



Orchestra BioMed Reports Third Quarter 2025 Financial Results and Highlights Recent Business Updates

November 10, 2025

- Secured \$147.6 million in proceeds and committed capital following completion of strategic transactions and concurrent public and private equity offerings, led by \$71.6 million in committed capital from Medtronic and Ligand, as well as \$30 million from Terumo
- Initiated patient enrollments in the Virtue Trial evaluating Virtue[®] Sirolimus AngioInfusion[™] Balloon ("Virtue SAB") trial versus commercially available paclitaxel-coated balloon
- Demonstrated partnership-driven business model execution with expanded strategic collaboration with Medtronic and new right of first refusal agreement with Terumo

NEW HOPE, Pa., Nov. 10, 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 third quarter ended September 30, 2025, and provided a business update highlighting recent financial and regulatory milestones.

Q3 2025 and Recent Business Highlights:

- **Completed multiple strategic transactions and concurrent public and private equity offerings totaling \$147.6 million in gross proceeds** to support continued advancement of the Company's pivotal trial-stage Atrioventricular Interval Modulation Therapy ("AVIM Therapy") and Virtue SAB clinical programs. Gross proceeds are comprised of:
 - \$55 million received or to be received by May 1, 2026, subject to certain conditions, in strategic investments from Ligand Pharmaceuticals Incorporated (Nasdaq: LGND, "Ligand") and Medtronic, plc (NYSE: MDT, "Medtronic")
 - \$62.6 million received from a \$46 million oversubscribed, underwritten public offering of common stock and prefunded warrants and \$11.6 million and \$5 million received from private placements of common stock to Medtronic and Ligand, respectively
 - \$30 million received from Terumo Corporation, including a \$10 million payment in exchange for granting Terumo a right of first refusal ("ROFR") and a \$20 million purchase of non-voting preferred stock, convertible into common stock at a minimum of \$12 per share (the "Preferred Stock")
- **Extended cash runway into Q4 2027**, supporting potentially significant value-creating catalysts, including:
 - BACKBEAT study enrollment completion in mid-2026
 - Follow up for the BACKBEAT study primary endpoint data
 - Completion of enrollment of the Virtue Trial (as defined below) in mid-2027
- **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[™] DCB paclitaxel-coated balloon for the treatment of coronary in-stent restenosis (the "Virtue Trial"). Target completion of enrollment is expected in mid-2027.
- **Entered into new strategic rights agreement with Terumo**, superseding prior agreement which is now terminated, and providing Terumo with a ROFR with respect to certain strategic transactions relating to Virtue SAB for the treatment of coronary artery disease.
 - Orchestra BioMed retains all development and distribution rights for Virtue SAB across all indications and has strategic optionality to explore potential transactions
 - Orchestra BioMed is sponsoring and in full operational control of the Virtue Trial
 - Orchestra BioMed received \$30 million for granting the ROFR and selling Terumo the Preferred Stock in additional payments on top of the prior \$30 million payment and \$5 million equity investment
- **Expanded strategic collaboration with Medtronic**, providing pathway for future development of AVIM Therapy-enabled leadless pacemakers.
- **Implemented FDA-approved BACKBEAT global pivotal study protocol enhancements**, broadening patient enrollment

criteria for a more than 24-fold increase in the potentially eligible patient pool.

Chairman and Chief Executive Officer Commentary from David Hochman:

Mr. Hochman stated: "The last several months have been a period of exceptional execution, during which we secured nearly \$150 million in capital and committed capital, positioning Orchestra BioMed to advance both of our pivotal-stage, high-impact programs with full momentum. Enrollment is actively underway in our pivotal, registrational trials for both AVIM Therapy and Virtue SAB. We are proud to have achieved a favorable realignment with Terumo, expanded our collaboration with Medtronic, and secured significant additional funding on terms we believe are highly attractive for shareholders, including a new strategic financial partnership with Ligand. As a result, we are well-financed through key clinical and regulatory milestones. We believe 2026 will be a landmark year for Orchestra, with the target completion of enrollment in the BACKBEAT study and active execution of the Virtue Trial toward completion of enrollment in the Virtue Trial in 2027."

