



DIVISION OF  
CORPORATION FINANCE

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

April 2, 2022

Mark Hilz  
Chief Executive Officer  
Heart Test Laboratories, Inc.  
550 Reserve St.  
Suite 360  
Southlake, Texas 76092

**Re: Heart Test Laboratories, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted February 28, 2022**  
**CIK 0001468492**

Dear Mr. Hilz:

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 on Form S-1 submitted February 28, 2022

Cover Page

1. We note your disclosure on the prospectus cover page that you intend to apply to list your common stock on the Nasdaq Capital Market but that there is no assurance that your listing application will be approved. Please tell us whether you have applied for listing and whether you will continue your offering if your listing is not approved. If you intend to proceed with your offering before receiving Nasdaq approval of your listing application, that, please clarify the listing of the common stock on the Nasdaq Capital Market is not a condition to the offering and include risk factor disclosure.

Industry and Market Data, page ii

2. We note your statement that you believe the cited sources to be reliable but have not independently verified the information contained in each publication. Please clarify that you are liable for all such information included in your registration statement.

Reverse Stock Split and Convertible Bridge Note Private Placement, page ii

3. We note your board of directors approved a reverse stock split on xx, 2022 and on pages 16, 58, and 60 that you have not reflected this stock split within your historical financial statements and related notes including your summary financial data. If the reverse stock split will occur prior to effectiveness of the registration statement, we remind you that you must revise your historical financial statements to reflect the reverse stock split based upon the guidance in ASC 260-10-55-12 and SAB Topic 4(C).

Glossary of Terms, page iv

4. Please move your glossary of terms to the back of your document and revise your disclosure to ensure that the terms are clear from their context the first time they are used. Please see Securities Act Rule 421(b)(3).

Summary of Risk Factors , page ix

5. Please move your Summary of Risk Factors section to immediately follow the Prospectus Summary and revise the section to include no more than two pages focusing on the principal factors that make an investment in you or in the offering speculative or risky, rather than listing each heading that appears in the Risk Factors section. For guidance, please refer to Item 105(b) of Regulation S-K.

Prospectus Summary, page 1

6. Please revise your summary to present a balanced view of your company and its current stage of development by focusing on the most material aspects of your company. As currently written, your summary focuses on the positive aspect of your business and includes a lengthy recitation of disclosures appearing in the Management's Discussion and Analysis and Business sections. Please revise to eliminate the predictive assumptions regarding FRA approval or clearance, clearly state that you have no commercially available FDA approved products and received an audit report that raised substantial doubt about your ability to continue as a going concern. Your summary should describe the material risks and obstacles you face in the same level of detail that you use to discuss the positive aspects of your business and market opportunity.
7. Please remove any statements related to safety and efficacy from your registrations statement, such as statements that MyoVista "detects cardiac dysfunction caused by heart disease and/or age related cardiac dysfunction." Statements related to safety and efficacy

are within the sole authority of the FDA. Similarly revise discussions of the advantages of your product candidate over currently available products are dependent on the FDA's conclusions related to safety and efficacy.

2021 Bridge Financing, page 10

8. We note your disclosure indicating that you informed the investors in your October 2021 private placement that if you engaged in an investment with a lead investor such investors would be given an opportunity to "exchange their initial Bridge Notes and Bridge Warrants for Bridge Notes and Bridge Warrants." The use of the terms "Bridge Notes" and "Bridge Warrants" to refer to the notes and warrants issued in both the October 2021 financing and the December 2021 financing is confusing. Please clarify whether the notes and warrants were identical or if the investors in the October 2021 financing exchanged their notes and warrants for notes and warrants identical to those issued in the December 2021 financing.
9. Please disclose the Conversion Price of the Bridge Note or clarify how the price will be determined.

Even if this offering is successful, we will need to raise substantial additional funding..., page 18

10. Please quantify the amount of additional funding you estimate you will need in order to commercialize MyoVista and clarify when you expect to need more financing or how far you expect to get in the development process with proceeds from this offering.

