



## Orchestra BioMed Reports First Quarter 2023 Financial Results and Provides Business Update

May 12, 2023

- Completed business combination and listing on Nasdaq generating gross proceeds of approximately \$70 million
- BackBeat CNT™ global pivotal study in hypertensive pacemaker patients on track for initiation in the second half of 2023 in collaboration with Medtronic
- Virtue SAB® U.S. pivotal study in coronary in-stent restenosis ("ISR") start planned for the second half of 2023 in collaboration with Terumo

NEW HOPE, Pa., May 12, 2023 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO, "Orchestra BioMed" or the "Company"), a biomedical company accelerating high-impact technologies to patients through risk-reward sharing partnerships, today reported its first quarter 2023 financial results and provided a business update.

"The first quarter of 2023 was a transformational period for Orchestra BioMed marked by our successful entrance into the public markets. In the last year, we completed our BackBeat CNT strategic collaboration with Medtronic, the global leader in cardiac pacing therapies, and significantly strengthened our balance sheet with support from leading healthcare and strategic investors. With these accomplishments, we believe we have long-term capital resources to execute pivotal clinical studies for our two lead programs, BackBeat CNT and Virtue SAB," stated David Hochman, Chairman, Co-founder and Chief Executive Officer of Orchestra BioMed. "We plan to start the BackBeat CNT and Virtue SAB pivotal studies this year and look forward to generating key data to support regulatory submissions for these high-impact therapeutic devices. It is an ideal time to be pursuing our innovative, partnership-enabled business model, and our team is focused on delivering significant value for our shareholders, physicians, and patients."

### Corporate highlights

- Completed successful business combination with Health Sciences Acquisition Corp 2 ("HSAC2"), a special purpose acquisition company sponsored by an affiliate of RTW Investments, LP ("RTW"), on January 26, 2023. Gross proceeds from the transaction were approximately \$70 million and the transaction was supported by approximately \$28 million in market purchases of HSAC2 stock and investments by funds managed by RTW affiliates and approximately \$10 million in market purchases of HSAC2 stock by an affiliate of Medtronic plc ("Medtronic").
- Strengthened senior leadership team with appointment of Avi Fischer, M.D., as Senior Vice President (SVP), Medical Affairs and Innovation; J.C. Simeon as SVP, Quality; George Papandreou, Ph.D., as General Manager and SVP, Focal Therapies; and Kunal Faldu as Vice President, Pharmaceutical Development.

### Pipeline highlights

- **BackBeat Cardiac Neuromodulation Therapy (CNT™) - Hypertension in Pacemaker Patients**
  - Global pivotal study evaluating the efficacy and safety of BackBeat CNT in adult patients with hypertension who are indicated for a pacemaker on track to start in the second half of 2023
- **Virtue® Sirolimus AngioInfusion™ Balloon (SAB) – Coronary Indications**
  - U.S. pivotal study evaluating Virtue SAB in adult patients with coronary ISR planned to start in the second half of 2023
  - Additional Virtue SAB clinical studies in coronary ISR and small vessel disease planned in partnership with Terumo, the Company's global strategic partner for development and commercialization of Virtue SAB

### Financials

- **Cash Position:** As of March 31, 2023, Orchestra BioMed had cash and cash equivalents and marketable securities of \$127.1 million, compared to \$83.7 million as of December 31, 2022. The increase in cash was primarily due to the net proceeds provided by the closing of the business combination with HSAC2, less cash used in operating activities during the quarter and fees and expenses associated with the business combination. Based on current clinical development and other research and development plans and budget estimates, the Company anticipates that the cash and cash equivalents and marketable securities are sufficient to fund operations into 2026.
- **Revenue:** Orchestra BioMed recognized \$1.2 million of revenue for the first quarter of 2023 compared to \$0.9 million for the first quarter of 2022. The increase was primarily due to increased recognition of partnership revenues earned under the Terumo agreement.
- **Research and Development Expenses:** Research and development (R&D) expenses were \$8.3 million for the first

quarter of 2023 compared to \$3.5 million for the first quarter of 2022. The increase was primarily due to additional costs associated with preparations for the launch of the Virtue SAB and BackBeat CNT pivotal clinical studies, as well as an increase of \$0.5 million in non-cash stock-based compensation expense.

