



## Orchestra BioMed Targeting BACKBEAT Trial Enrollment Completion By End of Q3 2026 and Data Presentation in Q2 2027

May 12, 2026

- *Orchestra BioMed targeting enrollment completion of BACKBEAT Global Pivotal Trial ("BACKBEAT Trial") by the end of Q3 2026*
- *Orchestra BioMed and Medtronic plc. (NYSE: MDT, "Medtronic"), the Company's strategic collaborator for the BACKBEAT Trial, intend to submit primary endpoint results for consideration as a late-breaker at a major cardiology conference in Q2 2027*
- *Medtronic plans to submit AVIM Therapy-related marketing application for FDA approval after primary endpoint data analyses and reports are complete and pursue subsequent global regulatory approvals, assuming primary safety and efficacy endpoints are met*

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 strategic partnerships with market-leading global medical device companies, today announced an update to the overall clinical and regulatory timeline for the BACKBEAT Trial evaluating Atrioventricular Interval Modulation Therapy ("AVIM Therapy") in pacemaker-indicated patients with uncontrolled hypertension despite medications. The Company is targeting completion of enrollment by the end of the third quarter of 2026. Further, the Company and Medtronic, its strategic collaborator for the BACKBEAT Trial and the commercialization of AVIM Therapy for the treatment of uncontrolled hypertension in patients indicated for a pacemaker, plan to submit the primary endpoint data for a late-breaking clinical trial presentation at a major cardiovascular conference in the second quarter of 2027. Lastly, assuming primary safety and efficacy endpoints are met, Medtronic plans to submit a marketing application for FDA approval after primary endpoint data analyses and reports are complete, and subsequently to pursue global regulatory approvals.

The updated BACKBEAT Trial timeline is supported by FDA approval of a reduction in the sample size for the clinical trial to a target total of 284 evaluable randomized subjects with the total enrollment target of 316 patients accounting for potential loss to follow up. The primary efficacy endpoint (between-group difference in 24-hour ambulatory systolic blood pressure "aSBP" at 3-month follow up) and primary safety endpoint (freedom from unanticipated serious adverse device events in the AVIM Therapy arm at 3-month follow up) remain robustly powered (>90% statistical power) at the revised sample size for the trial. The sample size is designed to detect a between group difference of at least 5 mmHg in aSBP. The change in sample size reflects collaboration among Orchestra BioMed, Medtronic and the FDA under the Breakthrough Devices program, and follows FDA approval of an amendment to the BACKBEAT Trial protocol received on May 8, 2026 by Orchestra BioMed.

**David Hochman, Chairman, Chief Executive Officer of Orchestra BioMed**, commented, "We are delighted to provide clarity on the anticipated overall timeline for the BACKBEAT Trial, which reflects ongoing global enrollment momentum and FDA alignment with a streamlined sample size that remains highly powered to assess AVIM Therapy's efficacy and safety at the 3-month primary endpoints. We believe BACKBEAT has the potential to be a landmark pivotal trial that can open up an entirely new therapeutic modality for patients at increased risk from high blood pressure and hypertensive heart disease."

**Robert C. Kowal, M.D., Ph.D., Vice President and General Manager for Cardiac Pacing Therapies in the Medtronic Cardiac Rhythm Management operating unit**, stated, "For decades, cardiac pacing has been foundational in the management of rhythm disorders. With the BACKBEAT Trial, Medtronic and Orchestra BioMed are investigating whether AVIM Therapy can extend the benefits of pacing to the field of hypertension management in high-risk patients. This update reflects our shared confidence in progress toward the completion of enrollment, the submission of data to the FDA, and the presentation of clinical evidence."

### **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<sup>®</sup> Sirolimus AngioInfusion<sup>™</sup> 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](http://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 study 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.

### **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 regulatory submissions, realizing the clinical and commercial value of the Company's product candidates, 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, 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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