



Orchestra BioMed Reports First Quarter 2025 Financial Results and Highlights Recent Regulatory and Clinical Milestones

May 12, 2025

- *FDA Breakthrough Device Designation Awarded to AVIM Therapy*
- *FDA IDE Approved for Virtue SAB U.S. Pivotal Trial for Launch*

NEW HOPE, Pa., May 12, 2025 (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 announced financial results for the first quarter ended March 31, 2025, and provided a business update highlighting continued regulatory momentum, disciplined operational execution, and a strengthening clinical development pipeline.

Q1 2025 Highlights:

- **U.S. Food and Drug Administration ("FDA") Breakthrough Device Designation ("BDD")** granted for atrioventricular interval modulation ("AVIM") therapy in patients with uncontrolled hypertension and increased cardiovascular risk, with or without an indication for a pacemaker, marking a major regulatory validation of the therapy's potential to improve hypertensive heart disease outcomes. FDA BDD enables prioritized regulatory interactions and strengthens potential access to add-on reimbursement.
- **BACKBEAT Global Pivotal Study** execution continuing to progress in strategic collaboration with Medtronic (NYSE: MDT).
- **New Clinical Data** presented demonstrating the favorable impact of AVIM therapy on cardiac function in patients with diastolic dysfunction, a key contributor to the development of heart failure, as late breaker at THT 2025.
- **Intellectual Property Expansion** continues with AVIM therapy patent estate reaching 137 issued patents worldwide, with recent additions bolstering coverage for both hypertension and heart failure indications.
- **FDA Investigational Device Exemption ("IDE") Approval** received for the Virtue® Sirolimus AngioInfusion Balloon ("SAB") U.S. pivotal trial, a randomized head-to-head study comparing Virtue SAB with the commercially available AGENT™ DCB paclitaxel-coated balloon (the "Virtue Trial"). Trial initiation is currently targeted for the second half of 2025.
 - Orchestra BioMed is sponsoring and in full operational control of the Virtue Trial; mediation with Terumo of certain other contractual terms is progressing.

Key Chief Executive Officer ("CEO") Commentary:

David Hochman, Chairman and CEO of Orchestra BioMed, stated: "We continued to make meaningful progress during the first quarter with significant inflection points for both our AVIM therapy and Virtue SAB programs. We believe the FDA's Breakthrough Device Designation for AVIM therapy signals meaningful recognition of its potential to meet the clinical needs of millions living with hypertensive heart disease, a population in which chronic high blood pressure can lead to various heart problems like left ventricular hypertrophy, diastolic dysfunction, heart failure, and coronary artery disease. We believe that AVIM therapy has the potential to provide a potent additional therapeutic option for these patients. We are focused on execution of the BACKBEAT global pivotal study alongside our strategic partner Medtronic as the critical pathway toward making AVIM therapy available to patients globally."

Mr. Hochman continued, "In parallel, we secured full IDE approval to conduct the Virtue Trial, a U.S. pivotal coronary study that will evaluate Virtue SAB, our investigational, non-coated drug-eluting balloon designed to deliver a large liquid dose of proprietary extended-release sirolimus, head-to-head against the commercially available AGENT paclitaxel-coated balloon. We believe the updated design of the trial, which we currently plan to initiate in the second half of the year, offers the most direct path to regulatory approval while showcasing the distinctive pharmacokinetic and therapeutic advantages of our proprietary technology. Taken together, these milestones mark tangible progress on multiple fronts. We continue to execute methodically and remain focused on advancing our pivotal trials, generating clinical evidence, and building long-term value for patients, physicians, shareholders and strategic partners alike."

Financial Results for the First Quarter Ended March 31, 2025

- **Cash and cash equivalents and Marketable securities** totaled \$49.9 million as of March 31, 2025.
- **Net cash used in operating activities and for the purchase of fixed assets** was \$16.7 million during the first quarter of 2025, compared with \$13.1 million for the first quarter in 2024, with the primary driver being increased research and development costs during the first quarter of 2025.

- **Revenue** for the first quarter of 2025 was \$0.9 million, compared with \$0.6 million for the first quarter in 2024. The increase was primarily due to recognition of partnership revenues earned under the agreement with Terumo.
- **Research and development expenses** for the first quarter of 2025 were \$13.5 million, compared with \$9.1 million for the first quarter in 2024. The increase was primarily due to additional costs associated with the ongoing BACKBEAT global pivotal study.
- **Selling, general and administrative expenses** for the first quarter of 2025 were \$6.3 million, compared with \$5.9 million for the first quarter of 2024. The increase was primarily due to an increase in stock-based compensation and increased professional fees associated with the overall growth of the business.
- **Net loss** for the first quarter of 2025 was \$18.8 million, or \$0.49 per share, compared with a net loss of \$13.5 million, or \$0.38 per share, for the first quarter of 2024. Net loss for the first quarter of 2025 included \$3.0 million in non-cash stock-based compensation expense as compared to \$2.6 million for the same period in 2024.

