Orchestra BioMed Reports Full Year 2024 Financial Results and Provides a Fourth Quarter Business Update

March 31, 2025

NEW HOPE, Pa., March 31, 2025 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO, “Orchestra BioMed” or the “Company”), a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing partnerships, today reported its full year 2024 financial results and provided a fourth quarter business update.

"We remain highly focused on execution of the BACKBEAT global pivotal study, which we believe has the potential to deliver landmark results that can establish AVIM therapy as a new standard of care for the treatment of uncontrolled hypertension in patients already indicated for a pacemaker. We also believe it can lay the foundation for expanding use of AVIM-enabled devices to manage blood pressure and improve cardiovascular function for hypertensive patients with high cardiovascular risk,” commented David Hochman, Chairman, Chief Executive Officer and Founder of Orchestra BioMed. “As we age, our arteries naturally lose elasticity and become stiffer, a process that increases the risk of cardiovascular problems and is linked to changes in blood pressure and heart function. One of the characteristics of this process is the development of diastolic dysfunction, a condition where the heart's ventricles cannot relax and fill with blood properly during the diastolic phase of the cardiac cycle. Our late-breaking data in patients with diastolic dysfunction recently presented at THT showed AVIM therapy’s ability to significantly improve ventricular relaxation and passive filling, highlighting its potential to drive better clinical outcomes through blood pressure reduction, as well as improvement of cardiac function."

“In parallel, we are encouraged by the progress of our Virtue SAB program as we actively prepare to initiate a U.S. coronary pivotal study with an updated trial design, currently under FDA review. The study is expected to randomize patients with coronary in-stent restenosis to treatment with Virtue SAB or Boston Scientific’s AGENT drug-coated balloon. We believe this design will optimally highlight the potential advantages of Virtue SAB’s proprietary design advantages which enables protected delivery of extended focal-release sirolimus without the need for a balloon coating,” continued Mr. Hochman. “With regard to our strategic partnership, we and Terumo are moving our negotiations into a formal mediation process. We believe this is the most efficient way to drive our relationship to a resolution, ideally during the second quarter of this year, ahead of potential initiation of the updated Virtue ISR-US pivotal study in the second half of the year.”

Fourth Quarter 2024 and Recent Highlights

- Continued site activation and patient enrollment of the BACKBEAT global pivotal study, in collaboration with Medtronic (NYSE: MDT), evaluating the efficacy and safety of atrioventricular interval modulation (“AVIM”) therapy in hypertensive pacemaker patients.
- Submitted a revised design to the U.S. Food and Drug Administration (“FDA”) for the Virtue ISR-US pivotal study in coronary in-stent restenosis (“ISR”), which will randomize Virtue® Sirolimus AngioInfusion™ Balloon (“SAB”) against Boston Scientific’s AGENT drug-coated balloon; initiation is targeted for the second half of 2025, pending FDA approval of an amended investigational device exemption (“IDE”) which is expected to be secured in the second quarter of 2025.
- To accelerate potential completion of ongoing partnership restructuring negotiations, Orchestra BioMed and Terumo have elected to enter a mediation process and are currently working on a procedural plan that would aim to conclude the mediation process in the second quarter of 2025.
- Enhanced board of directors with the appointment of three highly experienced independent directors:
  - Christopher Cleary, former Senior Vice President of Corporate Development at Medtronic, where he played a key role in establishing the strategic collaboration between Orchestra BioMed and Medtronic for AVIM therapy
  - John Mack, former President of Cardiac Surgery at Medtronic with extensive operational and strategic experience in the medical device industry
  - David Pacitti, Chief Executive Officer of Avanos Medical, former President of Siemens Medical Solutions USA, Inc. and Head of the Americas, Siemens Healthineers, with nearly 30 years of experience in cardiovascular device and procedural imaging
- Strengthened senior leadership team with the appointment of Mark Pomeranz as Executive Vice President & General Manager, Interventional Therapies. Mr. Pomeranz has over two decades of experience in medical devices, with particular emphasis on cardiology and gastrointestinal verticals. He most recently served as Chief Executive Officer of Motus GI Holdings.

