

345 Park Avenue New York, NY 10154-1895 **Direct** 212.407.4000 **Main** 212.407.4000 **Fax** 212.407.4990

September 23, 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

Registration Statement on Form S-4

Filed August 8, 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 of the Division of Corporation Finance of the Commission (the "Staff") this letter setting forth the Company's response to the comments contained in the Staff's letter dated September 3, 2022 (the "Comment Letter") regarding the Company's Registration Statement on Form S-4 (the "Initial Filing").

The Company has filed via EDGAR Amendment No. 1 to the Initial Filing (the "Amendment"), 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 the Amendment, 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 the Amendment. Capitalized terms used herein but not defined herein shall have the meanings assigned to them in the Amendment.

# Registration Statement and Proxy Statement on Form S-4 Cover Page

1. Please revise your cover page to disclose the valuation ascribed to Orchestra in the business combination and the number of shares to be issued at the closing to Orchestra shareholders. In your discussion of ownership percentages following the transaction, please revise to explain the effect of seeking shareholder approval for your Extension Proposal and provide context for the percentage of public shares that were redeemed in connection therewith.

<u>Response</u>: The Company has revised the cover page to include the valuation and to add a description of the effect of the Extension Proposal before the discussion of ownership percentages following the transaction in response to the Staff's comment. The Company notes that the number of shares to be issued at the closing to Orchestra Shareholders is included in the paragraph preceding the added description.

#### Frequently Used Terms, page 6

2. Although we do not object to your use of a glossary, please revise to ensure that all defined terms are also defined at first use, and that your disclosures are clear without frequent reliance on defined terms or reference to other documents. As examples only, it is unclear why "Outside Closing Date" is a defined term when it is defined as a specific date, and the term "Alternative Transaction" is defined only by reference to the merger agreement.

Response: The Company has revised the definitional disclosure throughout the Amendment in response to the Staff's comment.

# O: Why is HSAC2 proposing the Business Combination Proposal?, page 13

3. You state that the private warrants will become exercisable on the later of 30 days after the completion of your initial business combination and 12 months from the closing of the IPO, which you state elsewhere closed in August 2020. Please revise here, and elsewhere as appropriate, to clarify if the private warrants are currently exercisable, and, immediately after the business combination, will be exercisable for New Orchestra Common Stock.

Response: The Company respectfully advises that the private warrants are not currently exercisable and will not be exercisable immediately after the business combination. The Company has revised the disclosure on pages 14, 106 and 200 to clarify.

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

4. We refer to your disclosure that the Initial Shareholders will vote any shares they purchase in the open market in or after the HSAC2 IPO in favor of each of the Proposals. Please revise your disclosures to explain how such purchases and votes, and the ancillary agreements related thereto, are in compliance with each of the conditions set forth in the Tender Offers and Schedules C&DI 166.01. As one example, we note the C&DI states that one of the conditions is that this registration statement would state that any of your securities purchased by the SPAC sponsor or its affiliates would not be voted in favor of approving the business combination transaction, but your disclosures and agreements indicate that all of your shares owned by them, including shares purchased outside of the redemption offer, would be voted in favor of the transaction. Your disclosure also indicates that the price paid could be at a premium to market price and that there is no limit to the price that could be paid.

<u>Response</u>: The Company acknowledges the Staff's comment and confirms to the Staff that all securities of the Company acquired by the Sponsor and its affiliates outside of the redemption process will satisfy the conditions set forth in Tender Offers and Schedules C&DI 166.01. Further, the Company has reviewed related disclosure and made revisions to the disclosure on pages 16, 17, 32, 92-94, 114, 133, 134, 138, 201, 208, 217 and 325 in response to the Staff's comment.

#### What happens if a substantial number of the Public Shareholders vote in favor of Business Combination Proposal..., page 20

5. You state that in no event will HSAC2 redeem Public Shares in an amount that would cause your net tangible assets to be less than \$5,000,001. Please also include such disclosure in the answer to the question "Do I have redemption rights?" on page 17.

Response: The Company has revised the disclosure on pages 17 - 18 in response to the Staff's comment.

