Orchestra BioMed Reports Full Year 2025 Financial Results and Provides Fourth Quarter Business Update

March 12, 2026

- *$106.5 million cash position as of December 31, 2025 to be further enhanced by $35 million expected from Medtronic and Ligand in Q2 2026 from previously announced transactions, as well as Haemonetics' Vivasure acquisition proceeds*
- *$33.5 million in 2025 non-recurring revenue primarily driven by impact of new Virtue SAB agreement with Terumo that was announced in October 2025*
- *Strong balance sheet supports focused execution of pivotal trials for both AVIM Therapy and Virtue SAB programs*

NEW HOPE, Pa., March 12, 2026 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO) ("Orchestra BioMed" or the "Company"), a biomedical company accelerating high-impact technologies to patients through strategic partnerships with market-leading global medical device companies, today reported its full year 2025 financial results and provided a fourth quarter business update.

David Hochman, Chairman and Chief Executive Officer of Orchestra BioMed stated, "We are very proud of our significant clinical, strategic and financing accomplishments in 2025. We are now in an excellent financial and operational position to achieve upcoming value-driving milestones for both of our pivotal stage programs. In the second half of 2025, we leveraged our partnership-driven business model to substantially strengthen our financial position with nearly $150 million in new capital and capital commitments, including strategic transactions with Medtronic, Ligand and Terumo. With a strong balance sheet in place, we are fully focused on driving pivotal trial execution for both AVIM Therapy and Virtue SAB, high impact therapies designed to address major unmet needs in large, established global procedure markets."

Hochman continued, "As we enter 2026 with two pivotal trials underway, we remain focused on disciplined execution and long-term value creation for patients, clinicians and shareholders. We are encouraged by the accelerated pace of enrollment in the BACKBEAT global pivotal study following protocol amendments implemented in the fourth quarter and we plan to provide a substantive update in our next quarterly report. We are also pleased with the early progress of the Virtue Trial, which we initiated during the fourth quarter of 2025. We expect to provide additional updates on this trial, which is randomizing coronary in-stent restenosis patients to treatment with Virtue SAB versus the AGENT™ paclitaxel-coated balloon, as we gain further visibility into enrollment trends over the course of the year."

Q4 2025 and Recent Business Highlights:

- **Accelerated patient enrollment of the BACKBEAT global pivotal study**, in collaboration with Medtronic (NYSE: MDT), evaluating the efficacy and safety of Atrioventricular Interval Modulation Therapy ("AVIM Therapy") for the treatment of uncontrolled hypertension in patients indicated for a pacemaker.
- **Initiated patient enrollments in the Virtue SAB U.S. pivotal trial**, a randomized head-to-head IDE registrational clinical trial comparing Virtue SAB with the commercially available AGENT paclitaxel-coated balloon for the treatment of coronary in-stent restenosis (the "Virtue Trial").
- **Entered into an agreement with Terumo ("ROFR Agreement")** pursuant to which we and Terumo terminated our distribution agreement, and Orchestra BioMed granted Terumo a right of first refusal (the "ROFR") with respect to certain strategic transactions relating to Virtue® Sirolimus AngioInfusion™ Balloon ("Virtue SAB") for the treatment of coronary artery disease globally in exchange for a fee of $10.0 million. In connection with the ROFR Agreement, Terumo invested an additional $20.0 million in Orchestra BioMed through a new series of non-voting convertible preferred stock (the "Series A Preferred Stock"), which is convertible into common stock in the future, subject to certain conditions, at a minimum of $12 per share.
- **Up to $21 million in total proceeds** expected in connection with the acquisition of Vivasure Medical, previously a strategic holding of Orchestra BioMed, by Haemonetics. Orchestra BioMed expects to receive up to $10.7 million of these proceeds in 2026, including an initial upfront payment of $4.7 million received in January 2026 and the remainder expected later in the year as a first-milestone payment. The Company may receive additional proceeds in the future associated with potential revenue earnouts.

Financial Results for the Year Ended December 31, 2025

- **Revenue** for 2025 was $33.5 million, compared with $2.6 million for 2024, which represents an increase of 1,539%. The increase is primarily due to recognizing the remainder of the deferred revenue from our prior distribution agreement with Terumo of $15.4 million as a result of the termination of that agreement, $10.0 million in consideration for the ROFR, and $7.4 million associated with the premium paid above the fair market value of the Series A Preferred Stock.
- **Research and development expenses** for 2025 were $58.2 million, compared with $42.8 million for 2024, which represents an increase of 36%. The increase was primarily due to additional costs associated with the ongoing BACKBEAT global pivotal study and to advance the Virtue SAB program, including the Virtue Trial.
- **Selling, general and administrative expenses** for 2025 were $26.9 million, compared with $23.9 million for 2024, which represents an increase of 12%. The increase was primarily due to an increase in professional fees.
- **Net loss attributable to common stockholders** for 2025 was $52.7 million, or ($1.11) per share, compared with a net loss attributable to common stockholders of $61.0 million, or ($1.66) per share, for 2024 which represents a decrease of 14%. Net loss attributable to common stockholders for the year-ended 2025 included non-cash stock-based compensation expense of $12.0 million, compared with $10.6 million for the same period in 2024, representing an increase of 13%.
- **Net cash used in operating activities and for the purchase of fixed assets excluding the payment for the ROFR and the Series A Preferred Stock premium, which was recognized as revenue,** was $66.9 million during 2025, compared with $50.8 million for 2024, with the primary driver of this increase being increased cash outflows for research and development, including clinical trial activities, during 2025.
- **Cash and cash equivalents and Marketable securities** totaled $106.5 million as of December 31, 2025. The Company has commitments from Ligand and Medtronic to receive a combined $35.0 million in additional proceeds on or before May 1, 2026, based on the terms of agreements with those parties and subject to the conditions therein. Additionally, in January 2026, Haemonetics closed on the acquisition of Vivasure in which we expect to receive up to $10.7 million of proceeds in 2026, consisting of an upfront payment of approximately $4.7 million, which has already been received, and approximately $6.0 million expected to be received in a first milestone payment.

