CERTAIN PORTIONS OF THIS LETTER AS FILED VIA EDGAR HAVE BEEN OMITTED AND SUBMITTED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR THE OMITTED PORTIONS PURSUANT TO 17 C.F.R. § 200.83, WHICH HAVE BEEN REPLACED WITH THE FOLLOWING PLACEHOLDER "[***]" IN THE LETTER FILED VIA EDGAR.

FOIA Confidential Treatment Requested Under 17 C.F.R. § 200.83



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October 21, 2022

United States Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549 Attn: Doris Stacey Gama

Re: Health Sciences Acquisitions Corporation 2

Amendment No. 1 to Registration Statement on Form S-4

Filed September 23, 2022 File No. 333- 266660

Dear Ms. Gama:

On behalf of our client, Health Sciences Acquisitions Corporation 2 (the "Company"), we submit to the staff (the "Staff") of the Division of Corporation Finance of the Securities and Exchange Commission (the "Commission") this letter setting forth the Company's response to the comments contained in the Staff's letter dated October 12, 2022 (the "Comment Letter") regarding Amendment No. 1 to the Company's Registration Statement on Form S-4 ("Amendment No. 1").

The Company has filed via EDGAR Amendment No. 2 to the Company's Registration Statement on Form S-4 ("Amendment No. 2"), which reflects the Company's responses to the comments received from the Staff and certain other updated information. Please note that our responses below, insofar as relevant information relates to Orchestra BioMed, Inc. ("Orchestra") or matters arising from Orchestra's participation in the preparation of Amendment No. 2, are based on our discussions with and information received from Orchestra or its counsel, Paul Hastings LLP, who have similarly participated in the preparation and review of this response letter.

For ease of reference, each comment contained in the Comment Letter is printed below and is followed by the Company's response. All page references in the responses set forth below refer to the page numbers in Amendment No. 2. Capitalized terms used herein but not defined herein shall have the meanings assigned to them in Amendment No. 2.

Because of the commercially sensitive nature of information contained herein, this submission is accompanied by the Company's request for confidential treatment for selected portions of this letter. The Company has filed a separate letter with the Office of Freedom of Information and Privacy Act Operations in connection with the confidential treatment request, pursuant to Rule 83 of the Commission's Rules on Information and Requests, 17 C.F.R. § 200.83.

Amendment No. 1 to Registration Statement on Form S-4

Q: How will the Initial Shareholders vote?, page 16

1. We acknowledge your revised disclosures in response to prior comment 4. Please also revise to explain whether the various support agreements will be revised to reflect the revised disclosures.

Response: In response to the Staff's comment, the parties have elected to formally amend the Backstop Agreement and RTW Forward Purchase Agreement in order to simplify the resulting disclosure. Corresponding revisions appear on the cover page and pages 10, 27, 37, 92, 93, 94, 131, 140, 154 and 212.

Material U.S. Federal Income Tax Consequences

U.S. Federal Income Tax Consequences of the Domestication. . ., page 145

2. We note your response to previous comment 14. If counsel is providing a "should" opinion, please amend to clearly state this fact, explain the reason for counsel's inability to provide a "will" opinion, describe the degree of uncertainty in the opinion, and provide risk and other appropriate disclosure. In addition, please revise your short-form opinion so that the material tax consequence is clearly disclosed other than the issue giving rise to the uncertainty. Refer to Section III.C.4 of Staff Legal Bulletin No. 19.

Response: The opinion refers to the relevant section in the tax disclosure in which the material tax consequences are clearly disclosed. That same section of the tax disclosure, explains that the provisions of the Code that govern reorganizations are complex, and due to the absence of direct guidance on the application of Section 368 to a domestication of a corporation holding only investment-type assets such as HSAC2, the qualification of the Domestication as a reorganization is not entirely clear. As such, we are unable to provide a "will" opinion on the qualification of the Domestication as a reorganization. The disclosure further states that if the Domestication qualifies as a reorganization, a U.S. Holder that exchanges its HSAC2 Ordinary Shares pursuant to the Domestication should not recognize gain or loss on the exchange of HSAC2 Ordinary Shares for shares of HSAC2 Common Stock. Finally, the disclosure clarifies that if the Domestication fails to qualify as a reorganization, a U.S. Holder that exchanges its HSAC2 Ordinary Shares for shares of HSAC2 Common Stock in the Domestication will recognize gain or loss equal to the difference between (i) the fair market value of the HSAC2 Common Stock received and (ii) the U.S. Holder's adjusted tax basis in the HSAC2 Ordinary Shares exchanged therefor. As such, we believe all of the points in the comment are sufficiently addressed and do not believe any further revisions to the language in the opinion or the disclosure are needed.

Business of Orchestra, page 221

3. We acknowledge your revised disclosures in response to prior comment 16. Please further revise to avoid conclusory statements regarding your trials or your product candidates' performance. For example, your disclosure continues to refer to "compelling" or "promising" trial data. You may revise to discuss objective data, and balance your discussion of trial results with cautionary language regarding the preliminary nature of the results.