#### Redemption Rights, page 34

6. Please revise to explain the amount of funds from the trust account used for redemptions resulting from your seeking shareholder approval for your Extension Proposal. In addition, to the extent correct, please revise your disclosures throughout your prospectus as appropriate, including in this section, to explain that you converted all of the assets held in the trust account into cash prior to your shareholder meeting held to seek approval for your Extension Proposal. In this regard, we note that your proxy statement circulated for the meeting stated, "[d]ue to this uncertainty [resulting from the Investment Company Act of 1940], HSAC2 intends to convert all of the assets held in the Trust Account into cash prior to the General Meeting," but that your disclosures in this prospectus, including on page 213 and in the last paragraph on page 216, indicate that your trust account continues to hold investment securities.

Response: The Company has revised the disclosure on pages 35, 213 and 219 in response to the Staff's comment.

# The Business Combination and Merger Agreement

Interests of Certain Persons in the Business Combination, page 36

7. You state that each of your initial shareholders have agreed to waive their right to redeem. Please describe any consideration provide in exchange for this agreement.

Response: The Company has revised the disclosure on pages 36, 91, 114, 141 and 201 in response to the Staff's comment.

8. Please add a bullet to disclose the total potential ownership interest to be held by the sponsor and its affiliates, including assuming the purchase of shares through the Backstop Agreement and conversion and exercise of all securities.

Response: The Company has revised the disclosure on pages 37, 91 and 142 in response to the Staff's comment.

# Summary Risk Factors, page 40

9. Please expand the seventh bullet to explain that Orchestra and New Orchestra have granted a security interest to the lender over all Orchestra's assets, including intellectual property.

Response: The Company has revised the disclosure on page 40 in response to the Staff's comment.

10. Expand the eleventh bullet on page 41, as well as add a stand-alone risk factor in the Risk Factors section, to specifically discuss the risks and material effects arising from the fact that some patents for BackBeat CNT and CNT-HF expire as soon as 2025, and that some patents for Virtue SAB expire as soon as 2028. In addition, in the section regarding summary risks relating to the business combination, add a bullet to discuss that you are likely a PFIC, which could result in adverse tax consequences, as you further discuss on page 99.

Response: Orchestra respectfully submits that, as stated in the disclosure added on page 260 in response to comment 27, despite the near-term expiration of certain of Orchestra's material patents, Orchestra believes that its other patents, as well as its trade secrets and continuing technological know-how, provide Orchestra with sufficient intellectual property protection to develop its product candidates and protect its intellectual property. In addition, the Company has added the suggested PFIC risk factor on page 42.

#### Proposals to be Considered by HSAC2 Shareholders Proposal 1: The Business Combination Proposal, page 120

11. When discussing the potential targets that HSAC2 exchanged term sheets with you state that you ceased discussions with Candidate Four on January 11, 2022 due to accelerated discussions between the Company and Orchestra. You also state that you had teleconferences and submitted draft letter of intent in March and April 2022 with Candidate Three. Please state whether your discussions with Orchestra beginning on January 2022 had any effect on your dealings with Candidate Three as it did with Candidate Four. Also explain why the board determined not to pursue discussions with multiple parties on a simultaneous basis, and as you indicate that you have a right to appoint one person to the board of New Orchestra, please revise Proposal 7 to clarify which director was chosen by you.

Response: The Company advises the Staff that discussions with Candidate Three ended in April 2021, not April 2022, and discussions with Candidate Three had no impact on discussions with Orchestra, which began approximately eight months later. Additionally, the right to appoint a New Orchestra director was included in the term sheet but not the Merger Agreement. The Company has revised the disclosure on page 121 to correct dates and add clarifying detail regarding the chronology, and on page 128 to indicate that the right to appoint a director was forfeited during negotiation of the Merger Agreement.

#### D. Potential for a strong pipeline..., page 129

12. Please provide the basis for your statistic that as many as half of the 26 million patients worldwide suffering from heart failure suffer from a modified cardiac neuromodulation algorithm condition.

<u>Response</u>: Orchestra has revised the disclosure on page 130 to, among other things, update the number of patients worldwide suffering from heart failure and include reference to the source for the statement in response to the Staff's comment.