Financial Results for the Year Ended December 31, 2024

- **Cash and cash equivalents and Marketable securities** totaled $66.8 million as of December 31, 2024. During the year, our cash inflows included approximately $15.0 million in net cash proceeds from the sale of our Common Stock under a market sales agreement and approximately $15.0 million from the initial draw on our credit facility.
- **Net cash used in operating activities and for the purchase of fixed assets** was $50.8 million during 2024, compared with $46.2 million for 2023, with the primary driver of this increase being increased cash outflows for research and development during 2024.
- **Revenue** for 2024 was $2.6 million, compared with $2.8 million for 2023. The decrease was primarily due to decreased recognition of partnership revenues earned under the agreement with Terumo.
- **Research and development expenses** for 2024 were $42.8 million, compared with $33.8 million for 2023. The increase was primarily due to additional costs associated with the ongoing BACKBEAT global pivotal study.
- **Selling, general and administrative expenses** for 2024 were $23.9 million, compared with $20.3 million for 2023. The increase was primarily due to increased expenses related to stock-based stock compensation.
- **Net loss** for 2024 was $61.0 million, or ($1.66) per share, compared with a net loss of $49.1 million, or ($1.48) per share, for 2023. Net loss for the year-ended 2024 included non-cash stock-based compensation expense of $10.6 million, compared with $7.6 million for the same period in 2023.

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, the leading 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. 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

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 BACKBEAT (BradycArdia paCemaKer with atrioventricular interval modulation for Blood prEssure treAtmenT) global 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 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. 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, realizing the clinical and commercial value of BackBeat CNT and Virtue SAB, the Company's ability to conclude the mediation process with Terumo in the second quarter of 2025, and the potential safety and efficacy of the Company's product candidates. 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, 2024, which was filed with the Securities and Exchange Commission ("SEC") on March 31, 2025, and under the heading "Item1A. Risk Factors" in Part II of 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.

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

	December 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 22,261	$ 30,559
Marketable securities	44,551	56,968
Strategic investments, current portion	—	68
Accounts receivable, net	92	99
Inventory	173	146
Prepaid expenses and other current assets	2,094	1,274
Total current assets	69,171	89,114
Property and equipment, net	1,384	1,279
Right-of-use assets	2,103	1,555
Strategic investments, less current portion	2,495	2,495
Deposits and other assets	1,020	769
TOTAL ASSETS	$ 76,173	$ 95,212
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,134	$ 2,900
Accrued expenses and other liabilities	6,084	5,149
Operating lease liability, current portion	550	649
Deferred revenue, current portion	4,439	2,510
Total current liabilities	16,207	11,208
Deferred revenue, less current portion	10,989	14,923

Loan payable	14,292	—
Operating lease liability, less current portion	1,687	1,038
Other long-term liabilities	40	—
TOTAL LIABILITIES	43,215	27,169
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at December 31, 2024 and December 31, 2023.	—	—
Common stock, $0.0001 par value per share; 340,000,000 shares authorized; 38,194,442 and 35,777,412 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively.	4	4
Additional paid-in capital	342,780	316,903
Accumulated other comprehensive income (loss)	52	(10)
Accumulated deficit	(309,878)	(248,854)
TOTAL STOCKHOLDERS' EQUITY	32,958	68,043
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 76,173	$ 95,212

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

	Year Ended December 31,	
	2024	**2023**
Revenue:		
Partnership revenue	$ 2,005	$ 2,106
Product revenue	633	654
Total revenue	2,638	2,760
Expenses:		
Cost of product revenues	204	186
Research and development	42,804	33,822
Selling, general and administrative	23,931	20,258
Total expenses	66,939	54,266
Loss from operations	(64,301)	(51,506)
Other income (expense):		
Interest income, net	3,356	3,849
Loss on fair value adjustment of warrant liability	—	(294)
Loss on debt extinguishment	—	(1,151)
Loss on fair value of strategic investments	(68)	(18)
Other expense	(11)	—
Total other income	3,277	2,386
Net loss	$ (61,024)	$ (49,120)
Net loss per share		
Basic and diluted	$ (1.66)	$ (1.48)
Weighted-average shares used in computing net loss per share, basic and diluted	36,821,042	33,225,227
Comprehensive loss		
Net loss	$ (61,024)	$ (49,120)
Unrealized gain (loss) on marketable securities	62	(2)
Comprehensive loss	$ (60,962)	$ (49,122)