Response: Orchestra has revised the disclosure on pages 50, 127, 128, 222, 235, 245 and 246 in response to the Staff's comment.

Company, page 221

4. We note your response to comment 17. Please amend your filing to include a description of how Orchestra estimates a market opportunity of 3.2 million procedures valued at approximately \$3 billion for Virtue SAB to provide investors with context regarding these amounts.

<u>Response</u>: Orchestra has revised the disclosure on pages 219, 240 and 241 to include the description of how Orchestra estimates a market opportunity of 3.2 million procedures valued at approximately \$3 billion for Virtue SAB in response to the Staff's comment.

Product Pipeline, page 222

5. We acknowledge your response to prior comment 20. With respect to each milestone in the "Next Milestone" column, please revise to provide additional context regarding the expected timing. For example, we note your disclosure elsewhere that Orchestra currently anticipates applying for an IDE and initiating enrollment of the BackBeat CNT Pivotal Study in the second half of 2023. Please revise the table to disclose that Orchestra's planned application for IDE and the expected initiation of the study are both expected to be in the second half of 2023. As another example, please revise to clarify the process for the high-risk HTN indication when you state that you will seek to leverage data. If there has been no discussion yet regarding the expected trial timing with the FDA or comparable foreign regulator, or the ability to leverage other data, please revise the table to clearly indicate this information. In addition, please remove the "Estimated Market" column from the pipeline table, and to the extent necessary, please revise the widths of the columns representing the various trials to provide an accurate representation of the duration of the various stages (e.g., if the pivotal trial stage is expected to be twice as long as the clinical feasibility stage, please increase the width of the pivotal trial column accordingly).

<u>Response</u>: Orchestra has revised the pipeline table and related footnotes on page 221 to provide additional context regarding expected timing, to disclose the lack of discussions with the FDA or comparable foreign regulators regarding leveraging data and to remove the "Estimated Market" column in response to the Staff's comment.

With respect to the Staff's comment regarding revising the widths of the columns representing the various trials, Orchestra respectfully submits that it cannot accurately estimate the duration of the various stages of development of Orchestra's product candidates and that attempting do so would not provide meaningful information to investors, as it is virtually impossible to predict the timing of the FDA's approval process.

Bioelectronic Product Candidates...

Strategic Collaboration Agreement with Medtronic, page 224

6. We note your response to our previous comment 13 regarding existing reimbursement codes. Specifically, you state that based on your discussions with Orchestra, the terms of the Medtronic Agreement, and Orchestra's management's knowledge of the reimbursement codes for medical devices, you believe such increase in price is possible without new reimbursement codes. Please expand your discussion to explain this rationale. In addition, in the Business section, revise to provide the basis for Orchestra's estimates that its addressable annual market is \$10 billion.

Response: [***]. In addition, Orchestra has revised the disclosure on page 225 to provide the basis for its estimates of its addressable annual market.

Preclinical Data, page 228

7. We note your revised disclosures in response to comment 23. However, please further revise to explain how the chart "demonstrates the significant improvement in the entire 24-hour aSBP profile of the animal driven by BackBeat CNT." Also revise so that the graphical illustration shows the results of all the study animals, including the control, or advise.

Response: Orchestra has further revised the disclosure on pages 226 and 227 in response to the Staff's comment.

8. We refer to the revised lead-in disclosure to the second chart on page 228. You state that the chart shows "blood pressure levels did not return to higher baseline levels after BackBeat CNT was turned off, indicating that sympathetic nervous system responses were likely modulated by chronic delivery of BackBeat CNT." Please revise so that the statement does not imply an efficacious conclusion, and also explain how the illustration shows that blood pressure levels did not return to higher baseline levels when the green triangles appear to show a steady increase in systolic pressure as compared to the red line representing the use of the BackBeat CNT.

Response: Orchestra has revised the disclosure on page 227 in response to the Staff's comment.

Clinical Results

Acute Clinical Study, page 229

9. We note your response to comment 24 regarding treatment duration variation for different patients. Please amend to include what factors the managing physician considered in their determination to allow for longer duration.

Response: Orchestra has revised the disclosure on page 227 in response to the Staff's comment.

MODERATO I Single Arm Study, page 229

10. We acknowledge your revised disclosures in response to prior comment 25. You state that 21 patients consented to be followed for a longer study period, and you disclose the study results for this longer period for oSBP levels. Please also revise to state the 24-hour aSBP levels that were studied during the longer period for the 21 patients, and if these levels were not studied for the same period, please revise to explain why. Similarly, on page 232, please revise to state the corresponding aSBP results in the MODERATO II study at 24 months, or explain why aSBP levels were not studied for the same duration.

Response: Orchestra has revised the disclosure on pages 228 and 231 in response to the Staff's comment.