# The Board's Reasons for the Approval of the Business Combination B. BackBeat CNT Medtronic Collaboration..., page 129

13. You state that the Board believes the Medtronic Collaboration has the potential to drive global penetration into a greater than \$10 billion annual commercial opportunity. Please revise to provide the basis for the Board's belief. In your revised disclosure, please (1) include the basis for your various statements that Orchestra is expected to receive between \$500 and \$1,600 per BackBeat CNT enabled device, but that BackBeat CNT enabled pacemakers are expected to be sold under existing reimbursement codes, and (2) address your statement on page 54 that your estimates of the HTN patient population include patients who are asymptomatic or in the early stages of disease and who may never be likely candidates for treatment with Orchestra's products and the estimate of the market size in the last paragraph on page 225.

Response: The Company has revised the disclosure on page 130 to include the basis for the statement regarding a greater than \$10 billion annual commercial opportunity. The Company supplementally advises the Staff that the Board based its belief on the information disclosed on page 221, which states that the addressable annual market for pacemaker-indicated patients with HTN represents a potential annual revenue opportunity of over \$2 billion, and the addressable annual market for high-risk HTN patients not indicated for a pacemaker represents a potential annual revenue opportunity of over \$8 billion, for a total of greater than \$10 billion annual commercial opportunity.

The Company has revised the disclosure on page 130 to include the basis for the statement that Orchestra is expected to receive between \$500 and \$1,600 per BackBeat CNT-enabled device.

With respect to the Staff's comment regarding existing reimbursement codes, Orchestra has revised the disclosure on page 224 to discuss the basis for its belief that BackBeat CNT-enabled pacemakers can be supported by existing reimbursement codes.

In addition, Orchestra has revised the disclosure on page 55 to remove the inadvertent reference to HTN, as Orchestra's calculated addressable patient market for BackBeat CNT does not include patients who are asymptomatic or in the early stages of disease and who may never be likely candidates for treatment

#### Material U.S. Federal Income Tax Consequences, page 142

14. We note that your counsel's tax opinion will be filed by amendment. If it will be a short- form tax opinion, please revise to state clearly that the disclosure in the tax consequences section is the opinion of counsel. As it appears counsel is providing a "should" opinion, please revise to describe the degree of uncertainty in the opinion. Refer to Staff Legal Bulletin No. 19.

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 145 and 151.

# <u>Unaudited Pro Forma Condensed Consolidated Combined Financial Information, page 153</u>

15. Revise your narrative introduction here as well as your pro forma footnotes to more clearly disclose the extent to which the contingent earnout payments have been reflected in or excluded from your pro forma adjustments. Consider providing disclosure in the footnotes outlining the additional dilution that would be experienced if the earnouts are achieved, clearly identifying the extent to which such dilution has been excluded from the face of the pro forma presentation.

Response: Orchestra has revised the disclosure on pages 157 and 165 in response to the Staff's comment.

# Business of Orchestra, page 220

16. Please generally revise your disclosures throughout your prospectus regarding how Orchestra's product candidates are designed to achieve certain end results without qualifications, such as, for example, your various statements in the first paragraph on page 223, the first two paragraphs on page 226, and the first paragraph on page 240, as these types of statements are premature and imply efficacy, which can only be determined by the FDA and comparable regulatory authorities. We also note your references to "compelling" clinical data. While you may present the objective results of trials, any discussion of preliminary results should be sufficiently balanced with disclosure of the preliminary nature of such results, and should not imply efficacy. We also refer to your statement that Virtue SAB aims to be the "first-in-class" Sirolimus AngioInfusion Balloon to deliver extended focal release sirolimus during angioplasty. This term suggests that the product candidate is effective and likely to be approved by the FDA. You may discuss how your technology differs from technology used by competitors and, as applicable, that you are not aware of competing products that are further along in the development process. Statements such as these that you retain should be accompanied by cautionary language that the statements are not intended to give any indication that the product candidate has been proven effective or that it will receive regulatory approval. Please revise your disclosures accordingly.

