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

May 12, 2026

- *Orchestra BioMed targeting enrollment completion of BACKBEAT Global Pivotal Trial ("BACKBEAT Trial") by the end of Q3 2026*
- *Medtronic (NYSE: MDT) and Orchestra BioMed intend to pursue late-breaking clinical trial presentation at major cardiology conference in Q2 2027 and subsequent marketing application submission to FDA and global regulatory agencies, assuming primary endpoints are met*
- *FDA granted a second Breakthrough Device Designation ("BDD") for AVIM Therapy specific to patients with uncontrolled hypertension despite the use of anti-hypertensive medications, and an indication for a pacemaker*
- *Virtue Trial sites progressing with site activation and patient enrollment acceleration continuing throughout 2026*
- *Cash runway projected into Q4 2027 and through achievement of key upcoming clinical and regulatory milestones*

NEW HOPE, Pa., May 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 risk-reward sharing partnerships, today announced financial results for the first quarter ended March 31, 2026, and provided a business update highlighting momentum across the Company's pivotal-stage programs for Atrioventricular Interval Modulation ("AVIM") Therapy and Virtue ® Sirolimus AngioInfusion ™ Balloon ("Virtue SAB") supported by the Company's strong balance sheet.

David Hochman, Chairman and Chief Executive Officer of Orchestra BioMed stated, "We continued to make meaningful advancements across our late-stage cardiovascular pipeline during the first quarter. Along with the achievement of recently announced important regulatory, clinical and financing milestones, we are pleased to provide clarity on the expected timeline for the BACKBEAT Trial highlighting objectives for enrollment completion, late-breaking clinical trial presentation, and plans for potential regulatory submissions by our strategic collaborator Medtronic. With increasingly strong momentum continuing in the BACKBEAT Trial and the AVIM Therapy program, and great progress for the Virtue Trial and Virtue SAB, our team is excited about the significant value inflection points that lie ahead for Orchestra BioMed."

Q1 2026 and Recent Business Highlights:

- **Provided overall update on the BACKBEAT Trial timeline,** targeting enrollment completion by the end of the **third quarter of 2026** and announced plans with Medtronic to pursue presentation of primary endpoint data as a late-breaking clinical trial presentation at a major cardiovascular conference in the **second quarter of 2027**, assuming primary endpoints are met.
  - The updated timeline is supported by FDA approval of a reduction in sample size for the BACKBEAT Trial to a target total of 284 evaluable randomized subjects, with a total enrollment target of 316 patients accounting for potential loss to follow-up.
- **FDA granted AVIM Therapy a second FDA Breakthrough Device Designation ("BDD")** specific to patients with uncontrolled hypertension despite the use of anti-hypertensive medications, and an indication for a pacemaker.
  - The BDDs granted to AVIM Therapy collectively apply to indications that encompass both the broader population of patients with uncontrolled hypertension despite medication and increased cardiovascular risk, as well as the specific pacemaker-indicated population with uncontrolled hypertension being evaluated in the BACKBEAT Trial, representing a U.S. population of over 7.7 million patients.
  - BDD can support enhanced reimbursement pathways, including potential eligibility for New Technology Add-on Payment and Transitional Pass-Through payment, which can facilitate broader, more timely patient access and provider adoption.
- **Received $35 million in strategic capital under** previously disclosed agreements with Medtronic and Ligand (Nasdaq: LGND).
  - Received **$20 million from Medtronic** as payment for a secured subordinated promissory note convertible to capped prepaid revenue share, fulfilling Medtronic's previously disclosed funding commitment. This brings Medtronic's total capital contribution to Orchestra BioMed to nearly $82 million including prior equity investments, supporting the planned completion of the BACKBEAT Trial.
  - Received **$15 million tranche payment from Ligand** associated with the previously disclosed Royalty Purchase Agreement, bringing total capital received from Ligand to $40 million to date in exchange for tiered royalty interest in certain future AVIM Therapy and Virtue SAB revenue, as well as an equity investment.
- **Presented AVIM Therapy clinical and mechanistic data at HRS 2026**, including pre-randomization data from the

MODERATO II pilot study in which AVIM Therapy demonstrated a mean immediate reduction in office systolic blood pressure of 13.2 mmHg upon activation, with 97% of patients achieving a 5 mmHg or greater blood pressure reduction upon AVIM Therapy activation.
- **Advanced site activation and patient enrollment in the 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.

