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): September 19, 2023

ORCHESTRA BIOMED HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39421**	**92-2038755**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 September 19, 2023, Orchestra BioMed Holdings, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration granted the Company investigational device exemption approval to initiate the Company's planned BACKBEAT pivotal study of the Company's BackBeat Cardiac Neuromodulation Therapy product candidate, also known as Atrioventricular Interval Modulation (AVIM) therapy, to treat hypertension in patients indicated for a pacemaker. The BACKBEAT name of the study is an acronym for the full study title which is the **B**radyc**A**rdia pa**C**ema**K**er with atrioventricular interval modulation for **B**lood pr**E**ssure tre**A**tmen**T** pivotal study.

A copy of the press release and a copy of the slide presentation that the Company uses at investor and industry conferences and presentations are each attached to this Current Report on Form 8-K ("Current Report") as Exhibit 99.1 and Exhibit 99.2, respectively, and are each incorporated herein solely for purposes of this Item 7.01 disclosure. Additionally, the Company has posted the press release and slide presentation on its website at https://investors.orchestrabiomed.com under the Investor Relations section.

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 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Description**
99.1	Press Release dated September 19, 2023
99.2	Investor Presentation
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/ David Hochman
Name: David P. Hochman
Title: Chief Executive Officer

Date: September 19, 2023

Exhibit 99.1

Orchestra BioMed Granted FDA Approval of IDE to Initiate BACKBEAT Pivotal Study of BackBeat CNT™ for the Treatment of Hypertension in Pacemaker Patients

- *Hypertension is the most common comorbidity in the pacemaker population, affecting over 70% of patients or approximately 750,000 people annually worldwide*
- *Medtronic, Inc. and Orchestra BioMed have an exclusive strategic collaboration for global development and commercialization of BackBeat Cardiac Neuromodulation Therapy™ (CNT), now also known as Atrioventricular Interval Modulation ("AVIM") therapy, for hypertensive pacemaker patients*
- *BACKBEAT global pivotal study is expected to start before the end of 2023*
- *IDE supported by data from the MODERATO II randomized pilot study that showed AVIM therapy drove significant and sustained reductions in blood pressure in hypertensive pacemaker patients*
- *Orchestra BioMed management to host conference call today, September 19, 2023, at 8:30am ET*

New Hope, PA – September 19, 2023 – 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 the U.S. Food and Drug Administration ("FDA") granted approval of an investigational device exemption ("IDE") to initiate the global pivotal BACKBEAT (**B**radyc**A**rdia pa**C**ema**K**er with atrioventricular interval modulation for **B**lood pr**E**ssure tre**A**tmen**T**) study evaluating the efficacy and safety of atrioventricular interval modulation ("AVIM") therapy (also known as BackBeat CNT™) for treating hypertensive patients who are indicated for a dual-chamber cardiac pacemaker.

Orchestra BioMed and Medtronic, Inc. (NYSE: MDT) formed a strategic collaboration for the development and commercialization of AVIM therapy for hypertensive pacemaker patients in July 2022. Under the collaboration, Medtronic is providing Orchestra BioMed with development, clinical, and regulatory support for the BACKBEAT global pivotal study, which Orchestra BioMed is sponsoring. If approved, Medtronic will have exclusive global rights to commercialize AVIM-enabled pacing systems for this target population. Orchestra BioMed will share in the revenues generated from Medtronic sales of the AVIM-enabled pacing systems.

"We are thrilled to receive IDE approval from the FDA and move forward with plans to initiate the BACKBEAT global pivotal study, which is designed to support potential future regulatory review and potential approval of AVIM therapy for hypertensive patients indicated for a pacemaker. Achieving this milestone a little over a year after starting our strategic collaboration with Medtronic is a significant accomplishment for our company," said David Hochman, Chairman, Chief Executive Officer and Founder of Orchestra BioMed. "We believe this innovative therapy has the potential to substantially improve the standard of care for hypertensive pacemaker patients and we look forward to initiating the study before the end of 2023."

