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): November 14, 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.

A copy of a slide presentation that Orchestra BioMed Holdings, Inc. (the "Company") uses at investor and industry conferences and presentations 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 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	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: November 14, 2023

Exhibit 99.1

Forward-Looking Statements

This presentation has been prepared for informational purposes only from information supplied by Orchestra BioMed Holdings, Inc., referred to herein as "we," "our," "Orchestra BioMed," and "the Company," and from third-party sources indicated herein. Such third-party information has not been independently verified. Orchestra BioMed makes no representation or warranty, expressed or implied, as to the accuracy or completeness of such information.

Certain statements included in this document 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 potential safety and efficacy of our product candidates, the initiation and timing of our planned pivotal trials and reporting of top-line results, expected market sizes for our product candidates, the ability of our partnerships to accelerate clinical development, and our estimated future financial performance and financial position. These statements are based on various assumptions, whether or not identified in this document, 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 pr and circumstances are difficult or impossible to predict assumptions. Many actual events and circumstances are bey Company. These forward-looking statements are subject to uncertainties, including changes in domestic and foreign busi political, and legal conditions; risks related to regulatory appr product candidates; the timing of, and the Company's abilit regulatory and business milestones; the impact of competitive candidates; and the risk factors discussed under the heading "It the Company's quarterly report on Form 10-Q filed with t Exchange Commission on May 12, 2023 as updated by any risk the heading "Item 1A. Risk Factors" in the Company's subse reports on Form 10-Q.

The Company operates in a very competitive and rapidly chan risks emerge from time to time. Given these risks and unce cautions against placing undue reliance on these forward-loo only speak as of the date of this presentation. The Compa undertakes no obligation to update any of the forward-loo herein, except as required by law.

Orchestra BioMed Executive Overview

Partnership-enabled business model designed to:

- Accelerate innovation to patients
- Drive strong partner and shareholder value
- Yield exceptional future

Lead Program

BackBeat CNT™ (AVIM* therapy)

Targets >$10B annual hypertension markets

- Statistically significant double-blind, randomized pilot study trial efficacy data
- IDE approved
- Global pivotal study starting Q4 2023

Strategic collaboration

Medtronic

Double-digit revenue share

Pipeline Program

Virtue® SAB

- **Targets >$3B** annual artery disease markets
- Strong 3-year multi-center pilot study safety and efficacy data
- Conditional IDE approved; study expected in 2024

Strategic collaboration

TERUMO

Double-digit revenue share

Expected cash runway into 2H 2026

Major strategic & institutional investors

Medtronic rtw PERCEPTIVE ADVISORS

*AVIM = atrioventricular interval modulation

Orchestra BioMed's Partnership-Enabled Model Benef

Orchestra BioMed
Development

- Secure substantial long-term royalties
- Outsource commercialization
- Multiple pipeline opportunities

Shared Benefits
Innovation

- Improve patient lives
- Accelerate development
- Leverage expertise & resources

Strategic Pa
Commercia

- Enable new growt opportunities
- Outsource development
- Minimize P&L dilution

Advancing High-Impact Pipeline

Product Platforms	Target Indications	Preclinical	Clinical Feasibility	Clinical Pivotal	Partne
Lead Program					
BackBeat CNT™ (AVIM Therapy)	**Hypertension (HTN)** (pacing patients; HTN+P)	IDE Approved			Medtro
	High-Risk HTN[2] (non-pacing patients)				Medtro ROFN
CNT - HF	Heart Failure				
Pipeline Program					
Virtue® Sirolimus AngioInfusion™ Balloon (SAB)	**Coronary In-Stent Restenosis (ISR) – U.S.**	IDE Approved & FDA Breakthrough[3]			TERUM
	Coronary Small Vessel (SV)[1] **- U.S.**	FDA Breakthrough[4]			TERUM
	Coronary SV/ISR - Japan				TERUM

1Will seek to leverage data from HTN+P pilot and pivotal trials to support clinical and regulatory development for High-Risk HTN indication given that age and other demographic factors of the target population are expected to be similar, the type of hypertension treated will likely be isolated systolic hypertension which is co-morbidities are also expected to be common to both target populations. However, there have been no discussions with the FDA or a comparable foreign regulator in this regard. 2 Plan to leverage existing coronary ISR data to support potential Pivotal Study, although there have only been limited discussions with the FD 3Virtue SAB has received Breakthrough Device Designation for the balloon dilatation of the stenotic portion (up to 26 mm length) of a stented coronary artery (in-stent restenosis (ISR)) that is 2.25 to 4.0 mm in diameter, for the purpose of improving lumen diameter; 4Virtue SAB has received Breakthrough Device Designat stenotic portion (up to 26mm in lesion length) of a native coronary artery of 2.0 mm to 2.5 mm in diameter (small coronary arteries), for the purpose of improving lumen diameter;

