Orchestra BioMed Reports Third Quarter 2026 Financial Results and Highlights Recent Business Updates

November 10, 2026

- *BACKBEAT Global Pivotal Trial evaluating AVIM Therapy completed enrollment and exceeded enrollment target, with a total of 349 patients randomized.*
- *BACKBEAT Trial primary endpoint data planned to be submitted for late-breaking presentation at the Heart Rhythm Society 2027 ("HRS 2027").*
- *Medtronic planning to submit AVIM Therapy Premarket Approval ("PMA") supplement to the FDA following data presentation, assuming positive trial results.*
- *Site activation and patient enrollment accelerating in the Virtue Trial, the Company's U.S. Investigational Device Exemption ("IDE") pivotal trial comparing Virtue SAB head-to-head with the commercially available AGENT™ paclitaxel-coated balloon for coronary In-Stent Restenosis.*
- *Raised approximately $80.5 million in net proceeds through an underwritten public offering of common stock, which closed on November 9, 2026, including proceeds from the underwriters' full exercise of their option to purchase additional shares.*
- *$101.9 million of cash and cash equivalents, and marketable securities as of September 30, 2026 and public offering proceeds provide projected cash runway through 2028.*
- *Company hosting R&D Day on Thursday, November 12, 2026, in New York City and via live webcast, featuring in-depth reviews of AVIM Therapy and Virtue SAB with leading physician investigators.*

NEW HOPE, Pa., Nov. 10, 2026 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO, "Orchestra BioMed" or the "Company"), a biomedical innovation company accelerating high-impact technologies to patients through strategic collaborations with market-leading global medical device companies, today announced financial results for the third quarter ended September 30, 2026, and provided a business update on its two pivotal-stage investigational cardiovascular programs: Atrioventricular Interval Modulation Therapy ("AVIM Therapy") for the treatment of uncontrolled hypertension, for which the Company has a strategic collaboration with Medtronic (NYSE: MDT) for the treatment of pacemaker-indicated patients, and Virtue® Sirolimus AngioInfusion™ Balloon ("Virtue SAB") for the treatment of coronary artery disease.

David Hochman, Chairman and Chief Executive Officer of Orchestra BioMed, stated, "With the completion of enrollment of the BACKBEAT Trial, AVIM Therapy is nearing pivotal primary endpoint results. Alongside our collaborators at Medtronic, we now move to the completion of three-month follow-up in all patients, locking the primary endpoint database, and submitting a robustly powered data set for late-breaking presentation at HRS 2027 in May. We believe the results from the BACKBEAT Trial could set AVIM Therapy on a clear course to redefining the clinical impact of cardiac pacing and provide a powerful new therapeutic option for millions of higher-risk hypertensive patients who remain above blood pressure target despite medication."

Hochman continued, "The third quarter also saw Virtue Sirolimus AngioInfusion™ Balloon advance in its own IDE pivotal, randomized trial. The Virtue® Trial is testing Virtue SAB's fundamentally different approach to arterial drug delivery, liquid infusion of SirolimusEFR™ directly into the vessel wall without the need for a fragile balloon coating. We are also grateful to our new and existing shareholders that participated in the oversubscribed public equity offering we closed yesterday. The net proceeds from our public offering along with the over $100 million we had at the end of the quarter provide funding through 2028. We are in a strong position to deliver key value-creating milestones for both pivotal stage programs and support Medtronic as they drive toward potential global commercialization of AVIM Therapy. We look forward to showcasing both of our high-impact therapeutic device platforms at our investor R&D Day this Thursday, where leading physician investigators will join us to examine the clinical and commercial potential of AVIM Therapy and Virtue SAB."

Q3 2026 and Recent Business Highlights:

- **Completed enrollment in the BACKBEAT Trial in collaboration with Medtronic.** A total of 349 patients with uncontrolled hypertension and an implanted dual-chamber pacemaker were randomized across 92 sites in 15 countries. Orchestra BioMed and Medtronic intend to submit primary endpoint results for late-breaking presentation consideration at HRS 2027.
- **Received written confirmation from FDA that Medtronic's marketing submission for AVIM Therapy will be a PMA**

supplement. The submission is planned to be made promptly following presentation of the primary endpoint results of the BACKBEAT Trial, assuming positive trial results.