Use of Proceeds, page 56

11. We note that you intend to use the proceeds of the offering to repay outstanding debt and for working capital and general corporate purposes. Please revise your summary and risk factor sections to clarify that you will not be using the proceeds from the offering to develop MyoVista. Additionally, revise the discussion of "Liquidity and Capital Resources" to clarify your expected costs related to R&D, clinical studies and go-to-market strategies and how much you expect you will need to raise in future offerings of securities in order to complete the work necessary to commercialize MyoVista.

Bridge Notes, page 68

12. The following statements appear inconsistent:
  - "Pursuant to the 2021 Bridge Financing, as of February 25, 2021, The Company had issued the Bridge Notes in the aggregate amount of \$3.98 million."
  - "Through February 25, 2022, the Company received net proceeds (after OID) of \$3.58 million in connection with the 021 Bridge Financing."Please clarify whether you are referring to two separate issuances of Bridge Notes or if both statements refer to an issuance of notes beginning in December 2021.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Critical Accounting Policies and Estimates

Determination of Fair Value of Common Stock, page 72

13. 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 including 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. Please discuss with the staff how to submit your response.

Pricing and Valuation of Inventories, page 73

14. In light of the fact that you have not received FDA clearance to sell your MyoVista product in the United States and you maintain material inventory balances, it appears you should provide a more robust discussion of the uncertainties involved in valuing your inventory and the variability that is reasonably likely to result over time. Please revise your critical accounting policies to address the following:
- Discuss the current status of the FDA approval process, including any contingencies needed to be resolved prior to obtaining FDA approval, the risks affecting the probability of obtaining FDA approval, and the estimated timing of obtaining approval;
  - Address the risks and uncertainties surrounding market acceptance of the MyoVista product if approved and how this will affect the realization of your inventory;
  - Disclose the specific assumptions and estimates used to determine your reserves for slow-moving, excess, and obsolete inventories;
  - Disclose the specific assumptions and estimates used to determine net realizable value, including how you have determined sales prices;
  - Please explain why charges for inventory obsolescence and/or device development changes is only done on an annual basis, as stated on the top of pages 73 and F-8.

Stock-Based Compensation, page 73

15. Please provide us with your analysis as to whether a consent is required under Section 7(a) of the Securities Act and Securities Act Rule 436 for the disclosure of your stock volatility and other assumptions being determined by third party valuations as referenced on pages F-10, F-11, F-20 and in this section.
16. We note that you calculate your expected volatility within the Black-Scholes model based upon third party valuations. Please tell us and revise your filing to discuss how this complies with the guidance in ASC 718-10-50-1c through 2 and SAB Topic 14.

Previous FDA De Novo Submission, page 84

17. Will the previous algorithm validation dataset previously submitted be included in our new De Novo submission? If not, please explain why you believe it is appropriate to present the results here.

18. If it is appropriate to present the previous validation dataset, please include a discussion explaining how the data set was collected and how to interpret the results presented. For example, were the patient results compared to other tests used to validate the results? If so, please explain. Additionally, your discussion indicates that 16.9% of the patients indicated as borderline. Therefore, the table presenting Borderline Positive and Borderline Negative appears to present a subset of your results. Please present all results and explain how the percentages for sensitivity, specificity and accuracy are to be interpreted.

Clinical Studies, page 92

19. We note that you summarize the results from several peer-reviewed studies that used the proof-of-concept algorithms developed by the institutions from the MyoVista data collected. Please revise to provide the material details and parameters of your clinical studies, including endpoints, metrics utilized, statistical significance, number of participants, etc. Additionally, please file the authors' consents for each of the articles summarized.
20. We note statements throughout the prospectus that imply efficacy. For example, we note the graphic on page 80 comparing MyoVista's detection of diastolic dysfunction against a conventional ECG, the study conclusions and editorial comments on pages 93-94, and statements that the study results "demonstrated that the estimated e-prime values. . . . allowed prediction of LV diastolic dysfunction..." and "demonstrated 85% sensitivity and 72% specificity AUC 0.83." Please revise your disclosure to remove any conclusion or suggestion that your product candidate is effective or will have improved efficacy over conventional ECGs and instead refer to the relevant objective data from your clinical trials or studies that relate to your product candidate's performance. Statements related to efficacy are within the sole authority of the FDA.