Response: In response to the Staff's comment, Orchestra has revised the disclosure on pages 221, 224, 227, 242 and 249 to clarify that, while Orchestra's product candidates are designed to achieve certain end results, they may not prove to be safe and effective. In addition, in response to the Staff's comment, Orchestra has revised the disclosure on page 242 to eliminate reference to "first-in-class."

#### Company, page 220

17. Please describe how Orchestra estimates a market opportunity of 3.2 million procedures valued at approximately \$3 billion for Virtue SAB. Please also revise to provide the basis for your claim on page 222 that HFpEF affects over half of the 64 million heart failure patients worldwide.

Response: Orchestra respectfully advises the Staff that it has engaged and worked with an established market research firm to conduct market analysis around the Virtue SAB global opportunity. The third party employed both primary and secondary methods for data gathering and analysis. Primary analysis involved multiple Q&A calls with industry-leading key opinion leaders to help assess the addressable patient population and segment the most addressable patient segments. Secondary data analysis was conducted by mining numerous subscription-based market databases, Medicare data and published literature. After gathering initial disease prevalence data, both Orchestra and the third party spent extensive time collaborating on further delineating potential procedure volumes for coronary in-stent-restenosis ("ISR"), coronary small vessel disease ("SV"), and below-the-knee peripheral disease ("BTK") that can be addressed by Virtue SAB, taking into consideration patient treatment pathways, anticipated product benefits, competitive landscape and reimbursement. The market size calculations also took into account patients with high bleeding risk, which overlaps with all three target indications and Orchestra believes will be an important driver of potential adoption. Third-party data mining, for which references were tracked, combined with Orchestra's knowledge of market dynamics and anticipated product differentiation, helped Orchestra arrive at the global procedure count of 3.2 million. Orchestra determined average selling price estimates calculated by country or region based on existing competitive device prices, as well as estimated future pricing for Virtue SAB and future competitive devices. Orchestra cross-checked these estimates with Terumo, Orchestra's strategic partner for Virtue SAB. Using the specific regional market size calculations by indication and the estimated ASPs, Orchestra was able to calculate that the future addressable market value for Virtue SAB in its target indications to be at least \$3 billion.

In addition, Orchestra has revised the disclosure on page 223 to provide the source for the statement that HFpEF affects over half of the 64 million heart failure patients worldwide.

18. You state that Orchestra will share meaningfully in the revenues generated from Medtronic's sale of BackBeat CNT-enabled pace making systems. Please amend your description of the Medtronic agreement on page 223 so that the referenced percentage is within a ten-percent range.

Response: Orchestra has disclosed that it expects "to receive between \$500 and \$1,600 per BackBeat CNT enabled device sold based on a formula of the higher of (1) a fixed dollar amount per BackBeat CNT-enabled device (amount varies materially on a country-by-country basis) or (2) a percentage of the BackBeat CNT generated sales." In addition, Orchestra has revised the disclosure on page 224 to disclose that its estimated range "is derived from management's knowledge of the pacemaker market and the terms of the Medtronic Agreement." Orchestra respectfully submits that it has provided all the material information regarding the economics of the Medtronic Agreement, especially in light of its disclosure of the range of the dollar amounts it expects to receive from the sale of each BackBeat CNT-enabled device. Orchestra further respectfully submits that the percentage to be paid by Medtronic is highly confidential and the result of significant negotiation between Orchestra and Medtronic and is competitively sensitive information to both Orchestra and Medtronic, particularly given that disclosure of the percentage combined with the specific revenue share dollar range already disclosed would allow competitors of Medtronic and Orchestra to calculate specific current and future average selling prices for Medtronic's existing commercial pacemaker devices and future BackBeat CNT-enabled pacemaker devices, which is highly proprietary information.