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 AVIM therapy for the treatment of hypertension, the leading risk factor for death worldwide. Orchestra BioMed is also developing Virtue 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. The Company has received four Breakthrough Device Designations from the U.S. FDA across these two core programs, reflecting the significant potential of its technologies to address high unmet needs in cardiovascular care. 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 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. In addition to reducing blood pressure, clinical results using AVIM therapy demonstrate improvements in cardiac function and hemodynamics. 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 patients who have systolic blood pressure above target despite anti-hypertensive medication and who are indicated for or have recently received a dual-chamber cardiac pacemaker. AVIM therapy has been granted Breakthrough Device Designation by the FDA for the treatment of uncontrolled hypertension in patients who have increased cardiovascular risk.

About Virtue SAB

Virtue SAB is an investigational therapeutic combination drug-device designed to deliver a proprietary extended-release formulation of sirolimus, SirolimusEFR™ through a non-coated microporous AngioInfusion™ Balloon, protecting the drug in transit through the arteries and consistently delivering a large liquid dose, overcoming certain limitations of drug-coated balloons. SirolimusEFR delivered by Virtue SAB has been shown in published preclinical series involving hundreds of arterial deliveries to achieve sustained tissue levels well above the known required therapeutic tissue concentration for inhibiting restenosis (1 ng/mg tissue) for the entire critical healing period of approximately 30 days. 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 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 for Orchestra BioMed to evaluate the efficacy and safety of Virtue SAB in the Virtue Trial, a pivotal trial that will randomize Virtue SAB against commercially available AGENT™ DCB, a paclitaxel-coated balloon.

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, including the timing of initiation of the Virtue Trial, the potential benefits of BDD, including its ability to expedite FDA reviews and allow access to add-on reimbursement, realizing the clinical and commercial value of AVIM therapy and Virtue SAB, the potential safety and efficacy of the Company's product candidates, and the ability of the Company's partnerships to accelerate clinical development. 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 SEC on March 31, 2025 and the risk factor discussed under the heading "Item 1A. Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2025, which was filed with the SEC on May 12, 2025.

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

	March 31, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 18,348	\$ 22,261
Marketable securities	31,536	44,551
Accounts receivable, net	89	92
Inventory	135	173
Prepaid expenses and other current assets	1,795	2,094
Total current assets	51,903	69,171
Property and equipment, net	1,413	1,384
Right-of-use assets	1,956	2,103
Strategic investments, less current portion	2,495	2,495
Deposits and other assets	1,284	1,020
TOTAL ASSETS	\$ 59,051	\$ 76,173
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 5,563	\$ 5,134
Accrued expenses and other liabilities	5,392	6,084
Operating lease liability, current portion	590	550
Deferred revenue, current portion	3,944	4,439
Total current liabilities	15,489	16,207

Deferred revenue, less current portion	10,752	10,989
Loan payable	14,338	14,292
Operating lease liability, less current portion	1,516	1,687
Other long-term liabilities	99	40
TOTAL LIABILITIES	<u>42,194</u>	<u>43,215</u>
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at March 31, 2025 and December 31, 2024.	—	—
Common stock, \$0.0001 par value per share; 340,000,000 shares authorized; 38,312,512 and 38,194,442 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively.	4	4
Additional paid-in capital	345,449	342,780
Accumulated other comprehensive income	37	52
Accumulated deficit	(328,633)	(309,878)
TOTAL STOCKHOLDERS' EQUITY	<u>16,857</u>	<u>32,958</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 59,051</u>	<u>\$ 76,173</u>

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

	Three Months Ended March 31,	
	<u>2025</u>	<u>2024</u>
Revenue:		
Partnership revenue	\$ 732	\$ 497
Product revenue	136	123
Total revenue	<u>868</u>	<u>620</u>
Expenses:		
Cost of product revenues	44	34
Research and development	13,482	9,112
Selling, general and administrative	6,263	5,897
Total expenses	<u>19,789</u>	<u>15,043</u>
Loss from operations	(18,921)	(14,423)
Other income (expense):		
Interest income, net	166	1,016
Loss on fair value of strategic investments	—	(45)
Other expense	—	(11)
Total other income	<u>166</u>	<u>960</u>
Net loss	<u>\$ (18,755)</u>	<u>\$ (13,463)</u>
Net loss per share		
Basic and diluted	\$ (0.49)	\$ (0.38)
Weighted-average shares used in computing net loss per share, basic and diluted	38,235,409	35,777,877
Comprehensive loss		
Net loss	\$ (18,755)	\$ (13,463)
Unrealized (loss) gain on marketable securities	(15)	2
Comprehensive loss	<u>\$ (18,770)</u>	<u>\$ (13,461)</u>