Foreign Regulation, page 100

21. In addition to describing the United States' and Europe's regulation of medical devices, please also provide a brief overview of Australia's regulation of medical devices as it relates to MyoVista.

Intellectual Property, page 102

22. Please revise to disclose the expected expiration dates of your patents and pending applications for both your United States and foreign patents.

2013 Technology Agreement, page 103

23. Please revise the description of the agreement to disclose all all consideration, including the 448K Secured Promissory Note, 700K Secured Convertible Promissory Note and 300K Convertible Note, quantify the amounts that remain outstanding, any conversations that have occurred to date and the terms of any notes that remain outstanding.

Glasgow Licensing Agreement, page 103

24. The \$40,000 minimum annual payment appears inconsistent with the payment provisions in exhibits 10.5 and 10.6. Please clarify which section provides the obligation to pay the greater of \$40,000 or the royalty per unit provided.

Background and Experience of Directors and Executive Officers, page 106

25. Please revise the biographical sketches for your executive officers and director to disclose each person's principal occupation and employment during the most recent five years, the dates they served in those roles and the name and business of any corporation or other organization in which such occupation and employment were carried on. In this regard, we note that the dates for Mr. Bruce Bent's employment with The Matthews Group and MSW Investments Limited, and the date for Mr. Patrick Kanouff's employment with Davis & Ceriani, are not disclosed. Similarly, revise Patrick Kanouff's background to provide relevant dates and Brian Szymczk's background to disclose the dates of his employment with Apollo Endosurgery, identify the large surgical device manufacturer where he was currently employed and provide relevant dates and disclose the dates of his employment with Baker Botts LLP. Additionally, please revise the descriptions of each director's or nominee's business experience to discuss his or her "experience, qualifications, attributes or skills that led to the conclusion that the person should serve as a director for the registrant...in light of the registrant's business and structure." Refer to Item 401(e) of Regulation S-K.
26. We note your disclosure on page 110 that Andrew Simpson is a director of Kyngstone Limited. revise the description of his business experience to provide this information. See Item 401(e)(2) of Regulation S-K.

Outstanding Equity Awards at January 31, 2022, page 110

27. Please revise your Outstanding Equity Awards table to comply with the requirements of Item 401(f) of Regulation S-K.

Related Party Transactions, page 114

28. Please revise the descriptions of agreements with Front Range Ventures to clarify Peter Kanaouff's role.

Conversion, page 120

29. Please revise this section to disclose all conversion and exercise terms. To the extent that shares issuable or conversion terms are based on a formula, please provide the formula.

Potential Conflicts of Interest, page 140

30. We note your disclosure of a potential conflict of interest that arises from an affiliate and a principal of your underwriter, The Benchmark Company, LLC, holding a position as both

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April 2, 2022  
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a member of your company's Board of Directors of your company and the supervisory board of your parent, Biofrontera, AG. Please revise to provide more information about this potential conflict of interest, including the identify of the affiliated board member and the basis for why this conflict is not a "conflict of interest" for purposes of FINRA's Rule 5121(f)(5).

Please revise your filing to clarify your current relationship with Biofrontera and explain how this offering will affect this relationship.

Item 15. Recent Sales of Unregistered Securities, page II-3

31. Please provide a more detailed description of your sales of unregistered securities for the past 3 fiscal years, as required by Item 701 of Regulation S-K. For shares that were issued for services rendered, please provide a materially complete description of such services and when they were provided. For example, we note you issued warrants to purchase shares in June 2020 and June 2021 to July 2021, to third-party contractors. Please revise the description of such issuances to identify the investor or class of investor, such as accredited investor.

General

32. 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.

You may contact Tara Harkins at 202-551-3639 or Jeanne Baker at 202-551-3691 if you have questions regarding comments on the financial statements and related matters. Please contact Jordan Nimitz at 202-551-6001 or Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences