Orchestra BioMed Reports Full Year 2023 Financial Results and Provides Fourth Quarter Business Update

March 27, 2024

- *Initiated enrollment of the BACKBEAT global pivotal study evaluating AVIM therapy (also known as BackBeat Cardiac Neuromodulation Therapy) in hypertensive pacemaker patients in collaboration with Medtronic, plc (NYSE: MDT) in December 2023*
- *Orchestra BioMed and Terumo remain actively engaged to update operational plans and financial arrangements for Virtue® Sirolimus AngioInfusion™ Balloon ("SAB") development and commercialization for treatment of coronary and peripheral artery disease*
- *Expected runway of cash and cash equivalents and marketable securities, including certain potential future proceeds sufficient into 2H 2026, beyond anticipated BACKBEAT top-line results readout*

NEW HOPE, Pa., March 27, 2024 (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 full year 2023 financial results and provided a fourth quarter business update.

"2023 was a year of strong momentum for Orchestra BioMed as we made significant progress on our cardiovascular pipeline with the achievement of key regulatory milestones and completion of our successful Nasdaq listing," commented David Hochman, chairman, chief executive officer and founder of Orchestra BioMed. "In December, we initiated the BACKBEAT global pivotal study evaluating our lead program, AVIM therapy, in hypertensive pacemaker patients working alongside our strategic partner Medtronic, the global market leader in cardiac pacing therapies. We see a substantial market opportunity for AVIM therapy in this patient population, as well as in other high-risk hypertension populations."

Mr. Hochman continued, "We remain actively engaged with our other strategic partner, Terumo, to update our operational and financial plans to advance Virtue SAB for the treatment of patients with coronary in-stent restenosis, a breakthrough indication for which we have conditional Investigational Device Exemption approval from the FDA, as well as other breakthrough coronary and peripheral indications. Globally, the treatment of coronary in-stent restenosis and other challenging artery disease indications is rapidly shifting toward drug-coated balloons. We continue to believe Virtue SAB, the only non-coated balloon angioplasty system that provides protected focal delivery of extended-release sirolimus, has the potential to offer a best-in-class solution with important advantages for patients and physicians in an established target global market we estimate at over $4 billion annually. Overall, we look forward to continuing 2023's momentum in the year ahead with a focus on strong execution, the best validation of our partnership-enabled business model."

Fourth Quarter 2023 and Recent Highlights

Advancing AVIM Therapy in High Unmet Need Hypertension Populations

- Initiated enrollment of the BACKBEAT pivotal study evaluating the efficacy and safety of atrioventricular interval modulation ("AVIM") therapy in hypertensive pacemaker patients in December 2023, with a target for completion of enrollment in mid-2025.
- Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") indicated that the existing BACKBEAT global pivotal study, if sufficient to support FDA approval of BackBeat CNT would likely be sufficient to support a regulatory approval of AVIM therapy in Japan.
- Continued to explore future opportunities to utilize AVIM therapy and other forms of Cardiac Neuromodulation Therapy ("CNT") for high-risk populations with hypertension and heart failure.

Maximizing the Opportunity for Highly Differentiated Virtue SAB

- Initiation of Virtue ISR-US pivotal study of Virtue SAB for the treatment of coronary in-stent restenosis ("ISR"), as well as submissions to Japanese PMDA in coronary ISR and small vessel disease are pending ongoing operational and financial plan calibration with Terumo, strategic partner for development and commercialization of Virtue SAB for coronary and peripheral artery disease treatment.

Financial Results for the Year Ended December 31, 2023

- **Cash and cash equivalents and marketable securities** totaled $87.6 million as of December 31, 2023. Expected runway extended into the second half of 2026 based on internally prepared forecast reflecting updated operating priorities and certain potential future proceeds.
- **Net cash** used in operating activities and for the purchase of fixed assets was $46.2 million during 2023, compared with

$29.9 million for 2022, with the primary drivers of increased spending being costs associated with preparation for the initiation of the BACKBEAT pivotal study as well as expenses associated with being a public company.

- **Revenue** for 2023 was $2.8 million, compared with $3.5 million for 2022. The decrease was primarily due to decreased recognition of partnership revenues earned under the agreement with Terumo.
- **Research and development expenses** for 2023 were $33.8 million, compared with $21.9 million for 2022. The increase was primarily due to additional costs associated with preparation for the initiation of the BACKBEAT pivotal study.
- **Selling, general and administrative expenses** for 2023 were $20.3 million, compared with $14.0 million for 2022. The increase was primarily due to additional personnel costs, legal, insurance and finance costs, and additional costs related to being a public company.
- **Net loss** for 2023 was $49.1 million, or ($1.48) per share, compared with a net loss of $33.6 million, or ($2.24) per share, for 2022. Net loss for the year-ended 2023 included non-cash stock-based compensation expense of $7.6 million, compared with $3.4 million for the same period in 2022.

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 lead product candidate is atrioventricular interval modulation (AVIM) therapy (also known as BackBeat Cardiac Neuromodulation Therapy (CNT™)) for the treatment of hypertension, a significant risk factor for death worldwide. Orchestra BioMed is also developing the 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 AVIM therapy for the treatment of hypertension in pacemaker-indicated patients, and a strategic partnership with Terumo, 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, and follow us on LinkedIn.

