



## **Orchestra BioMed Debuts as Nasdaq-Traded Company with Lead Programs Targeting Hypertension and Artery Disease and Novel Partnership-Enabled Business Model**

January 27, 2023

*Business combination with Health Sciences Acquisitions Corporation 2, a special purpose acquisition company sponsored by an affiliate of RTW Investments, LP, completed on January 26, 2023*

*The combination was announced simultaneously with Orchestra's strategic collaboration with Medtronic to develop BackBeat Cardiac Neuromodulation Therapy™ as potential integrated hypertension treatment for cardiac pacemaker patients*

*Gross proceeds from transaction and previously completed financing led by RTW and Medtronic total approximately \$180 million and support cash runway into 2026*

*Orchestra BioMed Holdings, Inc. to commence trading on January 27 on Nasdaq Global Market under ticker symbol "OBIO"*

NEW HOPE, Pa., Jan. 27, 2023 (GLOBE NEWSWIRE) -- Orchestra BioMed, Inc. ("Orchestra BioMed"), a biomedical company accelerating high-impact technologies to patients through risk-reward sharing partnerships, today announced the closing of its previously announced business combination with Health Sciences Acquisitions Corporation 2 ("HSAC2") (Nasdaq: HSAQ). Common stock of the combined company (Nasdaq: OBIO or the "Company"), which is called "Orchestra BioMed Holdings, Inc.", will commence trading on January 27, 2023, on the Nasdaq Global Market under the ticker symbol "OBIO". Orchestra BioMed's management team, led by Chairman, Chief Executive Officer and Co-founder David Hochman, will lead the combined company.

The business combination, which had previously been approved by Orchestra BioMed stockholders, was approved by HSAC2 shareholders at a special general meeting held on January 24, 2023. Gross proceeds from the business combination were \$70 million including \$20 million in market purchases of HSAC2 stock by an affiliate of Medtronic plc ("Medtronic") and funds managed by RTW Investments, LP ("RTW"), a leading life sciences investment firm, as well as an additional investment by RTW concurrent with the closing. Together with proceeds from Orchestra BioMed's previously completed \$110 million Series D financing, total cash following the business combination is expected to provide the Company with a cash runway into 2026. The Series D financing included a \$40 million investment from Medtronic, a \$20 million investment from RTW, and investments from Perceptive Advisors, Terumo, SternAegis Ventures and others. The Company's cash resources are intended to support the execution of pivotal studies for BackBeat Cardiac Neuromodulation Therapy™ (CNT™) for the treatment of hypertension in cardiac pacemaker patients, and Virtue® Sirolimus AngioInfusion™ Balloon (SAB) in patients with coronary in-stent restenosis.

"Orchestra BioMed is pioneering an innovative business model designed to leverage partnerships with global medical device leaders like Medtronic and Terumo to accelerate the development and commercialization of high-impact device therapies like BackBeat CNT and Virtue SAB. With a strong balance sheet, a top-flight shareholder base, and world-class strategic collaborators, this transaction puts us in an excellent position to address the unmet needs of patients and physicians while seeking to generate differentiated growth for our stockholders," said Mr. Hochman. "We have several important milestones ahead of us, including the expected initiation of pivotal trials this year for both BackBeat CNT and Virtue SAB. These innovative technologies are supported by strong proof-of-concept clinical data, fueling our excitement for Orchestra BioMed as it enters the public markets and the next phase of its corporate evolution."

Roderick Wong, M.D., Managing Partner and Chief Investment Officer of RTW, added, "BackBeat CNT and Virtue SAB are supported by promising data and novel partnerships with global leaders across medtech that we believe will help accelerate clinical development and position them for commercial success. We are proud to be supporting this significant milestone and look forward to our continued work with Orchestra BioMed's leadership team, which has an exceptional track record of bringing novel medical technologies to market."

### **Advisors**

Jefferies LLC acted as lead financial advisor and a capital markets advisor to Orchestra BioMed. Piper Sandler & Co. acted as a capital markets advisor to Orchestra BioMed.

Chardan and Barclays acted as financial and capital markets advisors to HSAC2. Chardan acted as M&A advisor to HSAC2.

Paul Hastings LLP served as legal counsel for Orchestra BioMed. Loeb & Loeb LLP served as legal counsel for HSAC2. Latham & Watkins LLP served as legal counsel for Jefferies LLC, Piper Sandler & Co., Chardan and Barclays.

### **About Orchestra BioMed**

Orchestra BioMed is a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing partnerships with leading medical device companies. Orchestra BioMed's partnership-enabled business model focuses on forging strategic collaborations with leading medical device companies to drive successful global commercialization of products it develops. Orchestra BioMed's flagship product candidates include BackBeat Cardiac Neuromodulation Therapy™ (CNT™) for the treatment of hypertension, a significant risk factor for death worldwide, and Virtue® Sirolimus AngioInfusion™ Balloon (SAB) for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide. Orchestra BioMed has a strategic collaboration with Medtronic, one of the largest medical device companies in the world, for development and commercialization of BackBeat CNT for the treatment of hypertension in pacemaker-indicated patients, and a strategic partnership with Terumo

Corporation, a global leader in medical technology, for development and commercialization of Virtue SAB for the treatment of artery disease. Orchestra BioMed has additional product candidates and plans to potentially expand its product pipeline through acquisitions, strategic collaborations, licensing, and organic development. For further information about Orchestra BioMed, please visit [www.orchestrabiomed.com](http://www.orchestrabiomed.com).

