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

August 10, 2026

- *The BACKBEAT global pivotal trial ("BACKBEAT Trial"), conducted in collaboration with Medtronic, is on track to reach its target of 284 evaluable randomized patients by end of Q3 2026, with primary data presentation targeted for Q2 2027, assuming those endpoints are met.*
- *Virtue pivotal trial is advancing with further site activations and patient enrollments.*
- *$110 million cash balance provides projected runway into Q4 2027 and through key upcoming milestones, following $35 million in strategic capital from Medtronic and Ligand.*
- *Company to host R&D Day on November 12, 2026, in New York City, featuring in-depth reviews of both the AVIM Therapy and Virtue SAB programs.*

NEW HOPE, Pa., Aug. 10, 2026 (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 second quarter ended June 30, 2026, and provided a business update on its two pivotal-stage cardiovascular programs: Atrioventricular Interval Modulation Therapy ("AVIM Therapy") for the treatment of uncontrolled hypertension in pacemaker-indicated patients, being developed in strategic collaboration with Medtronic (NYSE: MDT), and Virtue® Sirolimus AngioInfusion™ Balloon ("Virtue SAB") for the treatment of coronary in-stent restenosis.

David Hochman, Chairman and Chief Executive Officer of Orchestra BioMed, stated, "The second quarter brought clarity on both the timeline and the scope of the AVIM Therapy opportunity that we are pursuing with Medtronic. We remain on track to reach or exceed our target of 284 evaluable randomized patients in the BACKBEAT Trial by the end of the third quarter of 2026 and maintain our objective to present primary endpoint data as a major conference late-breaker in the second quarter of 2027. The second FDA Breakthrough Device Designation for AVIM Therapy earned during the second quarter strengthens potential regulatory and reimbursement upside for this high-impact program."

Hochman continued, "Our conviction that Virtue SAB offers distinctive potential clinical advantages because of its differentiated approach to arterial drug delivery continues to grow as we advance site activations and patient enrollment for the Virtue pivotal trial. With a $110 million cash balance at quarter-end following $35 million received from Medtronic and Ligand during the quarter, both pivotal programs are funded through their next major milestones. We are excited to review each in detail at our R&D Day in November."

Q2 2026 and Recent Business Highlights:

- **BACKBEAT Trial is on track to reach target of 284 evaluable randomized patients by end of Q3 2026.** Assuming primary endpoints are met, Orchestra BioMed and Medtronic intend to submit primary endpoint data as a late-breaking clinical trial presentation at a major cardiovascular conference in the second quarter of 2027, followed by marketing application submissions to the FDA and global regulatory agencies.
- **Received $35 million in strategic capital under previously disclosed agreements with Medtronic and Ligand (Nasdaq: LGND).** Including this most recent investment, Medtronic's total capital contribution to Orchestra BioMed is nearly $82 million. Ligand has now provided $40 million in total capital to the Company.
- **FDA granted AVIM Therapy a second FDA Breakthrough Device Designation ("BDD")** specific to patients with uncontrolled hypertension despite anti-hypertensive medication who are indicated for a pacemaker. Together, AVIM Therapy's two BDDs now cover both the broad group of patients with uncontrolled hypertension and elevated cardiovascular risk and the pacemaker-indicated group studied in the BACKBEAT Trial.
- **Advanced site activation and patient enrollment in the Virtue SAB in the Treatment of Coronary In-Stent Restenosis ("ISR") Trial ("Virtue Trial"),** a multi-center, prospective, 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.
- **Added to the Russell 3000® and Russell 2000® Indexes.** Effective after the U.S. market close on June 26, 2026, Orchestra BioMed joined the broad-market Russell 3000® Index and the small-cap Russell 2000® Index at the conclusion of the 2026 Russell indexes reconstitution, broadening the Company's visibility among institutional investors and index funds benchmarked to the Russell indexes.

R&D Day: November 12, 2026

The Company will host an R&D Day on November 12, 2026 in New York City. The event will feature presentations from management and leading physician investigators covering the AVIM Therapy and Virtue SAB programs, including recent program and pipeline developments. Additional details, including registration and webcast information, will be announced in the future.

