Orchestra BioMed Reports Third Quarter 2023 Financial Results and Provides Business Update

November 13, 2023

- *U.S. FDA granted Investigational Device Exemption ("IDE") approval to initiate the BACKBEAT pivotal study evaluating AVIM therapy (BackBeat CNT) in hypertensive pacemaker patients*
- *BACKBEAT pivotal study on track to start enrollment before the end of 2023, with a mid-2025 target for completion of enrollment*
- *Expected operating cash runway sufficient into 2H 2026, beyond anticipated BACKBEAT top-line results readout, based on internal forecast*
- *FDA also granted conditional IDE approval for pivotal study of Virtue® SAB in coronary in-stent restenosis ("ISR") patients; Virtue ISR-US study initiation targeted for 2024, pending Terumo partnership restructuring*

NEW HOPE, Pa., Nov. 13, 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 third quarter 2023 financial results and provided a business update.

"This past quarter marked two major regulatory milestones for Orchestra BioMed, with the FDA granting IDE approval for pivotal studies for both BackBeat CNT (AVIM therapy) and Virtue SAB. We are excited to initiate enrollment of the BACKBEAT pivotal study imminently, taking a critical step closer to enabling Medtronic, our strategic partner, to deliver this highly innovative blood pressure treatment to patients," stated David Hochman, Chairman, Chief Executive Officer and Founder of Orchestra BioMed. "We believe the design of the BACKBEAT pivotal study positions us to report topline data from this landmark study within the timeframe of our anticipated operating cash runway."

"We are actively engaged with our colleagues at Terumo with the goal of updating our Virtue SAB strategic agreement and aligning our plans to advance this differentiated technology through pivotal studies and to the market," Mr. Hochman continued. "As the only non-coated balloon angioplasty system that enables protected delivery of extended release sirolimus directly to target arterial lesions, Virtue SAB has the potential to redefine the class of drug-eluting balloons, which are emerging as a preferred solution for the treatment of coronary artery disease."

Lead Program

BackBeat CNT™ (atrioventricular interval modulation (AVIM) therapy): large global opportunity for treating hypertension in targeted populations

- **Dual-chamber pacemaker-indicated patients with uncontrolled hypertension despite the use of antihypertensive medications**
  - BACKBEAT pivotal study evaluating the efficacy and safety of AVIM therapy in hypertensive pacemaker patients on track to start by the end of 2023.
  - Study to enroll up to 500 patients across approximately 80 sites globally, with a target for completion of enrollment in mid-2025.
- **High-risk hypertension (non-pacing) and heart failure patients**
  - Orchestra BioMed continues to explore future opportunities to utilize AVIM therapy for high-risk, older patients with hypertension and co-morbidities that are not already indicated for a pacemaker, as well as to develop cardiac neuromodulation therapy specifically for the treatment of heart failure (CNT-HF).

Pipeline Program

Virtue® Sirolimus AngioInfusion™ Balloon (SAB): large global opportunity for treatment of coronary and peripheral artery disease with differentiated "leave nothing behind" solution

- **Virtue SAB – Coronary Indications**
  - U.S. Food and Drug Administration ("FDA") granted IDE approval with conditions to initiate Virtue ISR-US pivotal study evaluating Virtue SAB in adult patients with coronary ISR.
  - Initiation of Virtue ISR-US study targeted for 2024 pending ongoing negotiations with Terumo to restructure existing strategic partnership agreement.
  - Planned Japanese Pharmaceutical and Medical Devices Agency submissions are on track to support Japanese registrational studies of Virtue SAB in coronary ISR and coronary small vessel disease.