David Kandzari, M.D., Chief of the Piedmont Heart Institute and Chief Scientific Officer for Piedmont Healthcare, Atlanta, GA and Co-Principal Investigator for the BACKBEAT Study, commented: "Hypertension is the world's leading modifiable risk for death and affects over one billion people worldwide. While existing pharmaceutical treatments can be effective, more than half of individuals with hypertension do not meet blood pressure treatment goals. A device-based treatment like AVIM therapy has the potential to complement existing standards of care and reduce blood pressure to improve clinical outcome."

The BACKBEAT pivotal study is a global, multi-center, prospective, randomized, double-blind study investigating the efficacy and safety of AVIM therapy in patients who recently underwent a Medtronic dual-chamber cardiac pacemaker implant and have uncontrolled hypertension ("HTN") despite the use of antihypertensive medications. The study will randomize approximately 500 patients 1:1 to AVIM along with continued medical therapy and pacing (treatment) or continued medical therapy and pacing alone (control). The study's primary efficacy endpoint is the between group difference in the change of mean 24-hour ambulatory systolic blood pressure ("aSBP") at three months post randomization. The primary safety endpoint is freedom from unanticipated serious adverse device effects in the treatment arm at three months post-randomization. Double-blind follow up will continue through 12 months to enable collection of additional clinical endpoints. The Company plans to begin enrollment in the BACKBEAT study before the end of 2023, upon completion of standard clinical trial initiation activities, including clinical center Institutional Review Board approvals.

"Hypertension is the most common comorbidity in the pacemaker population, affecting more than 70% of patients. Patients who have pacemakers are generally older and at higher risk for major cardiovascular events. AVIM therapy represents a potentially transformative hypertension treatment for these patients since it can be administered using the same pacemaker they already need and managed by the same physicians already caring for them," commented Andrea Russo, M.D., Academic Chief, Division of Cardiology, Director of Cardiac Electrophysiology and Arrhythmia Services, Cooper University Hospital, and Co-Principal Investigator of the BACKBEAT Study, "We are excited to participate in the BACKBEAT study, which has been thoughtfully designed to evaluate the safety and efficacy of this novel therapy."

The BACKBEAT study IDE was supported by encouraging results from MODERATO II, a prospective, multi-center, randomized, double-blind, pilot study of pacemaker patients with persistent HTN. MODERATO II showed that patients treated with AVIM therapy experienced net reductions of 8.1 mmHg in 24-hour aSBP and 12.3 mmHg in office systolic blood pressure (oSBP) at six months when compared to control patients.

Video Webcast Information

Orchestra BioMed will host a video webcast with slides today, September 19, 2023, at 8:30 a.m. ET to discuss the BACKBEAT Pivotal Study. This webcast can be accessed by clicking on the Events page of the Company's website, and this press release will be archived on the News Releases page. Within two hours of the webcast, a replay of the webcast and accompanying slides will be available on the Events page.

About Hypertension and the Risk of High Blood Pressure in the Pacemaker Population

Hypertension ("HTN") is characterized by elevated blood pressure which increases the force of blood pushing against blood vessels, requiring the heart to work harder and consume more oxygen. HTN accelerates the progression of atherosclerosis and leads to increased risk of major cardiac events like heart attack, heart failure, kidney disease and other end organ damage. HTN is the leading global risk factor for death, affecting an estimated 1.28 billion adults worldwide. In the United States, 122 million adults, or approximately 47% of all adults, are estimated to have HTN. While many patients do not notice high blood pressure, cardiovascular risk doubles for every 10 mmHg increase in systolic blood pressure and the mortality rate doubles with an increase of 20 mmHg in systolic blood pressure.

It is estimated that more than 70% of the approximately 1.1 million people globally who are implanted with cardiac pacemakers each year are also diagnosed with HTN. Based on updated ACC/AHA guidelines, an even higher percentage (approximately 80%) of U.S. patients that are indicated for the implant of a pacemaker have HTN. Pacemaker patients tend to be elderly and are more likely to suffer from co-morbidities such as atherosclerosis, hyperlipidemia, diabetes mellitus and chronic kidney disease, and harder to treat effectively with medical therapy for many reasons including co-morbidities and a high prevalence of isolated systolic HTN.

About AVIM Therapy (BackBeat CNT™)

AVIM therapy, also known as BackBeat CNT, 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. The planned global pivotal BACKBEAT (**B**radyc**A**rdia pa**C**ema**K**er with atrioventricular interval modulation for **B**lood pr**E**ssure tre**A**tmen**T**) study will further evaluate the safety and efficacy of AVIM therapy in lowering blood pressure in a similar target population of patients who have been indicated for, and recently implanted with, a dual-chamber cardiac pacemaker.