- **Selling, General and Administrative Expenses:** Selling, general and administrative expenses were \$4.4 million for the first quarter of 2023, compared to \$2.5 million for the first quarter of 2022. The increase was primarily due to additional personnel costs, legal, insurance and finance costs, transaction costs incurred related to the closing of the business combination and included an increase of \$0.9 million in non-cash stock-based compensation expense.
- **Other Income (Expense):** Other income was \$0.6 million for the first quarter of 2023, compared to other expense of \$0.6 million for the first quarter of 2022. Interest income (expense), net, increased by \$1.1 million from the first quarter of 2022 due to the higher cash balance and an increase in interest rates.
- **Net Loss:** Net loss was \$10.9 million for the first quarter of 2023, or \$0.40 per share, compared to a net loss of \$5.7 million, or \$0.62 per share, for the same period in 2022. The net loss for the first quarter of 2023 includes \$1.8 million in non-cash stock-based compensation expense and loss on fair value adjustment of warrant liability as compared to \$0.2 million for the first quarter of 2022.

#### **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 are also 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 peer-reviewed, double-blind, randomized pilot study, MODERATO II, showed that patients treated with 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 study to further evaluate the safety and efficacy of 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 global 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 study, a multi-center prospective, independent core lab-adjudicated clinical study 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 Orchestra BioMed**

Orchestra BioMed (Nasdaq: OBIO) 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), and follow us on [LinkedIn](#) and [Twitter](#).

References to information included on, or accessible through, websites and social media platforms do not constitute incorporation by reference of the information contained at or available through such websites or social media platforms, and you should not consider such information to be part of this press release.

#### **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 the sufficiency of our long-term capital resources to execute pivotal studies for our two lead programs, the expected runway of our current cash and cash equivalents, the potential efficacy of our product candidates, 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; and the risk factors discussed in Part II, "Item 1A. Risk Factors" of our quarterly report on Form 10-Q filed with the U.S. Securities and Exchange Commission on May 12, 2023.

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 undertakes no obligation to update any of the forward-looking statements made herein, except as required by law.

## References

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

**ORCHESTRA BIOMED HOLDINGS, INC.**  
**Condensed Consolidated Balance Sheets**  
(in thousands, except share and per share data)  
(Unaudited)

	<u>March 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 18,695	\$ 19,784
Marketable securities	108,438	63,915
Strategic investments, current portion	100	86
Accounts receivable, net	76	96
Inventory	232	276
Prepaid expenses and other current assets	<u>2,339</u>	<u>533</u>
<b>Total current assets</b>	129,880	84,690
Property and equipment, net	1,453	1,489
Right-of-use assets	2,032	2,187
Strategic investments, less current portion	2,495	2,495
Deposits and other assets	<u>421</u>	<u>4,711</u>
<b>TOTAL ASSETS</b>	<u>\$ 136,281</u>	<u>\$ 95,572</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,765	\$ 3,968
Accrued expenses and other liabilities	3,256	5,376
Operating lease liability, current portion	711	697
Warrant liability	—	2,089
Deferred revenue, current portion	<u>5,325</u>	<u>6,436</u>
<b>Total current liabilities</b>	12,057	18,566
Deferred revenue, less current portion	13,195	13,103
Loan payable, less current portion	9,527	9,490
Operating lease liability, less current portion	1,500	1,683
Other long-term liabilities	<u>249</u>	<u>196</u>
<b>TOTAL LIABILITIES</b>	36,528	43,038
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at March 31, 2023 and December 31, 2022.	—	—
Common stock, \$0.0001 par value per share; 340,000,000 shares authorized; 31,741,147 and 20,187,850 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively.	3	2
Additional paid-in capital	310,459	252,274
Accumulated other comprehensive loss	(35)	(8)
Accumulated deficit	<u>(210,674)</u>	<u>(199,734)</u>
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<u>99,753</u>	<u>52,534</u>

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY

\$ 136,281    \$ 95,572

**ORCHESTRA BIOMED HOLDINGS, INC.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
**(in thousands, except share and per share data)**  
**(Unaudited)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Revenue:</b>		
Partnership revenue	\$ 1,019	\$ 716
Product revenue	145	150
Total revenue	<u>1,164</u>	<u>866</u>
<b>Expenses:</b>		
Cost of product revenues	44	42
Research and development	8,254	3,474
Selling, general and administrative	<u>4,411</u>	<u>2,478</u>
Total expenses	<u>12,709</u>	<u>5,994</u>
<b>Loss from operations</b>	<u>(11,545)</u>	<u>(5,128)</u>
<b>Other income (expense):</b>		
Interest income (expense), net	885	(236)
Loss on fair value adjustment of warrant liability	(294)	(145)
Gain (loss) on fair value of strategic investments	<u>14</u>	<u>(220)</u>
Total other income (expense)	<u>605</u>	<u>(601)</u>
<b>Net loss</b>	<u>\$ (10,940)</u>	<u>\$ (5,729)</u>
<b>Net loss per share</b>		
Basic and diluted	\$ (0.40)	\$ (0.62)
Weighted-average shares used in computing net loss per share, basic and diluted	27,643,549	9,225,058

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