Highly Accomplished Executive Team & Board

David Hochman
Chairman, CEO, Founder

Darren R. Sherman
President, COO, Director, Founder

Andrew Taylor
Chief Financial Officer

Yuval Mika, Ph.D.
GM & CTO, Bioelectronic Therapies

George Papandreou, Ph.D.
GM & SVP, Focal Therapies

Hans-Peter Stoll, M.D., Ph.D.
Chief Clinical Officer

Avi Fischer, M.D.
SVP, Medical Affairs & Innovation

Bob Laughner
SVP, Regulatory & Quality

Ziv Belsky
VP, Research, Bioelectronic Therapies

Juan Lorenzo
SVP, Product Development, Focal Therapies

Executive Team: | **>300** Years of Experience | **~25** Avg Industry Years | **>100** Product Approvals | **>600** Autho

Independent Board Members

Jason Aryeh

Pamela Connealy

Eric S. Fain, M.D.

Eric

BackBeat CNT™

Atrioventricular interval modulation (AVIM) therapy

AVIM Therapy Overview

Unmet Need

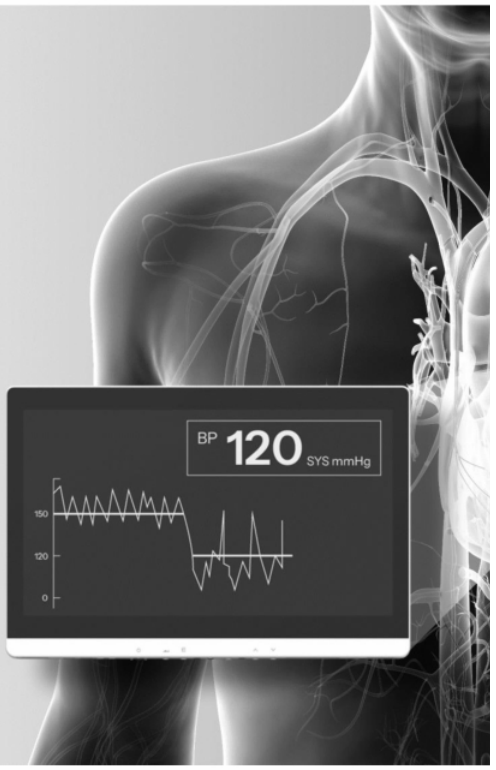
Hypertension is the **leading global risk factor for death** and **#1 comorbidity in the pacemaker population** (over 70%)[1]

Innovation

Pacemaker-delivered therapy designed to **immediately, persistently and substantially lower blood pressure**

Opportunity

Over 750K patients annually receiving pacemakers also have hypertension



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

Large Global Opportunity for Treating Hypertension in Target Populations

HTN + Pacemaker

750,000 patients

~70% of pacemaker patients[1]

>$2 Billion*

High Risk

2,400,000

~0.2% of HTN

>$8 Bill

- Same pacemaker patients, same device implant, and same treating physicians
- Leverageable existing reimbursement structures

- Older patients with uncontro and other significant comorbi
- Similar demographic to pacer high-risk, difficult-to-treat

*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)

Strategic 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]

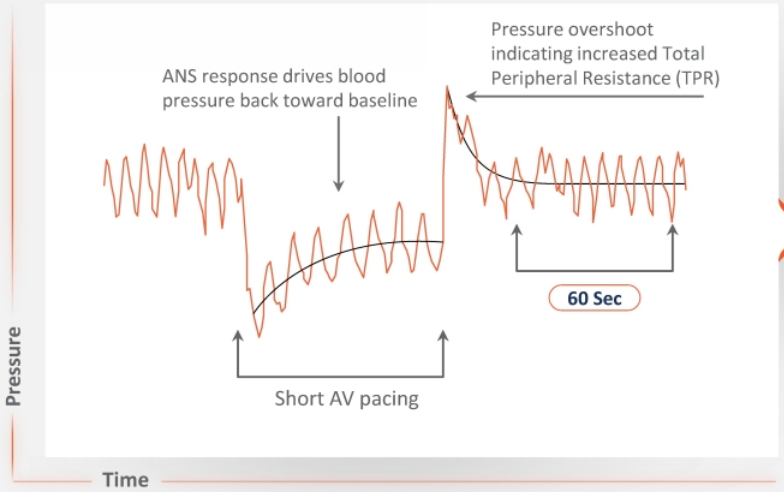
Medtronic

- Global market leader in cardiac pacing th annual revenues
- Providing leading device plus clinical & re resources
- Exclusive global commercial rights for AV pacemaker-indicated patients
- Right of first negotiation to expand globa treatment of non-pacemaker HTN patier
- **$50M equity investment** in Orchestra Bi

