

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): October 1, 2026

ORCHESTRA BIOMED HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39421
(Commission
File Number)

92-2038755
(IRS Employer
Identification No.)

150 Union Square Drive
New Hope, Pennsylvania 18938
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (215) 862-5797

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	OBIO	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On October 1, 2026, Orchestra BioMed Holdings, Inc. (the “Company”) issued a press release titled “Orchestra BioMed Exceeds Enrollment Target in the BACKBEAT Global Pivotal Trial of AVIM Therapy.” A copy of the press release is attached to this Current Report on Form 8-K (“Current Report”) as Exhibit 99.1 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information in Item 7.01 of this Current Report, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of such section. The information in Item 7.01 of this Current Report, including Exhibit 99.1, shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any incorporation by reference language in any such filing.

Item 8.01. Other Events.

On October 1, 2026, the Company announced that, as of September 30, 2026, 330 patients had been randomized in the BACKBEAT Global Pivotal Trial (“BACKBEAT Trial”), exceeding its previously announced target of 316 randomized patients. The BACKBEAT Trial is evaluating Atrioventricular Interval Modulation Therapy (“AVIM Therapy”) in pacemaker-indicated patients with uncontrolled hypertension despite the use of medication. The BACKBEAT Trial is being conducted with Medtronic plc (NYSE: MDT), the Company’s strategic collaborator for the BACKBEAT Trial and, subject to regulatory approval, for the commercialization of AVIM Therapy in pacemaker-indicated patients with uncontrolled hypertension despite the use of medication. The 330 patients enrolled in the BACKBEAT Trial have been randomized at 81 sites across 13 countries. The BACKBEAT Trial’s protocol, approved by the U.S. Food and Drug Administration, specifies 284 evaluable randomized subjects for the primary endpoint analysis, with a total enrollment target of 316 patients to account for potential loss to follow-up.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated as of October 1, 2026.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ORCHESTRA BIOMED HOLDINGS, INC.

By: /s/ Andrew Taylor

Name: Andrew Taylor

Title: Chief Financial Officer

Date: October 1, 2026

Orchestra BioMed Exceeds Full Enrollment Target in the BACKBEAT Global Pivotal Trial of AVIM Therapy

- 330 patients randomized as of September 30, 2026, surpassing full trial enrollment target
- Company reiterates prior guidance: primary endpoint data to be submitted for late-breaking presentation consideration at a major cardiovascular conference in Q2 2027
- Data expected to support future marketing application submissions by Medtronic to the FDA and other global regulatory agencies

NEW HOPE, Pa., Oct. 1, 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 medical device companies, today announced that it has surpassed full enrollment in the BACKBEAT Global Pivotal Trial (“BACKBEAT Trial”), exceeding its previously announced target of 316 randomized patients. The BACKBEAT Trial is evaluating Atrioventricular Interval Modulation Therapy (“AVIM Therapy”) in pacemaker-indicated patients with uncontrolled hypertension despite the use of medication. Hypertension is the most common modifiable risk factor for death worldwide and the most common comorbidity among the pacemaker population.¹

The BACKBEAT Trial (NCT06059638) is being conducted with Medtronic plc (NYSE: MDT, “Medtronic”), the Company's strategic collaborator for the BACKBEAT Trial and, subject to regulatory approval, for the commercialization of AVIM Therapy in pacemaker-indicated patients with uncontrolled hypertension despite the use of medication.

- As of September 30, 2026, 330 patients have been randomized in the BACKBEAT Trial at 81 sites across 13 countries.
- The BACKBEAT Trial’s protocol, approved by the U.S. Food and Drug Administration (the “FDA”), specifies 284 evaluable randomized subjects for the primary endpoint analysis, with a total enrollment target of 316 patients to account for potential loss to follow-up.