- **Advanced site activation and patient enrollment in the Virtue Trial**, the Company's U.S. IDE pivotal trial comparing Virtue SAB head-to-head with the commercially available AGENT™ paclitaxel-coated balloon for coronary in-stent restenosis ("ISR"). The prospective, multicenter, randomized, single-blind, non-inferiority trial has a planned enrollment of approximately 740 patients, with an enrollment completion target date by the end of 2027.

- **Virtue SAB mechanistic and clinical evidence presented at Transcatheter Cardiovascular Therapeutics 2026.** On November 1, 2026, Allen Jeremias, MD, Co-Principal Investigator of the Virtue Trial, presented Virtue SAB's differentiated mechanism of action for infusing a large liquid volume of submicron, particle-encapsulated SirolimusEFR™ directly into the vessel wall. Dr. Jeremias also outlined existing preclinical and clinical evidence and the pivotal IDE trial design.

- **AVIM Therapy was featured in two sessions at HRX Live 2026 in Atlanta**, including a sponsored roundtable on the Medtronic–Orchestra BioMed strategic collaboration and a panel exploring the expanding role of permanent cardiac pacing beyond bradycardia. The discussions highlighted AVIM Therapy's mechanism of action, clinical evidence and potential in hypertensive heart disease. A recording of the roundtable is available on the Company's website.

- **Received a $6.1 million milestone payment** on September 14, 2026, in connection with Haemonetics Corporation's (NYSE: HAE) acquisition of Vivasure Medical Limited ("Vivasure"). Together with approximately $5 million received in January 2026, total cash proceeds received from the transaction are approximately $11 million. The FDA recently approved the PerQseal® Elite vascular closure system, originally developed by Vivasure, for large-bore arterial procedures.

Public Offering

On November 9, 2026, the Company closed an underwritten public offering of 17,250,000 shares of its common stock at a price to the public of $5.00 per share, resulting in net proceeds to the Company of approximately $80.5 million (including proceeds from the underwriters' full exercise of their option to purchase additional shares), after deducting underwriting discounts and commissions and estimated offering expenses (the "Public Offering").

R&D Day: Thursday, November 12, 2026

The Company will host its R&D Day on Thursday, November 12, 2026, at 3:00 p.m. ET in New York City and via live webcast. Company leadership, leading cardiologists and trial investigators will discuss the clinical and treatment burden associated with uncontrolled hypertension in pacemaker-indicated patients and restenosis in coronary stent interventions, the potential for AVIM Therapy and Virtue SAB to address these unmet needs, key upcoming clinical milestones and the commercial potential of AVIM Therapy and Virtue SAB. Physician speakers include Vivek Reddy, MD, Marat Fudim, MD, Dean Kereiakes, MD, and Allen Jeremias, MD. Webcast of the R&D Day is available for registered participants and a replay of the event will be available through the Investors section of the Company's website.

Financial Results for the Third Quarter Ended September 30, 2026

- **Cash and cash equivalents and Marketable securities** totaled $101.9 million as of September 30, 2026, not including the $80.5 million in net proceeds from the Public Offering.

- **Net cash used in operating activities and for the purchase of fixed assets** was $19.9 million during the third quarter of 2026, compared with $14.9 million for the third quarter in 2025, with the primary drivers being increased research and development costs, including clinical trial activities, as well as personnel and consulting expenditures during the third quarter of 2026.

- **Research and development expenses** for the third quarter of 2026 were $17.7 million, compared with $14.0 million for the third quarter in 2025, which represents an increase of 26%. The increase was primarily due to additional costs associated with the ongoing BACKBEAT Trial and to advance the Virtue SAB program, including the Virtue Trial.

- **Selling, general and administrative expenses** for the third quarter of 2026 were $5.6 million, compared with $7.1 million for the third quarter of 2025, which represents a decrease of 21%. The decrease was primarily due to a decrease in legal and professional fees.

- **Net loss attributable to common stockholders** for the third quarter of 2026 was $19.6 million, or ($0.30) per share, compared with a net loss attributable to common stockholders of $20.8 million, or ($0.40) per share, for the third quarter of 2025, which represents a decrease of 6%. Net loss attributable to common stockholders for the third quarter of 2026 included $3.4 million in net interest expense for the third quarter of 2026 as compared to $1.2 million for the same period in 2025, of which a portion was non-cash in each period. Non-cash stock-based compensation expense was $2.3 million as compared to $3.0 million for the same period in 2025.

