

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

DIVISION OF CORPORATION FINANCE

August 25, 2021

Guido Baechler Chief Executive Officer Mainz Biomed B.V. Robert Koch Strasse 50 55129 Mainz Germany

> Re: Mainz Biomed B.V. Registration Statement on Form S-1 Filed August 3, 2021 File No. 377-05301

Dear Mr. Baechler:

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.

<u>F-1</u>

Prospectus Summary, page 1

- 1. Your prospectus Summary should provide a balanced presentation of your business. Please revise to discuss the challenges you face, including, as examples only, your competition, being a foreign entity, relying on laboratories, the preclinical nature of your other products, etc. as detailed in your "Risk Factors."
- 2. On page 4 of the Summary, in the section titled "Competitive Advantages & Operational Strengths" you state that "ColoAlert currently offers the highest sensitivity" of all the CRC tests. Please cite whatever studies or tests that determined that ColoAlert offered the highest sensitivity out of all CRC screening tests.

Please also discuss the current price of ColoAlert vs. other competitors, as price is an element you list under "Competitive Advantages & Operational Strengths."

Implications of Being an Emerging Growth Company, page 26

3. 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

Use of Proceeds, page 27

4. It is unclear from the Use of Proceeds if any of the proceeds will be used to pay off some of the debt Mainz has accumulated. Please specify whether or not the Use of Proceeds will be used to pay off debt.

Capitalization and Indebtedness, page 29

- 5. Please address the following in your capitalization table:
 - Revise to only include indebtedness, broken down by respective classifications (i.e. convertible debt, silent partnerships, loans payable, etc.) and further distinguishing between related party/non-related party debt, and stockholders' deficiency. As such:
 - Remove the line item 'Total Current Assets'
 - Remove the line item 'Total Current Liabilities' as not all liabilities from the balance sheet are included in the capitalization table.
 - If you continue to present a cash and cash equivalents line item, please include a double line underneath that line so as to distinguish it from the capitalization line items.
 - Include a line item for 'Accumulated other comprehensive income' and respective amounts for the Actual column to be consistent with what is reflected in the historical balance sheet as of December 31, 2020.
 - Include a total for capitalization at the bottom of the table.
- 6. Please provide a pro forma adjustment related to the 2,010,000 of units and 140,000 warrants sold on April 26, 2021 for total proceeds of \$603,000 or explain why this adjustment is not warranted.
- 7. On page F-29, you noted that the 3.5% SPAs are convertible to common shares of the Company at EUR\$1 per share in the event that the Company is involved in any of the following transactions: capital increases, a share or asset deal or a public offering. Tell us what consideration was given to provide a pro forma adjustment related to this conversion.

Company Information, page 32

8. You disclose on F-39 that Mainz and PharmGenomics were under common control. Revise to address the following:

- Revise this section to more clearly describe the extent and basis of common control between the two entities, separately quantifying significant ownership interests.
- Discuss the prior relationships between the owners, clearly identifying relationships with ColoAlert AS and any other related parties.
- Revise to provide a diagram of the ownership structure of Mainz and PharmGenomics before the merger, after the merger, and after the offering (including the effects of the selling shareholders portion of the offering).
- Revise this section, your MD&A, as well as your pro forma financial statements to clearly disclose the accounting for the the merger, including your basis for that accounting.
- Tell us the accounting guidance on which you relied for that determination.
- 9. You view the acquisition of PharmaGenomics as a "probable acquisition." Please disclose the anticipated date when this acquisition will happen.

Results of Operations

Comparison of the Year Ended December 31, 2020 and 2019, page 48

- 10. Revise to separately quantify each of the factors discussed related to the increases/decreases in each financial statement line item. Specifically address the following:
 - regarding the increase in revenues, quantify the increase in the amount of statutory healthcare system reimbursements related to third party laboratory testing conducted during 2020 compared to 2019.
 - provide a breakdown of product sales between your significant products for each periods presented.
 - quantify the one-time license fees for the ColoAlert product in 2019 and revise Note 13 on page F-31 to provide separate quantification there as well.
 - regarding your operating expenses, please separately quantify each factor noted (i.e. consulting fees, advertising, bad debt expense, professional fees, salaries and benefits, etc.) and provide an explanation for each increase/decrease.

<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> <u>Critical Accounting Policies and Significant Judgments and Estimates, page 50</u>

11. You disclose on page II-2 that you issued 200,000 ordinary shares to your Chief Executive Officer. Revise your MD&A to discuss this issuance as well as any other equity issuances for compensation. Revise your MD&A as well as your footnotes to disclose how you accounted for these shares, including how you determined the value of the shares. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features. Please discuss with the staff how to submit your response.

Material Agreements, page 64

12. Please revise to disclose the type of patent protection granted and the applicable jurisdiction of your patents and pending applications.

<u>PharmGenomics GmbH</u> <u>Notes to the Financials Statements</u> <u>2. Basis of Presentation</u> Basis of Presentation and Statement of Compliance, page F-18

13. You note here that your financial statements have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board and interpretations of the International Financial Reporting Issues Committee and similar disclosure is provided on page 50; however your auditors noted in their audit report that your financial statements have been presented in conformity with accounting principles generally accepted in the United States. Please revise for consistency. Revise your summary financial data disclosures on pages 9-10 and 47 as well as your pro formas beginning on page F-36 to clearly identify the accounting standards used.

<u>3. Summary of Significant Accounting Policies and Use of Estimates and Judgments</u> Research and Development, page F-20

14. Please include your accounting policy related to government grants received for research and development (R&D) purposes. Refer to IAS 20. Also, in light of the significant emphasis on R&D activities in the forepart of your document, revise to separately report R&D expenses as a separate line item on the face of your income statement or tell us how you determined that was not appropriate. To the extent you are able to support your decision not to report R&D on a separate line item, revise your footnotes to provide a table of R&D by line item on which they are reflected in your income statement. Revise your MD&A to provide a breakdown of R&D expenses by type of expense as well as by product candidate.

15. Government Grants, page F-32

15. Please disclose the remaining balance at December 31, 2020 of the grant from the German Federal Ministry of Research and Education for the development of PancAlert of up to approximately €440,000 and the grant from the European Fund for Economic and Regional Development for the development of GenoStrip of up to approximately €205,000.

Mainz Biomed B.V. Notes to the Financials Statements Note 2. Basis of Preparation and Going Concern, page F-7

16. You note here that your financial statements have been prepared in accordance with International Financial Reporting Standards. However, your audit report states that your financial statements are in conformity with accounting principles generally accepted in the United States. Please revise for consistency. To the extent, these financials were prepared in accordance with International Financial Reporting Standards, revise to specifically confirm, if true, that they were prepared in accordance with "International Financial Reporting Standards as issued by the International Accounting Standards Board."

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 Sasha Parikh at (202) 551-3627 or Kevin Vaughn at (202) 551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Gary Guttenberg at (202) 551-6477 or Celeste Murphy at (202) 551-3257 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: William Rosenstadt