About Orchestra BioMed

Orchestra BioMed (Nasdaq: OBIO) is a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing partnerships with leading medical device companies. Orchestra BioMed's partnership-enabled business model focuses on forging strategic collaborations with leading medical device companies to drive successful global commercialization of products it develops. Orchestra BioMed's flagship product candidates include Atrioventricular Interval Modulation (AVIM) therapy (BackBeat CNT) for the treatment of hypertension, the leading risk factor for death worldwide, and Virtue® Sirolimus AngioInfusion™ Balloon (SAB) for the treatment of atherosclerotic coronary artery disease, the leading cause of mortality worldwide. Orchestra BioMed has a strategic collaboration with Medtronic, one of the largest medical device companies in the world, for development and commercialization of AVIM therapy for the treatment of hypertension in pacemaker-indicated patients, and a strategic partnership with Terumo, a global leader in medical technology, for development and commercialization of Virtue SAB for the treatment of artery disease. Orchestra BioMed has additional product candidates and plans to potentially expand its product pipeline through acquisitions, strategic collaborations, licensing, and organic development. For further information about Orchestra BioMed, please visit www.orchestrabiomed.com, and follow us on LinkedIn and Twitter.

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.

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 and design of the BACKBEAT pivotal study, the FDA's approval of the BACKBEAT pivotal study, the Company providing additional information to the FDA and the Company's late-stage development programs, strategic partnerships and plans to expand its product pipeline. 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; failure to realize the anticipated benefits of the business combination; risks related to regulatory approval of the Company's product candidates; 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 quarterly report on Form 10-Q filed with the U.S. Securities and Exchange Commission on May 12, 2023, as updated by any risk factors disclosed under the heading "Item 1A. Risk Factors" in the Company's subsequently filed quarterly reports on Form 10-Q.

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:
Bob Yedid
LifeSci Advisors
516-428-8577
Bob@lifesciadvisors.com

Media Contact:
Kelsey Kirk-Ellis
Orchestra BioMed
(484) 682-4892
kkirkellis@orchestrabiomed.com

Orchestra BioMed

BACKBEAT Study Overview:

BradycArdia paCemaKer with AV interval modulation for Blood prEssure treAtmenT

September 2023

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AVIM Therapy Overview

Strategic collaboration with
Medtronic

Atrioventricular Interval Modulation (AVIM) *therapy (also known as* ***BackBeat CNT™****) is designed to immediately, persistently and substantially reduce blood pressure*

Unmet Need

- Hypertension is the **leading global risk factor for death**
- Hypertension is also the **#1 comorbidity in the pacemaker population (over 70%)**[1]
- Older population at **increased risk for major cardiovascular events** & challenges with drug compliance

Innovation

- Bioelectronic therapy **designed to immediately, persistently and substantially lower blood pressure**
- Seamlessly integrated into existing Medtronic dual-chamber pacemakers
- **Compelling clinical data** from two pilot studies, including a randomized double-blind study

Initial Opportunity

- **Same target patient population** that already needs a pacemaker
- **Same implant procedure** and large **trained physician pool**
- Leverages **existing pacemaker reimbursement**

[1]Company estimates based on published sources, including National Inpatient Survey (NIS) and National Health and Nutrition Examination Survey (NHANES)

Orchestra BioMed

Ideal Collaboration

Orchestra BioMed

- Developed BackBeat CNT (AVIM therapy) from concept stage; owns all related IP
- Conducted all prior development work including MODERATO I & II clinical studies
- Partnered with Medtronic for global regulatory approval and commercialization
- Sponsor for the BACKBEAT Study
- **$500 - $1,600 revenue share** per AVIM-enabled device[1]

AVIM Therapy:

Patented investigational bioelectronic treatment for hypertension

Medtronic

- Global market leader in cardiac pacing therapy: **>$1.5B** in annual revenues
- Providing leading device plus clinical & regulatory resources
- Exclusive global commercial rights for AVIM therapy in pacemaker-indicated patients
- Right of first negotiation to expand global rights for the treatment of non-pacemaker HTN patients
- **$50M equity investment** in Orchestra BioMed

[1] Amount is based on higher of (1) a fixed dollar amount per device (amount varies materially on a country-by-county basis) or (2) a percentage of sales.