#### Product Pipeline, page 221

- 19. We refer to the last two rows in your table for SirolimusEFR. Based on your disclosures elsewhere, including on page 247, it does not appear that you have selected target indications for these product candidates yet. Given the early stage of development for these product candidates, as well as your limited disclosures regarding these discovery programs, it seems premature to highlight these products in the pipeline table. Please explain why these programs are sufficiently material to your business to warrant inclusion in your pipeline table or remove them.
  - Response: In response to the Staff's comment, Orchestra has refined the pipeline table on page 223 and the disclosure on page 250 to clarify that urology indications (urethral strictures and benign prostatic hyperplasia) and osteoarthritis are Orchestra's current lead preclinical stage indications for SirolimusEFR and planned feasibility work is expected to be focused on these indications. Orchestra continues to believe there are broader array of potential applications for SirolimusEFR, but it has removed additional indications from the table given the priority for the indications mentioned above. In general, Orchestra believes these indications are sufficiently material to include in the pipeline table because, as the expanded disclosure explains: (1) sirolimus is a well-known pharmaceutical agent with an anti-proliferative mechanism that is well-suited to address the inflammation and fibrosis that underlies that conditions for which Orchestra aims to develop treatment; (2) SirolimusEFR has been specifically developed to enable focal delivery and extended release of sirolimus, making it more suitable for potential clinical benefit in the indicated conditions versus systemic delivery; (3) Orchestra anticipates being able to leverage the chemistry, manufacturing and controls work it has conducted for Virtue SAB and the drug master file it has prepared in support of SirolimusEFR to accelerate the development of product candidates for these indications; (4) there are approved and development-stage products for both of these indications that work by device/drug mechanisms similar to SirolimusEFR (with balloon treatment/delivery in the case of urology); and (5) Orchestra has preliminary strategic partner interest in one of these indications already.
- 20. Please revise the pipeline table to include columns for Phase 1, 2, and 3 clinical trials or otherwise provide additional information in your table to clearly explain the phase of regulatory review for each of the product candidates shown. We also note that you indicate that the next trials for BackBeat CNT and Virtue SAB will be pivotal trials. Please revise your disclosures as appropriate to explain why you believe the next trial will be pivotal when your disclosure on page 232 indicates that you have not yet discussed the Backbeat CNT study with the FDA and other regulatory bodies, and you have similar disclosures regarding the regulatory uncertainties for Virtue SAB, including your disclosures on page 75 that you have not even received confirmation from the FDA that it only needs to be approved as a combination product rather than needing two separate approvals. Further, ensure the text under the pipeline table is legible. Where applicable, clearly identify the party sponsoring and conducting the upcoming trial. In addition, we note that you labeled the arrow for BackBeat CNT with the term "CE Mark" but you state elsewhere, including on page 232, that you do not intend to commercialize the Moderato system in the EU on its own. Accordingly, please remove the "CE Mark" label or otherwise clearly explain this information.

Response: In response to the Staff's comment, Orchestra respectfully advises the Staff that all of the device therapies shown in Orchestra's pipeline are Class III medical devices that would be subject to review and approval by the CDRH division of the FDA under the designation of requiring Pre-Market Approval ("PMA"). Such devices are not developed in defined phases of Phase 1, 2 and 3, which only applies to new pharmaceuticals. Devices are typically developed in two clinical stages: (1) clinical feasibility studies that provide indications of efficacy and safety in studies that are typically not statistically powered; and (2) pivotal clinical studies that are statistically powered to prove safety and efficacy in support of a PMA submission. As such, describing Orchestra's pipeline stages of development in terms of Phase 1, 2, and 3 would not be accurate.

In addition, Orchestra's Virtue SAB product has been formally designated a combination product device by the FDA, meaning that the device function is considered primary to the drug component which is considered secondary. Further, the product has received breakthrough device designation for all three current target clinical indications: coronary ISR, coronary SV and peripheral BTK. As such, based on current FDA published guidelines, there are currently no active questions about Virtue SAB's designation as a device that would require results from a single statistically powered pivotal trial to support potential FDA approval for each of these indications. However, we believe the risk factor language reflects the potential risk that such FDA guidelines change or that the FDA alters its opinion or designation of Virtue SAB at some point in the future.

