

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

September 3, 2022

Roderick Wong Chief Executive Officer Health Sciences Acquisitions Corp 2 40 10th Avenue, Floor 7 New York, NY 10014

> Re: Health Sciences Acquisitions Corp 2 Registration Statement on Form S-4 Filed August 8, 2022 File No. 333-266660

Dear Dr. Wong:

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.

#### 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.

#### 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.

#### Q: 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.

### 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.

# 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.

#### 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.

## <u>The Business Combination and Merger Agreement</u> 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.
- 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.

#### 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.
- 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.

# <u>Proposals to be Considered by HSAC2 Shareholders</u> 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.

### 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 form heart failure suffer from a modified cardiac neuromodulation algorithm condition.

# 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.

#### 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.

#### Unaudited Pro Forma Condensed Consolidated Combined Financial Information, page 153

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.

#### 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.

#### 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.
- 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.

#### 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.
- 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.

#### 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.
- 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.

#### 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.
- 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.

#### 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.

#### 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.

#### 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.

#### 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.

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.

<u>Critical Accounting Policies and Estimates</u> <u>Stock-Based Compensation, page 312</u>

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.

<u>Consolidated Financial Statements of Orchestra Biomed, Inc.</u> Terumo Partnership Agreement, page F-47

- 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.
- 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.

#### **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).

#### 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.

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 Christine Torney at 202-551-3652 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Doris Stacey Gama at 202-551-3188 or Dorrie Yale at 202-551-8776 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Janeane Ferrari, Esq.