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 by 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 (NYSE: MDT), one of the largest medical device companies in the world and the global leader in cardiac pacing therapies, for the development and commercialization of AVIM Therapy for the treatment of uncontrolled hypertension in pacemaker-indicated patients. AVIM Therapy has two FDA Breakthrough Device Designations. The BACKBEAT Trial has completed enrollment.

Virtue SAB is a first-of-its-kind, non-coated drug delivery AngioInfusion balloon system designed to infuse a large liquid dose of a proprietary extended-release formulation of sirolimus, SirolimusEFR™, for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide. Virtue SAB exceeded the published tissue concentrations of leading limus drug-eluting stents and demonstrated positive three-year clinical data in coronary ISR in the SABRE study, a multicenter, prospective, independent core laboratory–adjudicated pilot clinical study of 50 patients conducted in Europe. Virtue SAB has been granted Breakthrough Device Designation by the FDA for the treatment of coronary in-stent restenosis, coronary small vessel disease, and below-the-knee peripheral artery disease, in each case, within specified parameters. The Virtue Trial evaluating Virtue SAB for the treatment of coronary in-stent restenosis is currently enrolling patients.

CAUTION: Investigational devices. Limited by United States law to investigational use.

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 enrollment, timing, implementation, results and design of the Company's ongoing pivotal trials, the timing of the presentation of clinical data, the timing of regulatory submissions, realizing the clinical and commercial value of AVIM Therapy and Virtue SAB, the potential safety and efficacy of the Company's product candidates, the size of the potential markets for the Company's product candidates, the ability of the Company's partnerships to accelerate clinical development and the Company's projected cash runway. 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.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 27,761	$ 34,690
Marketable securities	74,146	71,822
Accounts receivable, net	56	95
Inventory	221	310
Prepaid expenses and other current assets	987	994
Total current assets	103,171	107,911
Property and equipment, net	2,284	1,715
Right-of-use assets	1,001	1,496
Strategic investments	—	2,495
Deposits and other assets	1,280	1,240
TOTAL ASSETS	$ 107,736	$ 114,857
LIABILITIES, SERIES A PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,030	$ 6,095
Accrued expenses and other liabilities	8,367	9,890
Operating lease liability, current portion	831	751
Total current liabilities	14,228	16,736
Royalty purchase agreement	36,795	16,482
Note payable	21,152	—
Loan payable	14,462	14,268
Derivative liability	1,593	2,749
Operating lease liability, less current portion	304	936
Other long-term liabilities	456	308
TOTAL LIABILITIES	88,990	51,479
Series A Preferred Stock, $0.0001 par value per share; 200,000 issued and outstanding at September 30, 2026 and December 31, 2025; aggregate liquidation preference of $20,000	10,964	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; 61,453,041 and 57,032,963 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively.	6	6
Additional paid-in capital	433,704	416,083
Accumulated other comprehensive (loss) income	(153)	60
Accumulated deficit	(425,775)	(362,579)
TOTAL STOCKHOLDERS' EQUITY	7,782	53,570
TOTAL LIABILITIES, SERIES A PREFERRED STOCK AND STOCKHOLDERS' EQUITY	$ 107,736	$ 114,857

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,	
	2026	2025
Revenue:		
Partnership revenue	$ —	$ 721

Product revenue	91	140
Total revenue	91	861
Expenses:		
Cost of product revenues	28	49
Research and development	17,734	14,027
Selling, general and administrative	5,625	7,098
Total expenses	23,387	21,174
Loss from operations	(23,296)	(20,313)
Other income (expense):		
Interest expense, net	(2,463)	(515)
Change in the fair value of derivative liability	867	—
Gain on sale of strategic investments	6,142	—
Total other income (expense)	4,546	(515)
Net loss	(18,750)	(20,828)
Adjustment to carrying value of Series A Preferred Stock	(867)	—
Net loss attributable to common stockholders	$ (19,617)	$ (20,828)
Net loss attributable to common stockholders per share		
Basic and diluted	$ (0.30)	$ (0.40)
Weighted-average shares used in computing net loss attributable to common stockholders per share, basic and diluted	64,620,127	52,186,503
Comprehensive loss		
Net loss	$ (18,750)	$ (20,828)
Unrealized (loss) gain on marketable securities	(72)	29
Comprehensive loss	$ (18,822)	$ (20,799)