11. We refer to your revised disclosures here and elsewhere in response to prior comment 26. Please further revise these disclosures to disclose the non-cardiac related serious adverse events, and with respect to the SAEs, explain the number that were determined to be related to the device or procedure, and the number that were determined to be unrelated. Disclose these SAEs in your summary discussion and in your risk factor on page 57.

<u>Response</u>: Orchestra has revised the disclosure on pages 57, 229, 230 and 246 in response to the Staff's comment. Orchestra respectfully advises the Staff that there is no "summary discussion" where such disclosure would be appropriate. However, Orchestra has disclosed the SAEs where appropriate in the Risk Factors and in the "Business of Orchestra" section.

SirolimusEFR - Additional Focal Therapies Product Candidates and Development Initiatives, page 249

12. We acknowledge your revised disclosures in response to prior comment 19 and your statements that you may be able to leverage certain data. Please revise to clearly explain that there is no guarantee that you will be able to pursue these trials at an accelerated pace or at a reduced cost, and revise your reference in the last paragraph in this section to being able to "rapidly advance" these product candidates.

Response: Orchestra has revised the disclosure on page 249 in response to the Staff's comment.

Consolidated Financial Statements of Orchestra Biomed, Inc.

- 3. Terumo Partnership Agreement, page F-49
- 13. Please revise to address the following regarding your responses to prior comments 29 and 31:
 - In your response to prior comment 29 you indicate that you only track research and development expenses related to the Virtue SAB product candidate. Since you do track that information, revise your MD&A to quantify the amounts expensed related to that product candidate for each period presented.

<u>Response</u>: Orchestra has revised the disclosures on pages 313 and 315 for the interim and annual periods, respectively, to quantify the amounts expensed related to the Terumo Partnership in response to the Staff's comment.

• In your response to prior comment 31 and related revised disclosures, you indicate that the amount of revenues recorded for the Terumo Partnership is based on the estimated and actual research and development expenses for this product candidate. Further, your revised disclosure discusses the significant changes to both your actual and estimated future expense which resulted in negative partnership revenue for 2021. You further disclose that you experienced further material cost increases during 2022, which led to further changes to your estimates and revenue recognition pattern. Accordingly, revise your MD&A and footnotes to quantify the expenses related to your Terumo Partnership for each period presented.

<u>Response</u>: Orchestra has revised the disclosure on page 313, 315, F-50 and F-80 for the interim and annual periods, respectively, to quantify the amounts expensed in response to the Staff's comment.

• Further given their impact on revenues recognized in the historical periods presented, disclose the estimated costs to complete the project and quantify the changes in those estimates you experienced during the periods presented which led to the significant changes in revenues reported.

Response: As noted in Orchestra's response to the second bullet of comment 31 of the Staff's comment letter dated September 3, 2022, Orchestra respectfully submits that, while it is required to disclose certain information regarding known trends in its MD&A, it is not required under federal securities laws to provide quantified forward-looking statements regarding, among other things, its projected expenses. Accordingly, Orchestra has provided general disclosure on page 311 regarding amounts it expects to spend under the Terumo Partnership (net of anticipated potential milestones) on non-clinical research and development activities, as well as amounts it expects to spend on the execution of the multinational BackBeat CNT pivotal trial and the Virtue SAB ISR-US pivotal trial between the second half of 2022 and the end of 2025. Orchestra acknowledges the Staff's comment regarding quantifying the changes in estimates, and respectfully submits that such amounts are commercially sensitive and providing Orchestra's competitors with access to this information would put Orchestra at a competitive disadvantage. However, Orchestra has enhanced the disclosures on pages 313, 315, F-50 and F-80 by providing the actual costs incurred under the Terumo Partnership for all historic periods presented as discussed above, and by providing the total percentage change in the estimated costs to complete the project as compared to the prior estimate, which enables a reader to further understand the changes in revenues reported during the periods.

• Revise to confirm, if true, that you update those cost estimates on a quarterly basis.

<u>Response</u>: Orchestra has revised the disclosure on page 313, 315, F-50 and F-80 to clarify that Orchestra evaluates its estimates of total costs expected to be incurred through the completion of the combined performance obligation at each quarterly reporting date, and updates its estimates as necessary, in response to the Staff's comment.

• You disclose on page F-50 that you experienced "unexpected changes to regulatory requirements" that caused you to amend your original project plan. Revise to more clearly identify those changes to your regulatory requirements.

Response: Orchestra has revised the disclosure on pages F-50 and F-79 in response to the Staff's comment.

Confidential Treatment Requested by Health Sciences Acquisitions Corporation 2 HSAQ-6

Please do not hesitate to contact Giovanni Caruso at (212) 407-4866 or Janeane Ferrari at (212) 407-4209 at Loeb & Loeb LLP with any questions or comments regarding this letter.

Sincerely,

/s/ Loeb & Loeb LLP

Loeb & Loeb LLP

Copy: Roderick Wong

Alice Lee

Health Sciences Acquisitions Corporation 2

Samuel Waxman, Esq. Yariv Katz, Esq. Keith Pisani, Esq. Paul Hastings LLP