summary, page 1

4. Please clarify in the Summary that the company has not generated revenues since inception, has not applied for any regulatory approvals, has no sales, marketing or distribution capabilities or experience, and no granted patents or pending patent applications.

5. Please revise the Summary to include the following:
   - a brief description of the traditional Chinese medicine (TCM) industry in China, and specifically in Hong Kong, to the extent they differ.
   - the key differences between the TCM industry and the regulated pharmaceutical industry in China and Hong Kong
   - a discussion of the regulatory requirements that must be obtained, including the type of regulatory approvals products have or will need to receive, prior to commercialization in Hong Kong and the U.S.
   - relating to the U.S., please clearly state that your products would each be considered a "drug" and regulated as such by the U.S. Food and Drug Administration, including the requirements that they obtain premarket approval and go through clinical trials, or tell us why you do not believe these regulations would apply. Refer to 21 U.S.C. 321(g)j(1) (defining "drug").
   - highlight the time and cost required to seek approval under the Chinese Medicine Ordinance, from the FDA, and as otherwise required prior to commercialization and sale of products.

   To the extent your revised disclosure in response to the above includes information that is not discussed in greater detail outside of the Summary, please include an appropriately titled section in the body of the prospectus with further information. Potential shareholders should be able to ascertain the early stage of development of the company's product candidates and clearly understand the regulatory hurdles that must be overcome prior to revenue generation.

6. We note the broad claims you make both in the Summary and elsewhere regarding safety and efficacy of the TCM formulae, discussing improvement of symptoms and benefits relating to the TCM formulae, stating that you "expect" the results of your second research study "will show improvements in patients' symptoms", and that you "have not

observed any side effects." Given the early stage of development of your product, the limited testing performed to date, and the lack of regulatory approval sought or received, please revise both the Summary and the body of the prospectus to remove these and any statements that state or imply your potential product candidates are safe or effective, as such determinations are premature and solely within purview of regulatory authorities.

7. Please revise your disclosure throughout the prospectus to clarify that you have not yet developed and identified a specific product candidate to progress through regulatory approvals and commercialization, if true. We note, for example, your risk factor disclosure on page 9 that "one of [y]our standardized TCM formulae candidates" is under research and development, your statements referring to "each of [y]our TCM formulae candidates" implying you have numerous individual candidates under development, and your disclosure throughout the document of the study of seven patients with "personalized TCM formulae candidates" for each. To the extent you have identified a specific product candidate, revise your disclosure throughout the prospectus to refer to the product candidate(s) individually, rather than simply referencing the "TCM formulae".

Our Corporate History, page 3

8. We note you identified at least one entity on page ii, formed in the British Virgin Islands, which is not included in this chart. Revise the disclosure here and on page 44 to depict all entities in your corporate structure, both before and after the offering, including your strategic partnership with your TCM practitioner. In doing so, depict the percentage of ownership of public shareholders as well as material beneficial holders following the offering. Clarify which entities do business in which countries, including in the U.S. (California), as discussed on page 34. Clarify the purpose and nature of the relationship with the British Virgin Islands entity and the relative responsibilities of each of the subsidiaries and affiliated entities.

Risk Factors, page 8

9. Please revise the document in light of the Division of Corporation Finance's November 23, 2020 "Disclosure Considerations for China-Based Issuers." In particular, it appears the filing does not address the following:
   - To the extent they exist, "clear and prominent disclosure of PCAOB inspection limitations and lack of enforcement mechanisms, as well as the risks relating to the quality of the financial statements";
   - Update the risk factor at the bottom of page 23 regarding auditor access requirements to reflect the progress of recent legislation. Highlight "the possibility that legislative or other regulatory action in the United States may result in listing standards or other requirements that, if the company cannot meet, may result in *delisting* and adversely affect the company's liquidity or the trading price of the company's securities that are listed or traded in the United States";
   - Add a risk factor that addresses the limitations on the ability of U.S. regulators to

conduct investigations and inspections within China; and

- To the extent you rely on contractual arrangements to exercise control over your operating subsidiaries and receive economic benefits from certain portions of equity interests in those subsidiaries, revise to clarify, and disclose that such contractual arrangements may not be as effective as direct ownership in controlling your subsidiaries. Prominently disclose your subsidiaries that are subject to these contractual arrangements. Disclose the percentage of revenues in your consolidated financial statements that will be derived from those subsidiaries.

Risks Related to Our Product Development, Regulatory Approval, Manufacturing and Commercialization, page 9

10. In the risk factor at the bottom of page 12, you address risks that will arise "[a]fter [you] obtain approval for [y]our TCM formulae from Chinese Medicine Ordinance Regulatory Office." Revise this and any similar statements in your document to remove the assumption that you will obtain regulatory approval, as this is not within your control or known at this time.

11. Please revise your raw materials risk factor on page 16 to clarify the extent to which your raw materials are generally available and whether the TCM Practitioner could obtain the required materials from a different vendor if the current vendor cannot meet the demand. In this regard, we note your disclosure on page 58 regarding Hong Kong regulations relating to endangered species of animals and plants. Please clarify in the risk factor whether any of your raw materials are sourced from endangered species of animals or plants and note the regulation's applicability, or clarify why the regulation has been discussed on page 58.

General Company Related Risks, page 17

12. Please expand the second risk factor on page 18, regarding key personnel, and its heading to disclose the family relationship between the Chairman and the CEO and to emphasize that the company's business is wholly dependent on the TCM Practitioner. Please also include a discussion of these risks in your Summary risks section.

Risks Related to the Offering and Our Ordinary Shares, page 20

13. On page 27 you describe risks of being a shareholder in a controlled company. Revise your disclosure to address whether a controlling shareholder owes fiduciary duties to a company and its minority shareholders under Cayman Islands law. Discuss how any fiduciary duties owed by a controlling shareholder may differ under Cayman Islands law from U.S. corporate law and how that might affect the ability of minority shareholders or the company to protect their respective interests.

Use of Proceeds, page 30

14. Please revise your use of proceeds disclosure to indicate how far you expect the proceeds to progress each of the listed uses. To the extent you will require additional funding beyond the proceeds to further each of the listed uses, clearly state this following the table. In addition, we note your statement on page 17 that you "may" need additional financing in order to meet your continuing obligations and to attain profitability. This statement should be consistent with your use of proceeds disclosure.

Dilution , page 33

15. Please explain to us how you calculated the net tangible book value to be US$495,300 or US$49.53 per Ordinary Share as of June 30, 2020.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Financial Operations Overview, page 35

16. Please revise to clarify why your research and development expenses relate to marketing efforts when you do not have a product that has obtained regulatory approval for marketing. In addition, in your discussion of Selling and Marketing expenses on page 36, clarify what you mean by “marketing efforts for new patient acquisition.”

Our Business
Assessment Methodology, page 46

17. Please revise your disclosure to clarify the length of time between when the patients ceased their existing medical treatment and started receiving the TCM formuale in your study. In this regard, please clarify how you determined your observations of changes in “eye contact, appetite, longer sleep duration, communication, sociability, cognition, awareness and attentiveness, complexion, mood and temper,” were not effects of prior medication or ceasing prior medication.

18. Please revise your disclosure both here and in the risk factors to clearly address the inaccuracies and/or biases that may be involved when relying on information collected and reported by the parents of your study participants. Please also indicate whether you will be able to the preliminary stages of regulatory approval with the information collected, or whether additional pre-clinical studies will need to be conducted prior to initiating the approval process in either Hong Kong or the U.S.

19. Because each of the study participants was treated with a "personalized TCM formulae" rather than a standardized product candidate, the data collected is not directly comparable. Therefore, please remove the graphs on pages 47-54 that compile the results for all participants. Alternatively, please provide your analysis as to why the information as provided may not be construed as misleading.

Competition and Competitive Advantages, page 54

20. Revise to provide much greater detail about your competition, including the market reach of the drugs currently approved to treat these conditions, the research and results that support their continued use, their greater financial resources, and your hurdles to entry.

21. Here and on page 56, revise to delete the references to "exceptional track record" and "over one hundred ADHD or ASD patients being treated" where your only reported study treated seven children for a maximum of three months.

Specialty of TCM Formulae, page 55

22. You state that your "TCM formulae rely on TCM theory that the blockage of or reduced blood flow, and damage of the interconnecting central nervous system, endocrine system and blood circulatory system disrupt the production of hormones and transmission of neurotransmitters . . . leading to a defective encoding and decoding of functions, and resulting in deficient or abnormal social behaviors that are the hallmarks of ADHD and ASD." Provide the studies that support this theory or revise it to clarify and emphasize that you have no support for the theory.

Intellectual Property, page 56

23. Revise to address all forms of intellectual property on which you rely, as discussed in the summary on page 1 and in the risk factor on page 14.

Regulations, page 57

24. Currently you describe multiple Chinese regulations; however, you do not explain whether or how they relate to your potential products. Please revise to clarify. Notably it is unclear why you are describing food safety laws in addition to healthcare regulations.

Executive Compensation, page 65

25. To be consistent throughout the document, revise to also provide the compensation amounts in United States Dollars.

Related Party Transactions, page 67

26. Revise to disclose all material terms of the partnership agreements, including the termination dates, the notice requirement for termination by either party, and the term of the yearly donation of 3% of net revenues. In addition, clarify whether disclosure of confidential information is prohibited, or if it is merely subject to prior written notice.

Taxation, page 82

27. Please file a tax opinion to support your conclusion that the company is not likely a passive foreign investment company, as stated on page 84. See Section III of Staff Legal Bulletin No. 19 for guidance.

Index to Consolidated Financial Statements
Note 1. Nature of Business and Organization, page F-7

28. We note your disclosures on page 1 and throughout the filing that you entered into a partnership agreement with Mr. Sik-Kee Au, your TCM Practitioner in January 2018. Please revise your notes to the financial statements to explain the key terms of this agreement and how you are accounting for it.

Exhibits

29. For exhibits 3.1 and 10.1-10.4, please file the actual agreements rather than the form of agreements. Please also file the employment agreement with Dr. Yi-Chung Chao discussed on page 65. Refer to Item 601(b)(10) of Regulation S-K.

30. Please file the consent of each director nominee as an exhibit to your registration statement. See Rule 438 of Regulation C under the Securities Act. Please also file consents from each expert and named counsel as an exhibit, as required by Item 601(b)(23) of Regulation S-K.

General

31. 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.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

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.