Financial Results for the Third Quarter Ended September 30, 2023

- **Cash and cash equivalents and Marketable securities** totaled $108.5 million as of September 30, 2023.
- **Operating cash runway** extended into the second half of 2026 based on internally prepared forecast reflecting updated operating priorities.
- **Net cash** used in operating activities and for the purchase of fixed assets was $10.3 million during the third quarter of 2023, compared with $7.5 million for the same period in 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 the third quarter of 2023 was $0.4 million, compared with $1.2 million for the same period in 2022. The decrease was primarily due to decreased recognition of partnership revenues earned under the agreement with Terumo.
- **Research and development expenses** for the third quarter of 2023 were $8.6 million, compared with $5.9 million for the same period in 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 the third quarter of 2023 were $6.3 million, compared with $5.3 million for the same period in 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 the third quarter of 2023 was $13.3 million, or $0.38 per share, compared with a net loss of $10.3 million, or $0.51 per share, for the same period in 2022. Net loss for the third quarter of 2023 included non-cash stock-based compensation expense of $3.5 million, compared with $2.2 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 flagship 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 and X (formerly 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.

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 IDE-approved global pivotal BACKBEAT (**B**radyc**A**rdia pa**C**ema**K**er with atrioventricular interval modulation for **B**lood pr**E**ssure tre**A**tmen**T**) 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 and timing of the Company's planned pivotal trials and reporting of top-line results, realizing the clinical and commercial value of BackBeat CNT and Virtue SAB, the expected runway of the Company's current cash and

cash equivalents, the potential 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 agreements 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; 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 under the heading "Item 1A. Risk Factors" in the Company's quarterly report on Form 10-Q filed with the U.S. Securities and Exchange Commission on November 13, 2023 as updated by any risk factors disclosed under the heading "Item 1A. Risk Factors" in the Company's subsequently filed quarterly reports on Form 10-Q.

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.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 19,078	$ 19,784
Marketable securities	89,410	63,915
Strategic investments, current portion	362	86
Accounts receivable, net	86	96
Inventory	137	276
Prepaid expenses and other current assets	1,116	533
Total current assets	110,189	84,690
Property and equipment, net	1,355	1,489
Right-of-use assets	1,714	2,187
Strategic investments, less current portion	2,495	2,495
Deposits and other assets	604	4,711
TOTAL ASSETS	$ 116,357	$ 95,572
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,150	$ 3,968
Accrued expenses and other liabilities	4,301	5,376
Operating lease liability, current portion	747	697
Warrant liability	—	2,089
Deferred revenue, current portion	3,676	6,436
Loan payable, current portion	9,599	—
Total current liabilities	21,473	18,566
Deferred revenue, less current portion	13,845	13,103
Loan payable, less current portion	—	9,490
Operating lease liability, less current portion	1,117	1,683
Other long-term liabilities	266	196
TOTAL LIABILITIES	36,701	43,038
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at September 30, 2023 and December 31, 2022.	—	—
Common stock, $0.0001 par value per share; 340,000,000 shares authorized; 35,743,972 and 20,187,850 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively.	4	2
Additional paid-in capital	315,765	252,274
Accumulated other comprehensive loss	(77)	(8)
Accumulated deficit	(236,036)	(199,734)

TOTAL STOCKHOLDERS' EQUITY	79,656	52,534
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 116,357	$ 95,572

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

	Three Months Ended September 30,	
	2023	**2022**
Revenue:		
Partnership revenue	$ 271	$ 986
Product revenue	148	177
Total revenue	419	1,163
Expenses:		
Cost of product revenues	41	56
Research and development	8,558	5,899
Selling, general and administrative	6,344	5,275
Total expenses	14,943	11,230
Loss from operations	(14,524)	(10,067)
Other income (expense):		
Interest income, net	915	63
Gain on fair value adjustment of warrant liability	—	36
Loss on debt extinguishment	—	—
Gain (loss) on fair value of strategic investments	293	(314)
Total other income (expense)	1,208	(215)
Net loss	$ (13,316)	$ (10,282)
Net loss per share		
Basic and diluted	$ (0.38)	$ (0.51)
Weighted-average shares used in computing net loss per share, basic and diluted	35,243,598	20,187,773
Comprehensive loss		
Net loss	$ (13,316)	$ (10,282)
Unrealized loss on marketable securities	19	—
Comprehensive loss	$ (13,297)	$ (10,282)

Investor Contact:
Bob Yedid
LifeSci Advisors
(516) 428-8577
Bob@lifesciadvisors.com

Media Contact:
Kelsey Kirk-Ellis
Orchestra BioMed
(484) 682-4892
Kkirkellis@orchestrabiomed.com