Financial Results for the Second Quarter Ended June 30, 2026

- **Cash and cash equivalents and Marketable securities** totaled $110.0 million as of June 30, 2026.
- **Net cash used in operating activities and for the purchase of fixed assets** was $19.6 million during the second quarter of 2026, compared with $15.6 million for the second 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 second quarter of 2026.
- **Research and development expenses** for the second quarter of 2026 were $16.6 million, compared with $13.9 million for the second quarter in 2025, which represents an increase of 20%. 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 second quarter of 2026 were $5.8 million, compared with $6.3 million for the second quarter of 2025, which represents a decrease of 7%. The decrease was primarily due to a decrease in stock-based compensation expense.
- **Net loss attributable to common stockholders** for the second quarter of 2026 was $24.1 million, or ($0.38) per share, compared with a net loss attributable to common stockholders of $19.4 million, or ($0.50) per share, for the second quarter of 2025, which represents an increase of 23%. Net loss attributable to common stockholders for the second quarter of 2026 included $2.7 million in interest expense for the second quarter of 2026 as compared to $0.5 million for the same period in 2025, of which a portion was non-cash in the current period. Non-cash stock-based compensation expense was $2.5 million as compared to $3.2 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 a 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 FDA Breakthrough Device Designations 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 in-stent restenosis, 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.

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 trial is evaluating 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 two Breakthrough Device Designations by the FDA for the treatment of uncontrolled hypertension in patients who have increased cardiovascular risk.

About Virtue SAB

Virtue SAB is designed to deliver a proprietary extended-release formulation of sirolimus, SirolimusEFR™ through a non-coated microporous AngioInfusion™ Balloon that protects the drug in transit to 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 pilot clinical study of 50 patients 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.

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 potential benefits of Breakthrough Device Designation, 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.

Investor Contact:
Silas Newcomb
Orchestra BioMed
snewcomb@orchestrabiomed.com

Media Contact:
Nina Premutico
Orchestra BioMed
npremutico@orchestrabiomed.com

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

	June 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 20,472	$ 34,690
Marketable securities	89,491	71,822
Accounts receivable, net	51	95
Inventory	250	310
Prepaid expenses and other current assets	977	994
Total current assets	111,241	107,911
Property and equipment, net	2,045	1,715
Right-of-use assets	1,171	1,496
Strategic investments	—	2,495
Deposits and other assets	1,243	1,240
TOTAL ASSETS	$ 115,700	$ 114,857
LIABILITIES, SERIES A PREFERRED STOCK AND STOCKHOLDERS' EQUITY		

CURRENT LIABILITIES:		
Accounts payable	$ 6,132	$ 6,095
Accrued expenses and other liabilities	6,531	9,890
Operating lease liability, current portion	808	751
Total current liabilities	13,471	16,736
Royalty purchase agreement	34,593	16,482
Note payable	20,442	—
Loan payable	14,397	14,268
Derivative liability	2,460	2,749
Operating lease liability, less current portion	520	936
Other long-term liabilities	397	308
TOTAL LIABILITIES	86,280	51,479
Series A Preferred Stock, $0.0001 par value per share; 200,000 issued and outstanding at June 30, 2026 and December 31, 2025; aggregate liquidation preference of $20,000	10,097	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; 60,105,049 and 57,032,963 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively.	6	6
Additional paid-in capital	426,423	416,083
Accumulated other comprehensive (loss) income	(81)	60
Accumulated deficit	(407,025)	(362,579)
TOTAL STOCKHOLDERS' EQUITY	19,323	53,570
TOTAL LIABILITIES, SERIES A PREFERRED STOCK AND STOCKHOLDERS' EQUITY	$ 115,700	$ 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 June 30,	
	2026	**2025**
Revenue:		
Partnership revenue	$ —	667
Product revenue	88	169
Total revenue	88	836
Expenses:		
Cost of product revenues	25	46
Research and development	16,590	13,853
Selling, general and administrative	5,829	6,264
Total expenses	22,444	20,163
Loss from operations	(22,356)	(19,327)
Other (expense) income:		
Interest (expense) income, net	(1,768)	(36)
Change in the fair value of derivative liability	324	—
Gain on sale of strategic investments	45	—
Total other (expense) income	(1,399)	(36)
Net loss	(23,755)	(19,363)
Adjustment to carrying value of Series A Preferred Stock	(324)	—
Net loss attributable to common stockholders	$ (24,079)	(19,363)
Net loss attributable to common stockholders per share		

Basic and diluted	$	(0.38)	(0.50)
Weighted-average shares used in computing net loss attributable to common stockholders per share, basic and diluted		63,812,098	38,392,716
Comprehensive loss			
Net loss	$	(23,755)	(19,363)
Unrealized loss on marketable securities		(41)	(21)
Comprehensive loss	$	(23,796)	(19,384)