References to Websites and Social Media Platforms

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.

About AVIM Therapy (BackBeat CNT™)

AVIM therapy, also known as BackBeat CNT™, is an investigational therapy compatible with standard dual-chamber pacemakers designed to substantially and persistently lower blood pressure. It has been evaluated in pilot studies in patients with hypertension who are also indicated for a pacemaker. MODERATO II, a double-blind, randomized, pilot study, showed that patients treated with AVIM therapy 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) at six months when compared to control patients. The global IDE BACKBEAT (BradycArdia paCemaKer with atrioventricular interval modulation for Blood prEssure treAtmenT) pivotal study will further evaluate the safety and efficacy of AVIM therapy in lowering blood pressure in a similar target population of patients who have been indicated for, and recently implanted with, a dual-chamber cardiac pacemaker.

About Virtue SAB

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 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 FDA for specific indications relating to coronary ISR, coronary small vessel disease and peripheral artery disease below-the-knee. The FDA granted IDE approval to initiate the Virtue ISR-US study to evaluate this novel treatment in coronary ISR patients. Orchestra BioMed has a strategic partnership with Terumo (Terumo, TSE: 4543), a global leader in medical technology headquartered in Tokyo, Japan, as well as Terumo Medical Corporation, its U.S. subsidiary, to collaborate on the global development and commercialization of Virtue SAB in coronary and peripheral vascular indications.

Forward-Looking Statements

Certain statements included in this press release 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 initiation, enrollment, timing, implementation and design of the Company's planned and ongoing pivotal trials and reporting of top-line results, the sufficiency of regulatory approval of BackBeat CNT by the FDA to support regulatory approval in Japan, realizing the clinical and commercial value of BackBeat CNT and Virtue SAB, the expected runway of the Company's current cash, cash equivalents, marketable securities and expected proceeds from a revised Terumo agreement, the potential safety and efficacy of the Company's product candidates, the ability of the Company's partnerships to accelerate clinical development, the Company's late-stage development programs, strategic partnerships and plans to expand its product pipeline, and the Company's ability to negotiate mutually agreeable adjustments to its current agreement with Terumo. These statements are based on various assumptions, whether or not identified in this press release, 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; risks related to regulatory approval of the Company's commercial product candidates and ongoing regulation of the Company's product candidates, if approved; 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 under the heading "Item 1A. Risk Factors" in the Company's annual report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on March 27, 2024.

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.

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

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 30,559	$ 19,784
Marketable securities	56,968	63,915
Strategic investments, current portion	68	86
Accounts receivable, net	99	96
Inventory	146	276
Prepaid expenses and other current assets	1,274	533
Total current assets	89,114	84,690
Property and equipment, net	1,279	1,489
Right-of-use assets	1,555	2,187
Strategic investments, less current portion	2,495	2,495
Deposits and other assets	769	4,711
TOTAL ASSETS	$ 95,212	$ 95,572
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 2,900	$ 3,968
Accrued expenses and other liabilities	5,149	5,376
Operating lease liability, current portion	649	697
Warrant liability	—	2,089
Deferred revenue, current portion	2,510	6,436
Total current liabilities	11,208	18,566
Deferred revenue, less current portion	14,923	13,103
Loan payable	—	9,490
Operating lease liability, less current portion	1,038	1,683
Other long-term liabilities	—	196
TOTAL LIABILITIES	27,169	43,038
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at December 31, 2023 and December 31, 2022.	—	—
Common stock, $0.0001 par value per share; 340,000,000 shares authorized; 35,777,412 and 20,187,850 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively.	4	2
Additional paid-in capital	316,903	252,274
Accumulated other comprehensive loss	(10)	(8)
Accumulated deficit	(248,854)	(199,734)
TOTAL STOCKHOLDERS' EQUITY	68,043	52,534
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 95,212	$ 95,572

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

	Year Ended December 31,	
	2023	2022
Revenue:		
Partnership revenue	$ 2,106	$ 2,862
Product revenue	654	671
Total revenue	2,760	3,533
Expenses:		
Cost of product revenues	186	211
Research and development	33,822	21,945
Selling, general and administrative	20,258	14,034
Total expenses	54,266	36,190
Loss from operations	(51,506)	(32,657)
Other income (expense):		
Interest income, net	3,849	50
Loss on fair value adjustment of warrant liability	(294)	(1,350)
Loss on debt extinguishment	(1,151)	(682)
(Loss) gain on fair value of strategic investments	(18)	1,031
Total other income (expense)	2,386	(951)
Net loss	$ (49,120)	$ (33,608)
Net loss per share		
Basic and diluted	$ (1.48)	$ (2.24)
Weighted-average shares used in computing net loss per share, basic and diluted	33,225,227	14,988,584
Comprehensive loss		
Net loss	$ (49,120)	$ (33,608)
Unrealized loss on marketable securities	(2)	(8)
Comprehensive loss	$ (49,122)	$ (33,616)

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