About Orchestra BioMed

Orchestra BioMed is a biomedical innovation company accelerating high-impact technologies to patients through strategic collaborations with market-leading global medical device companies. The Company's two flagship product candidates - Atrioventricular Interval Modulation (AVIM) Therapy and Virtue® Sirolimus AngioInfusion™ Balloon (Virtue SAB) - are currently undergoing pivotal clinical trials for their lead indications, each representing multi-billion-dollar annual global market opportunities. AVIM Therapy is a bioelectronic treatment for hypertension, the leading risk factor for death worldwide, and is designed to be delivered as a firmware upgrade to a pacemaker and achieve immediate, substantial and sustained reductions in blood pressure in patients with hypertensive heart disease. The Company has a strategic collaboration with Medtronic, one of the largest medical device companies in the world, for the development and commercialization of AVIM Therapy for the treatment of uncontrolled hypertension in pacemaker-indicated patients. AVIM Therapy has FDA Breakthrough Device Designation for these patients, as well as an estimated 7.7 million total patients in the U.S. with uncontrolled hypertension despite medical therapy and increased cardiovascular risk. Virtue SAB is a highly differentiated, first-of-its-kind non-coated drug delivery angioplasty balloon system designed to deliver a large liquid dose of proprietary extended-release formulation of sirolimus, SirolimusEFR™, for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide. Virtue SAB has been granted Breakthrough Device Designation by the FDA for the treatment of coronary ISR, coronary small vessel disease and below-the-knee peripheral artery disease. For further information about Orchestra BioMed, please visit www.orchestrabiomed.com, and follow us on LinkedIn.

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 proceeds expected to be received by the Company pursuant to the achievement of certain milestones *in connection with the acquisition of Vivasure by Haemonetics; and the timing of any update on anticipated enrollment completion and potential primary endpoint results with respect to the BACKBEAT global pivotal study as well as the provision of any update on the Virtue Trial. 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, 2025, which was filed with the SEC on March 12, 2026.*
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)
(unaudited)

	December 31, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 34,690	$ 22,261
Marketable securities	71,822	44,551
Accounts receivable, net	95	92
Inventory	310	173
Prepaid expenses and other current assets	994	2,094
Total current assets	107,911	69,171
Property and equipment, net	1,715	1,384
Right-of-use assets	1,496	2,103
Strategic investments	2,495	2,495
Deposits and other assets	1,240	1,020
TOTAL ASSETS	$ 114,857	$ 76,173
LIABILITIES, SERIES A PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 6,095	$ 5,134
Accrued expenses and other liabilities	9,890	6,084
Operating lease liability, current portion	751	550
Deferred revenue, current portion	—	4,439
Total current liabilities	16,736	16,207
Deferred revenue, less current portion	—	10,989
Royalty purchase agreement	16,482	—
Loan payable	14,268	14,292
Derivative liability	2,749	—
Operating lease liability, less current portion	936	1,687
Other long-term liabilities	308	40
TOTAL LIABILITIES	51,479	43,215
Series A Preferred Stock, $0.0001 par value per share; 200,000 issued and outstanding at December 31, 2025 and 0 issued and outstanding at December 31, 2024; aggregate liquidation preference of $20,000 at December 31, 2025	9,808	—
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized;	—	—
Common stock, $0.0001 par value per share; 340,000,000 shares authorized; 57,032,963 and 38,194,442 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively.	6	4
Additional paid-in capital	416,083	342,780
Accumulated other comprehensive income	60	52
Accumulated deficit	(362,579)	(309,878)
TOTAL STOCKHOLDERS' EQUITY	53,570	32,958

TOTAL LIABILITIES, SERIES A PREFERRED STOCK AND STOCKHOLDERS' EQUITY	$ 114,857	$ 76,173

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

	Year Ended December 31,	
	2025	**2024**
Revenue:		
Partnership revenue	$ 32,871	$ 2,005
Product revenue	611	633
Total revenue	33,482	2,638
Expenses:		
Cost of product revenues	190	204
Research and development	58,185	42,804
Selling, general and administrative	26,914	23,931
Total expenses	85,289	66,939
Loss from operations	(51,807)	(64,301)
Other (expense) income:		
Interest (expense) income, net	(1,148)	3,356
Change in the fair value of derivative liability	254	—
Loss on fair value of strategic investments	—	(68)
Other expense	—	(11)
Total other (expense) income	(894)	3,277
Net loss	(52,701)	(61,024)
Adjustment to carrying value of Series A Preferred Stock	(254)	—
Net loss attributable to common stockholders	$ (52,955)	$ (61,024)
Net loss attributable to common stockholders per share		
Basic and diluted	$ (1.11)	$ (1.66)
Weighted-average shares used in computing net loss attributable to common stockholders per share, basic and diluted	47,747,078	36,821,042
Comprehensive loss		
Net loss	$ (52,701)	$ (61,024)
Unrealized gain on marketable securities	8	62
Comprehensive loss	$ (52,693)	$ (60,962)