#### **About BackBeat CNT and the Strategic Collaboration with Medtronic**

BackBeat CNT is an investigational bioelectronic treatment designed to lower blood pressure. It is compatible with standard pacemakers as a firmware upgrade and has been evaluated in pilot studies in patients with hypertension who also are indicated for pacemakers. It is estimated that more than 70% of the approximately 1.1 million people globally who are implanted with cardiac pacemakers each year are also diagnosed with hypertension<sup>1</sup>.

The recent peer-reviewed, double-blind, randomized pilot study, MODERATO II, showed that patients treated with the BackBeat CNT experienced net reductions of 8.1 mmHg in 24-hour ambulatory systolic blood pressure (aSBP) and 12.3 mmHg in office systolic blood pressure (oSBP) when compared to control patients at six months. Orchestra BioMed plans to conduct a global pivotal trial to further evaluate the safety and efficacy of the BackBeat CNT in lowering blood pressure in a similar target population of patients who have been indicated for, and recently received, a cardiac pacemaker implant. The strategic collaboration with Medtronic will provide Orchestra BioMed with development, clinical, and regulatory support for this planned multi-national study. Upon regulatory approval, Medtronic will have the global rights to commercialize BackBeat CNT-enabled pacing systems for this target population. Orchestra BioMed will share in the revenues generated from Medtronic sales of the BackBeat CNT-enabled pacing systems.

#### **About Virtue SAB and the Strategic Collaboration with Terumo**

Virtue SAB is a patented drug/device combination product candidate in development for the treatment of certain forms of artery disease that is designed to deliver a proprietary, investigational, extended-release formulation of sirolimus, SirolimusEFR™, to the vessel wall during balloon angioplasty without any coating on the balloon surface or the need to leave a stent or other permanent implant in the artery. Virtue SAB demonstrated positive three-year clinical data in coronary in-stent restenosis (ISR) in the SABRE trial, a multi-center prospective, independent core lab-adjudicated clinical trial of 50 patients conducted in Europe. Virtue SAB has been granted Breakthrough Device designation by the U.S. Food and Drug Administration for specific indications relating to coronary ISR, coronary small vessel disease and peripheral artery disease below-the-knee.

Under the terms of their collaboration agreement, Orchestra BioMed and Terumo plan to execute a global clinical program in an effort to gain regulatory approval for commercial sale of Virtue SAB in multiple markets and indications. Terumo made an upfront payment of \$30 million to Orchestra BioMed and Terumo will potentially make additional future clinical and regulatory milestone payments. Orchestra BioMed will share meaningfully in future commercial revenues of Virtue SAB through royalties and per unit payments as the exclusive supplier of SirolimusEFR. Orchestra BioMed retains the rights to develop and license SirolimusEFR and other technologies used in Virtue SAB for clinical applications outside of coronary and peripheral vascular interventions.

#### **About HSAC2**

Health Sciences Acquisitions Corporation 2 was a blank check company formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses. The sponsor of HSAC2 was HSAC 2 Holdings, LLC, an affiliate of RTW Investments, LP.

#### **About RTW Investments, LP**

RTW Investments, LP is a New York-based, global, full life-cycle investment firm that focuses on identifying transformational and disruptive innovations across the biopharmaceutical and medical technologies sectors. As a leading partner of industry and academia, RTW combines deep scientific expertise with a solution-oriented investment approach to advance emerging medical therapies by building and supporting the companies and/or academics developing them. For further information about RTW, please visit [www.RTWfunds.com](http://www.RTWfunds.com).

#### **References**

1. Company estimates based on published sources, including National Inpatient Survey (NIS) and National Health and Nutrition Examination Survey (NHANES)

#### **Forward-Looking Statements**

Certain statements included in this document that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “would,” “plan,” “predict,” “potential,” “seem,” “seek,” “future,” “outlook” and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements relating to our expected cash runway, the potential efficacy of our BackBeat CNT product candidate, the timing of our planned pivotal trials, and the ability of our partnerships to accelerate clinical development. These statements are based on various assumptions, whether or not identified in this document, and on the current expectations of the Company's management and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as and must not be relied on as a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and may differ from assumptions. Many actual events and circumstances are beyond the control of the Company. These forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political, and legal conditions; failure to realize the anticipated benefits of the business combination; risks related to regulatory approval of the Company's product candidates; the timing of, and the Company's ability to achieve, expected regulatory and business milestones; the impact of competitive products and product candidates; the impact of COVID-19; and the risk factors identified under the heading “Risk Factors—Risks Related to Orchestra's Business and New Orchestra Following the Business Combination” in the proxy statement/prospectus filed by HSAC2 with the U.S. Securities and Exchange Commission pursuant to Rule 424(b)(3) on December 16, 2022.

The Company operates in a very competitive and rapidly changing environment. New risks emerge from time to time. Given these risks and uncertainties, the Company cautions against placing undue reliance on these forward-looking statements, which only speak as of the date of this press release. The Company does not plan and, subject to applicable law, undertakes no obligation to update any of the forward-looking statements made

herein, except as required by law.

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