Large Global Opportunity for Treating Hypertension in Target Populations

HTN + Pacemaker

750,000 patients

~70% of pacemaker patients[1]

>$2 Billion

High Risk HTN

2,400,000 patients

~0.2% of HTN patients

>$8 Billion

>$10 Billion Potential Annual Global Market Opportunity*

>3.1M Addressable HTN Patients

High Risk HTN (Non-pacemaker) - Older patients with isolated systolic hypertension (ISH) and other comorbidities

Medtronic is the global leader in pacemakers

*Total addressable market in 2025 based on company estimates; 1Company estimates based on published sources, including National Inpatient Survey (NIS) and National Health and Nutrition Examination Survey (NHANES); Definition: Hypertension (HTN)

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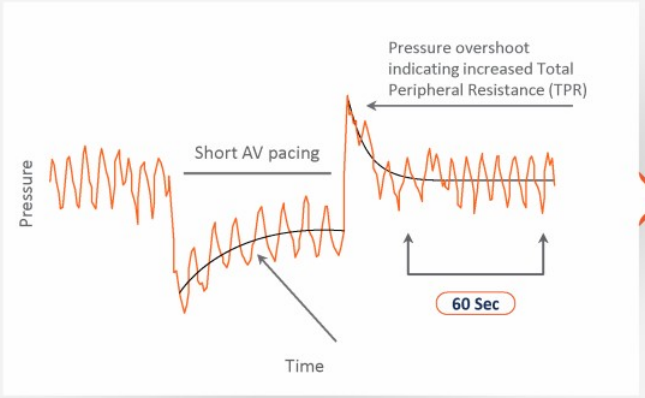
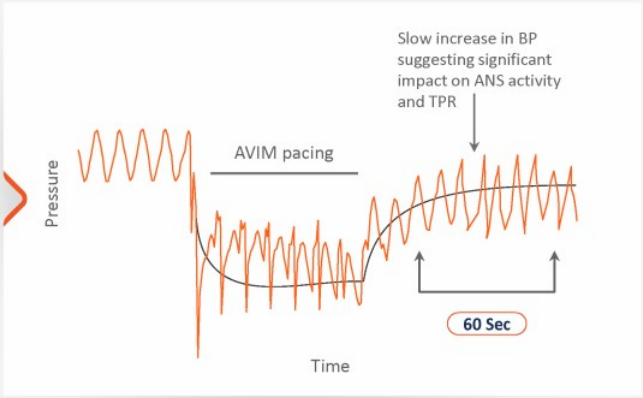
Novel Mechanism of Action Designed to Substantially Reduce Blood Pressure

Bioelectronic Control of Ventricular Filling Immediately **Reduces Blood Pressure**



AVIM ACTIVATION

AVIM-Mediated Pressure Patterns **Modulate Autonomic Nervous System (ANS) Response**



AV (Atrioventricular), TPR (Total Peripheral Resistance)