Further, Orchestra's belief that the next studies for target indications for Virtue SAB will be pivotal is based on (1) Orchestra's knowledge and expertise regarding the development of Class III medical devices; (2) the fact that the device procedure (angioplasty) that Virtue SAB performs is well established clinical practice and the drug (sirolimus) Virtue SAB delivers is a well-known and proven drug in the field of interventional cardiology; and (3) the fact that Orchestra has performed extensive preclinical testing as well as conducted a clinical feasibility study showing that Virtue SAB is capable of performing the procedure and delivering the drug. As such, the logical next step in development would be to conduct a well-designed, statistically powered pivotal study for each indication to demonstrate efficacy and safety. Further, Orchestra has held multiple pre-submission meetings with the FDA and agreed on the study design for the pivotal Virtue ISR-US study. Terumo, with advice and input from Orchestra, has held an initial pre-submission with the FDA regarding the coronary SV indication in which a potential pivotal trial was discussed. Further, companies with competitive devices to Virtue SAB have or are conducting pivotal trials in the peripheral BTK indication and certain Orchestra executives have been involved in prior BTK studies. As such, Orchestra is confident that a next step in development of Virtue SAB for BTK would be a pivotal study.

Regarding the planned pivotal study for BackBeat CNT, Orchestra and Medtronic are confident that the logical next step for development of BackBeat CNT for the primary target population of hypertensive patients indicated for a pacemaker would be a well-designed, statistically powered pivotal study based on the following: (1) two clinical feasibility studies, including a double-blind, randomized study (MODERATO II), have already been completed, showing potential for the therapy that now needs to be proven in a larger study; (2) Medtronic is the global market leader in cardiac pacing therapies and, as such, has extensive knowledge and experience in the development of novel therapies in this field; (3) Orchestra personnel have extensive knowledge and experience in the development of active implantable bioelectronic therapies; and (4) the pacemaker device into which Medtronic is currently working to integrate BackBeat CNT is already approved and commercialized and, as such, BackBeat CNT results from a pivotal trial would be evaluated as a supplement to Medtronic's existing PMA (or comparable regulatory approval outside the United States). Further, Medtronic has had a recent preliminary informal discussion with the FDA regarding BackBeat CNT and formal pre-submission meetings are being planned for the relative near term.

In addition to the detail provided above for the Staff's review, Orchestra has revised the pipeline table on page 223 to, among other things, make the footnotes legible, to include the study sponsors and to remove "CE Mark" from the BackBeat CNT arrow.

#### BackBeat Cardiac Neuromodulation Product Candidate (CNT), page 223

21. We note you provide p-values for the primary endpoint of the MODERATO II study. At first use, please provide a brief explanation of p-value, how it is used to measure statistical significance, and how it relates to regulatory approval.

Response: Orchestra has revised the disclosure on page 224 in response to the Staff's comment.

22. Please further revise your disclosure in the second paragraph on page 226 to explain the intended mechanism of the product candidate in terms a lay investor would understand.

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

# Preclinical Data, page 227

23. We note your figure labeled "Reduction in 24-Hr aSBP" includes a key that identifies which plot line refers to Baseline and CNT. Please amend to clearly indicate which plot line is which and expand the narrative disclosure to explain the significance of the chart as both lines appear to show a decrease

Response: Orchestra has revised the figure and expanded the disclosure on page 228 in response to the Staff's comment.

24. Expand your discussion of the study described on the bottom of page 227 to clarify why the treatment varied in duration for different patients.

Response: Orchestra has revised the disclosure on page 229 in response to the Staff's comment.

## MODERATO I Single Arm Study, page 228

25. Please revise to clarify the narrative disclosure describing the graphics, and clearly explain whether the co-efficacy endpoints were met. Additionally, clarify whether baseline refers to pre-implementation.

Response: Orchestra has revised the disclosure on page 229 and 230 in response to the Staff's comment.

## Clinical Results, page 243

26. Please revise to clarify whether the SABRE study's primary and secondary efficacy and safety endpoints were met and who conducted the study. Please also expand your narrative disclosure to explain the significance of the information in the graph and ensure that the footnotes are legible. For this study and the Moderato studies, please also disclose any serious adverse events.