The BACKBEAT Trial is a global, multi-center, prospective, randomized, double-blind pivotal trial. Patients are randomized 1:1 to AVIM Therapy combined with continued medical therapy and pacing (treatment) or continued medical therapy and standard pacing alone (control). The primary efficacy endpoint of the BACKBEAT Trial is the between-group difference in the change in 24-hour ambulatory systolic blood pressure (“aSBP”) at three-month follow-up from pre-randomization baseline. The primary safety endpoint is freedom from unanticipated serious adverse device events in the AVIM Therapy arm at three-month follow-up. The protocol-specified sample size provides greater than 90% statistical power for both primary endpoints and is designed to detect a between-group difference of at least 5 mmHg in aSBP.

David Hochman, Chairman & Chief Executive Officer of Orchestra BioMed, commented, “Achieving and surpassing full enrollment of the BACKBEAT Trial is a defining milestone for Orchestra BioMed, for our collaboration with Medtronic and potentially for the millions of high cardiovascular risk patients who remain above blood pressure target despite the medications available to them today. We are grateful for and excited about the enrollment momentum built across our global trial site network over the last year. I want to thank the patients and their families who chose to participate, and the clinical teams and investigators at our trial sites globally whose commitment made this milestone possible. Our focus now turns to completing three-month follow-up, database lock, and the delivery of a rigorous, well-powered data set next spring.”

¹ World Health Organization, Global Report on Hypertension 2025 (an estimated 1.4B adults aged 30–79 with hypertension in 2024, 33% of that age group; ~23% of those living with hypertension have their blood pressure effectively controlled).

Robert C. Kowal, M.D., Ph.D., Vice President and General Manager for Cardiac Pacing Therapies in the Medtronic Electrophysiology Therapies operating unit, stated, “For decades, cardiac pacing has been foundational in the management of rhythm disorders. Reaching full enrollment in the BACKBEAT Trial brings us a big step closer to understanding whether AVIM Therapy can extend the role of cardiac pacing therapy to include hypertension management for patients at increased cardiovascular risk. We are proud of the collaborative work our team and Orchestra BioMed’s team have done alongside investigators around the world, and we look forward to the primary endpoint results.”

Vivek Reddy, M.D., Executive Chairman of the BACKBEAT Clinical Steering Committee, Director of Cardiac Arrhythmia Services at The Mount Sinai Fuster Heart Hospital and Director of Electrophysiology for the Mount Sinai Health System, commented, “Randomized, double-blind evidence is the highest standard by which a new therapeutic modality earns its place in clinical practice, and that is exactly what the BACKBEAT Trial was designed to generate. The pilot data for AVIM Therapy have been exciting, consistent and mechanistically coherent, but the field needs a pivotal trial to answer the question definitively. On behalf of the Steering Committee, I want to recognize the investigators, coordinators and other professionals whose work enabled the trial to reach full enrollment, and I look forward to seeing the three-month primary endpoint results.”

Clinical, Regulatory and Commercial Next Steps

Orchestra BioMed and Medtronic intend to submit the BACKBEAT Trial’s primary endpoint results for consideration as a late-breaking clinical trial presentation at a major cardiovascular conference in the second quarter of 2027. Assuming positive results from the BACKBEAT Trial, Medtronic plans to submit AVIM Therapy marketing applications to the FDA and other global regulatory agencies promptly.

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. In MODERATO II, a double-blind, randomized pilot study, AVIM Therapy-treated patients had a mean reduction of 11.1 mmHg in 24-hour ambulatory systolic blood pressure (aSBP) from pre-randomization baseline at six months, representing a net reduction of 8.1 mmHg versus control patients. At the same time point, the net reduction in office systolic blood pressure (oSBP) was 12.3 mmHg versus control.

Additional MODERATO II data showed an immediate mean oSBP reduction of 13.2 mmHg when AVIM Therapy was activated during setup before randomization, with 97% of patients achieving a reduction of at least 5 mmHg. In addition to reducing blood pressure, clinical results using AVIM Therapy demonstrate improvements in cardiac function and hemodynamics.

The BACKBEAT (BradyArDIA 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.

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 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, the size of the potential markets for 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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