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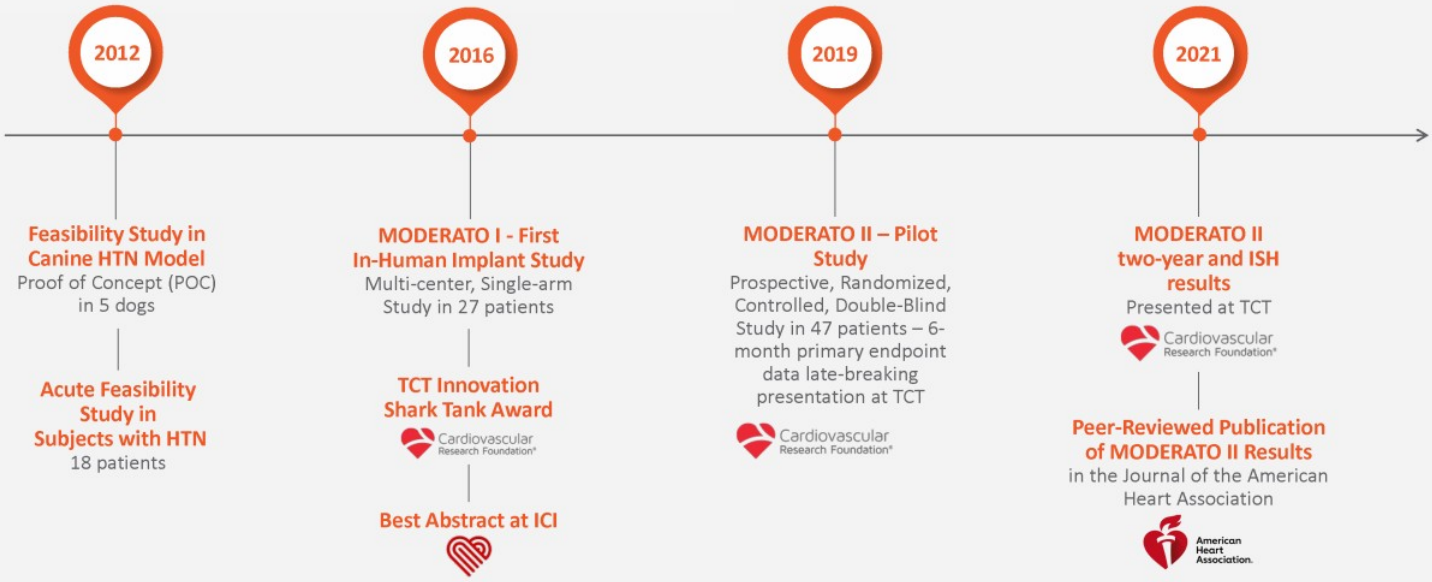
Existing Body of Clinical Data Supporting Efficacy and Safety



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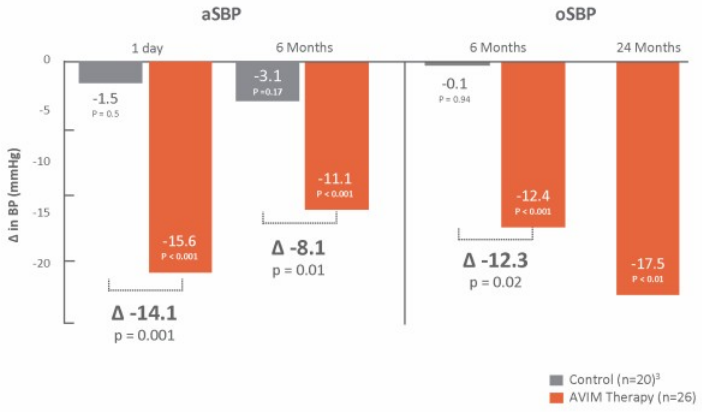
MODERATO II Randomized, Double-Blind Results

BackBeat CNT™ showed encouraging results in MODERATO II, a prospective, multi-center, randomized, (BackBeat CNT + Medical Therapy vs. Continued Medical Therapy), double-blind, pilot study of pacemaker patients with persistent hypertension

Significant Reduction in 24-Hr aSBP and oSBP[1,2]



-11.1 mmHg
in 24-Hour aSBP at 6 months

0%
MACE vs. 9.5% in control group at 6 months

-17.5 mmHg
in oSBP at 2 years

85%
of patients with reduction in aSBP

[1]Kalaras et al. Journal of the American Heart Association. 2021;10:e020492 ahajournals.org/doi/10.1161/JAHA.120.020492; [2]Burkhoff MODERATO II Study 2-Year Results TCT 2021; [3]24-Hr aSBP Control (n=19),1 control patient could not be measured despite repeat measurement (patient had extremely high blood pressure); Definitions: Major Adverse Cardiac Events (MACE) included death, heart failure, clinically significant arrhythmias (i.e., persistent or increased atrial fibrillation, serious ventricular arrhythmias), myocardial infarction, stroke and renal failure in treatment group calculated per patient, Office Systolic Blood Pressure (oSBP); Ambulatory Systolic Blood Pressure (aSBP)

Orchestra BioMed

BACKBEAT Study Summary

Prospective, multi-center, double-blind study investigating the efficacy and safety of AVIM therapy in patients indicated for a dual-chamber pacemaker who also have uncontrolled hypertension (HTN) despite the use of antihypertensive medications