Response: Orchestra has (i) revised the disclosure on page 246 in response to the Staff's comment regarding the study meeting its primary and secondary performance endpoints and safety endpoint, (ii) revised the disclosure on page 245 regarding who conducted the study and (iii) revised the disclosure on page 246 to explain the significance of the information in the graph and to ensure that the footnotes are legible and (iv) revised the disclosure on pages 231 and 246 to provide disclosure regarding serious adverse events.

#### Intellectual Property, page 255

27. Please revise your intellectual property disclosure so that for each technology, you clearly describe the number of patents covering each type of patent protection, the expiration of each patent (or patent family), and the jurisdiction of each such patent. In this regard, it may be useful to provide this disclosure in tabular form to support the narrative already included, and clearly indicate which patents are licensed to your partners. Please also revise your disclosures so that investors can use it to determine the term of the agreements with Medtronic and Terumo, as well as the end date of those parties' revenue sharing or royalty obligations. In addition, describe any material effects that may arise from any patents that are soon to expire.

Response: Orchestra has revised the disclosure on pages 258 - 262 in response to the Staff's comment.

#### Management after the Business Combination, page 289

28. Please revise the biographical descriptions of your directors and executive officers to more closely align with the information required by Item 401 of Regulation S-K.

Response: Orchestra has revised the biographical descriptions on pages 295 - 298 in response to the Staff's comment.

# Orchestra's Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations, page 305

29. For each annual and interim period presented, please revise to provide a breakdown of your research and development expenses by product candidate. To the extent you are not able to track your expenses by product candidate, provide a breakdown of such unallocated amounts by the nature of the expenses.

Response: Due to the proportional performance revenue recognition model for its Terumo Partnership Agreement, in which partnership revenues are measured during each period based on the costs incurred pursuant to the agreement relative to the total estimated costs expected to be incurred during the performance period, Orchestra does track the expenses with respect to its Virtue SAB product candidate. However, Orchestra does not track its expenses for its other product candidates. Accordingly, Orchestra respectfully submits that providing this granular level of disclosure with respect to the expenses only related to the Terumo Agreement is not as meaningful to investors as providing a breakdown of research and development expenses by the functional area of such costs. In addition, Orchestra respectfully submits that many similarly situated issuers do not provide the granular disclosure requested by the Staff. Orchestra has added disclosure on page 311 that states: "Orchestra does not track expenses by product candidate, unless tracking such expenses is required pursuant to the revenue recognition model for a collaborative arrangement."

Orchestra has revised the disclosure on page 313 and 315 to provide a further breakdown of its research and development expenses in response to the Staff's comment.

# Critical Accounting Policies and Estimates Stock-Based Compensation, page 312

30. Revise this section to provide a tabular breakdown of the grants of stock-based compensation during 2022 through the date of the filing. For each grant by date, quantify the number of underlying shares, strike price, estimated fair value of the shares used to value the grant, and compensation recognized to date. Disclose the methods used to value the grants, including discounts applied as well as the extent to which the business combination was considered in reaching the valuation. Explain how the valuation used compares to the implied value given the exchange ratio in the merger as well as the preferred share issuances.

Response: Orchestra has added disclosure on pages 322 and 323 in response to the Staff's comment.

- 31. Please revise your disclosure to address the following regarding the revenues and expenses related to the Terumo Partnership:
  - Revise Note 3 in Orchestra's annual and interim financial statements as well as Orchestra's Management's Discussion and Analysis (MD&A) to quantify the expenses related to the Terumo Partnership and clearly identify the line items in which they are reported.
  - You disclose here on pages F-47 and F-48 as well as on page 307 that changes in the estimated total costs to complete the research and development services resulted to changes in the timing of your revenue recognition. Revise your Note 3 as well as page 307 to quantify the increases in the expected costs, identify the reasons for the increases, and discuss your expectations for future trends in this area. Revise Note 3 to Orchestra's interim financial statements on page F-76 as well as Orchestra's MD&A to discuss the extent to which there were additional changes to estimated total costs experienced during 2022, and disclose any resulting impact.
  - Revise Note 3 to Orchestra's interim financial statements on page F-76 as well as Orchestra's MD&A to discuss the extent to which there were additional changes to estimated total costs experienced during 2022, and disclose any resulting impact.
  - You disclose on page 64 that Orchestra did not meet certain milestone timeline requirements set forth in the Terumo Partnership. Revise Orchestra's MD&A to provide updates on the extent to which you are meeting and failing to meet certain of the timeline requirements, and identify any resulting financial and logistical impacts.