Financial Results for the Third Quarter Ended September 30, 2025

- **Cash and cash equivalents and Marketable securities** totaled \$95.8 million as of September 30, 2025. On November 7, 2025, we received \$30.0 million pursuant to new strategic rights and Terumo stock purchase agreements. 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.
- **Net cash used in operating activities and for the purchase of fixed assets** was \$14.9 million during the third quarter of 2025, compared with \$13.8 million for the third quarter in 2024, with the primary driver being increased research and development costs during the third quarter of 2025.
- **Revenue** for the third quarter of 2025 was \$0.9 million, compared with \$1.0 million for the third quarter in 2024.
- **Research and development expenses** for the third quarter of 2025 were \$14.0 million, compared with \$11.6 million for the third 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 third quarter of 2025 were \$7.1 million, compared with \$5.7 million for the third quarter of 2024. The increase was primarily due to an increase in professional fees.
- **Net loss** for the third quarter of 2025 was \$20.8 million, or \$0.40 per share, compared with a net loss of \$15.4 million, or \$0.41 per share, for the third quarter of 2024. Net loss for the third quarter of 2025 included \$3.0 million in non-cash stock-based compensation expense as compared to \$2.4 million for the same period in 2024.

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 (NYSE: MDT), 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 drug delivery angioplasty balloon system designed to deliver a 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](#).

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 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 a highly differentiated, first-of-its-kind drug delivery angioplasty balloon system designed to deliver a proprietary extended-release formulation of sirolimus, SirolimusEFR™. It uses a non-coated microporous AngioInfusion™ Balloon to protect the drug in transit and consistently deliver 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 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 the treatment of coronary ISR, coronary small vessel disease and peripheral artery disease below-the-knee.

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 ongoing pivotal trials, including the timing of completion of enrollment in the BACKBEAT study and the Virtue Trial, the receipt of committed capital, the Company’s expected cash runway, 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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Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	<u>September 30,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
ASSETS		
CURRENT ASSETS:		

Cash and cash equivalents	\$	42,012	\$	22,261
Marketable securities		53,808		44,551
Accounts receivable, net		52		92
Inventory		365		173
Prepaid expenses and other current assets		1,531		2,094
Total current assets		<u>97,768</u>		<u>69,171</u>
Property and equipment, net		1,595		1,384
Right-of-use assets		1,653		2,103
Strategic investments, less current portion		2,495		2,495
Deposits and other assets		1,296		1,020
TOTAL ASSETS	\$	<u>104,807</u>	\$	<u>76,173</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES:

Accounts payable	\$	8,473	\$	5,134
Accrued expenses and other liabilities		6,837		6,084
Operating lease liability, current portion		696		550
Deferred revenue, current portion		4,649		4,439
Total current liabilities		<u>20,655</u>		<u>16,207</u>
Deferred revenue, less current portion		8,659		10,989
Royalty purchase agreement		16,167		-
Loan payable		14,204		14,292
Operating lease liability, less current portion		1,135		1,687
Other long-term liabilities		248		40
TOTAL LIABILITIES		<u>61,068</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 September 30, 2025 and December 31, 2024.		-		-
Common stock, \$0.0001 par value per share; 340,000,000 shares authorized; 56,464,731 and 38,194,442 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively.		6		4
Additional paid-in capital		412,512		342,780
Accumulated other comprehensive income		45		52
Accumulated deficit		(368,824)		(309,878)
TOTAL STOCKHOLDERS' EQUITY		<u>43,739</u>		<u>32,958</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	<u>104,807</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 September 30,	
	2025	2024
Revenue:		
Partnership revenue	\$ 721	\$ 803
Product revenue	140	184
Total revenue	<u>861</u>	<u>987</u>
Expenses:		
Cost of product revenues	49	68
Research and development	14,027	11,595
Selling, general and administrative	7,098	5,666
Total expenses	<u>21,174</u>	<u>17,329</u>
Loss from operations	<u>(20,313)</u>	<u>(16,342)</u>

Other (expense) income:

Interest (expense) income, net	<u>(515)</u>	<u>916</u>
Total other (expense) income	(515)	916
Net loss	<u>\$ (20,828)</u>	<u>\$ (15,426)</u>
Net loss per share		
Basic and diluted	\$ (0.40)	\$ (0.41)
Weighted-average shares used in computing net loss per share, basic and diluted	52,186,503	37,621,495
Comprehensive loss		
Net loss	\$ (20,828)	\$ (15,426)
Unrealized gain on marketable securities	29	121
Comprehensive loss	<u><u>\$ (20,799)</u></u>	<u><u>\$ (15,305)</u></u>