Randomize approximately **500 patients across ~80 study sites** globally

Inclusion and exclusion criteria apply learnings from MODERATO II and other recent HTN clinical studies

Study endpoints:

- **Efficacy endpoint:** Between group difference in the **change of mean 24-hour aSBP at 3 months** post randomization
- **Safety endpoint:** Freedom from **unanticipated serious adverse device events at 3 months** post randomization
- **Secondary/additional endpoints**: Double-blind follow-up will continue through 12 months to enable collection of additional clinical results and secondary endpoints

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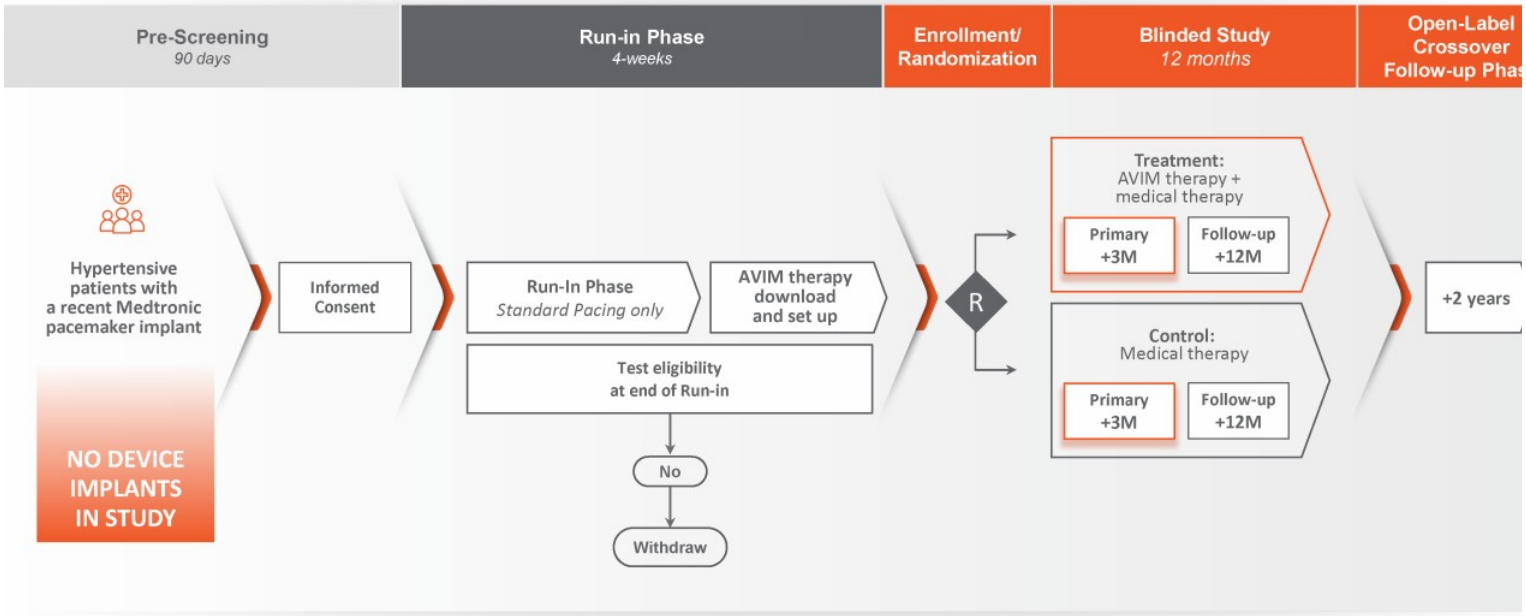
BACKBEAT Study Design



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Key Takeaways

- Hypertension is the leading global risk factor for death and #1 comorbidity in pacemaker patients
- Large established pacemaker market and implanting physician community, as well as existing reimbursement
- Patient population with favorable risk-benefit profile as they already require a pacemaker and additional therapy provided by same device offers potential for substantial blood pressure reduction
- MODERATO pilot studies demonstrate immediate, substantial and persistent blood pressure reduction in combination with background medical therapy
- BACKBEAT study robustly powered to generate data in support of potential regulatory approval and commercialization
- Medtronic is the ideal collaborator as the global market leader in cardiac pacing therapy