Financial Results for the First Quarter Ended March 31, 2026

- **Cash and cash equivalents and Marketable securities** totaled $94.4 million as of March 31, 2026. On May 1, 2026, we received $35 million, which includes $20 million from Medtronic and $15 million from Ligand pursuant to the terms of agreements with those parties.

- **Net cash used in operating activities and for the purchase of fixed assets** was $22.4 million during the first quarter of 2026, compared with $16.7 million for the first quarter in 2025, with the primary drivers being increased research and development costs, including clinical trial activities, as well as personnel and consulting expenditures, which include non-recurring payments, during the first quarter of 2026.

- **Revenue** for the first quarter of 2026 was $0.1 million, compared with $0.9 million for the first quarter in 2025. The decrease was primarily due to the elimination of recognized revenue from our prior distribution agreement with Terumo, which was terminated in October 2025.

- **Research and development expenses** for the first quarter of 2026 were $15.8 million, compared with $13.5 million for the first quarter in 2025, which represents an increase of 17%. 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 first quarter of 2026 were $6.4 million, compared with $6.3 million for the first quarter of 2025, which represents an increase of 2%. The increase was primarily due to an increase in professional fees.

- **Net loss attributable to common stockholders** for the first quarter of 2026 was $20.7 million, or ($0.33) per share, compared with a net loss attributable to common stockholders of $18.8 million, or ($0.49) per share, for the first quarter of 2025, which represents an increase of 10%. Net loss attributable to common stockholders for the first quarter of 2026 included $2.9 million in non-cash stock-based compensation expense 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, 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 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:
Kelsey Kirk
Orchestra BioMed
kkirkellis@orchestrabiomed.com

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

	March 31, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 28,367	$ 34,690
Marketable securities	66,033	71,822
Accounts receivable, net	84	95
Inventory	277	310
Prepaid expenses and other current assets	1,448	994
Total current assets	96,209	107,911
Property and equipment, net	1,848	1,715

Right-of-use assets	1,337	1,496
Strategic investments	—	2,495
Deposits and other assets	1,264	1,240
TOTAL ASSETS	$ 100,658	$ 114,857
LIABILITIES, SERIES A PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 6,313	$ 6,095
Accrued expenses and other liabilities	6,594	9,890
Operating lease liability, current portion	785	751
Total current liabilities	13,692	16,736
Royalty purchase agreement	17,787	16,482
Loan payable	14,333	14,268
Derivative liability	2,784	2,749
Operating lease liability, less current portion	730	936
Other long-term liabilities	367	308
TOTAL LIABILITIES	49,693	51,479
Series A Preferred Stock, $0.0001 par value per share; 200,000 issued and outstanding at March 31, 2026 and December 31, 2025; aggregate liquidation preference of $20,000	9,773	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; 58,630,715 and 57,032,963 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively.	6	6
Additional paid-in capital	424,496	416,083
Accumulated other comprehensive (loss) income	(40)	60
Accumulated deficit	(383,270)	(362,579)
TOTAL STOCKHOLDERS' EQUITY	41,192	53,570
TOTAL LIABILITIES, SERIES A PREFERRED STOCK AND STOCKHOLDERS' EQUITY	$ 100,658	$ 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 March 31,	
	2026	**2025**
Revenue:		
Partnership revenue	$ —	$ 732
Product revenue	110	136
Total revenue	110	868
Expenses:		
Cost of product revenues	32	44
Research and development	15,781	13,482
Selling, general and administrative	6,373	6,263
Total expenses	22,186	19,789
Loss from operations	(22,076)	(18,921)
Other (expense) income:		
Interest (expense) income, net	(821)	166
Change in the fair value of derivative liability	(35)	—
Gain on sale of strategic investments	2,241	—
Total other income	1,385	166
Net loss	(20,691)	(18,755)

Adjustment to carrying value of Series A Preferred Stock	35	—
Net loss attributable to common stockholders	$ (20,656)	$ (18,755)
Net loss attributable to common stockholders per share		
Basic and diluted	$ (0.33)	$ (0.49)
Weighted-average shares used in computing net loss attributable to common stockholders per share, basic and diluted	62,721,869	38,235,409
Comprehensive loss		
Net loss	$ (20,691)	$ (18,755)
Unrealized loss on marketable securities	(100)	(15)
Comprehensive loss	$ (20,791)	$ (18,770)