In response to the first bullet point of the Staff's comment, Orchestra respectfully advises the Staff that, as noted above in the response to comment 29, Orchestra does not track expenses for all of its product candidates, and Orchestra believes that providing a breakdown of research and development expense by functional area is more meaningful information for investors. As noted in the response to comment 29, Orchestra has revised the disclosure on pages 313 and 315 to provide a further breakdown of its research and development revenues to provide investors with additional information regarding its expenses and has stated on page 311 that it "... does not track expenses by product candidate, unless tracking such expenses is required pursuant to the revenue recognition model for a collaborative arrangement."

In response to the second bullet point of the Staff's comment, 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. Orchestra has provided disclosure on page 311 regarding the fact that it expects its research and development expenses to increase in the future as it continues to develop products. Orchestra has revised its disclosure on pages 313, 315, F-50 and F-80 to identify the reasons for the increases in the expected costs under the Terumo Agreement in response to the Staff's comment. In addition, Orchestra respectfully submits that it has followed the disclosure requirements of ASC 250, *Accounting Changes and Error Corrections* ("ASC 250), and has disclosed the effect on net loss and earnings per share on pages F-50 and F-80. Finally, Orchestra notes that it 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.

In response to the third bullet point of the Staff's comment, Orchestra has provided revised disclosure on pages 313 and F-80 to identify the reasons for the expected increase in costs in 2022. In addition, Orchestra respectfully submits that it has followed the disclosure requirements of ASC 250 and has disclosed the effect on net loss and earnings per share on page F-80.

In response to the fourth bullet point of the Staff's comment, Orchestra has revised the disclosure on pages 65, 236 and 310.

# **Exhibits**

32. We note your discussions of the Integer Agreement, including on page 253. Please provide your analysis regarding whether or not this agreement should be considered a material contract in accordance with Item 601(b)(10).

Response: Orchestra has advised the Company that the Integer Agreement is the type of agreement that ordinarily accompanies the kind of business conducted by Orchestra and its subsidiaries. In this context, the Integer Agreement would only be required to be filed if it fell within any of the categories in clauses (A) through (D) of Item 601(b)(10)(ii) of Regulation S-K. Among those provisions, the only potentially applicable provision is Item 601(b)(10)(ii)(B), which requires the filing of:

Any contract upon which the registrant's business is substantially dependent, as in the case of continuing contracts to sell the major part of registrant's products or services or to purchase the major part of registrant's requirements of goods, services or raw materials or any franchise or license or other agreement to use a patent, formula, trade secret, process or trade name upon which registrant's business depends to a material extent;

The Company has been advised by Orchestra that, Orchestra has no intention to:

- commercialize the pacemaker hardware technology developed and manufactured under the Integer Agreement and utilized for the BackBeat CNT clinical trials;
- have any additional Integer pacemaker hardware manufactured; or
- use the Integer pacemaker hardware technology in any planned or future clinical trials.

Accordingly, the Company respectfully submits Orchestra's business is not substantially dependent upon the Integer Agreement, and that Integer Agreement is not required to be filed as an exhibit to the registration statement pursuant to Item 601(b)(10) of Regulation S-K.

#### General

33. We note that Chardan and Barclays were underwriters for your initial public offering and advised you on the business combination transaction with Orchestra. We also note press reports that certain financial advisors are ending their involvement in SPAC business combination transactions. Please tell us, with a view to disclosure, whether you have received notice from either of these institutions about it ceasing involvement in your transaction and how that may impact your deal or the deferred underwriting compensation owed to them for your initial public offering.

Response: The Company respectfully advises the Staff that it has received no such notice from its financial advisors. The Company further undertakes that if it receives such a notice, the Company will make appropriate disclosure in the proxy statement/prospectus, including the impact on the transaction and deferred underwriting or other compensation owed to advisors.

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