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

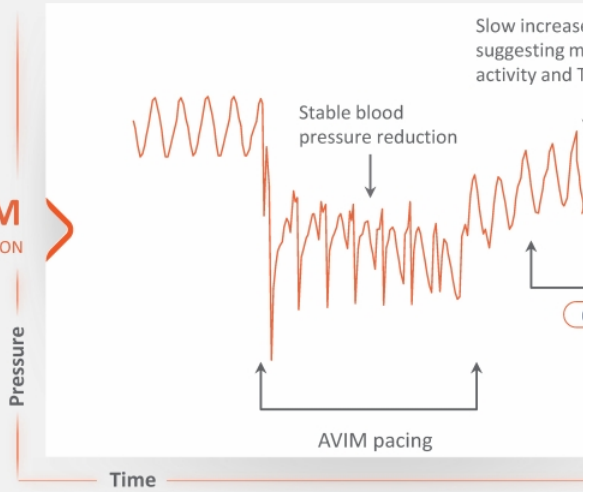
Novel Mechanism of Action Designed to Substantially Reduce Blood Pressure

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



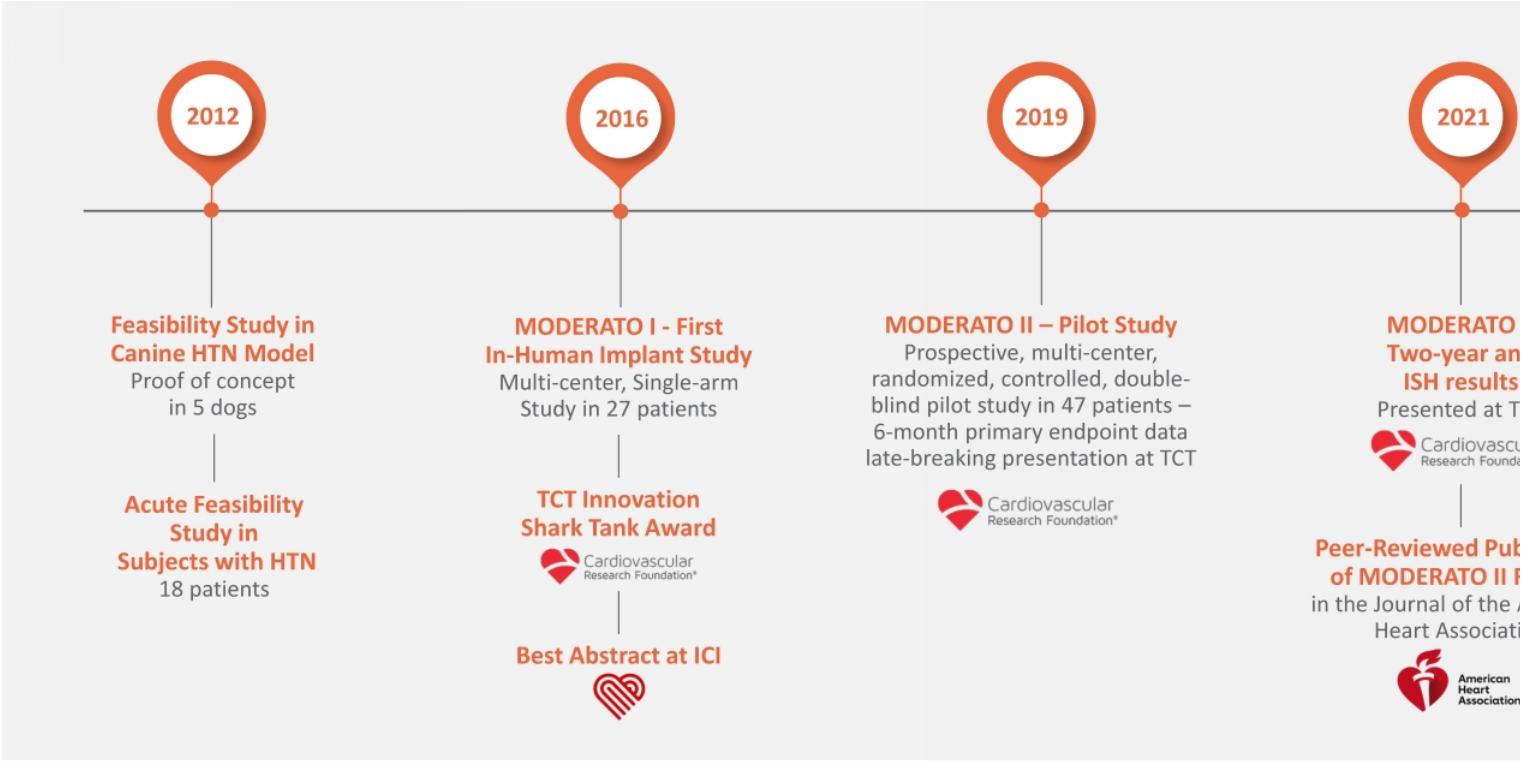
AVIM ACTIVATION

AVIM-Mediated Pressure Pa **Modulate Autonomic Ner System (ANS) Respons**



AV (Atrioventricular), TPR (Total Peripheral Resistance)

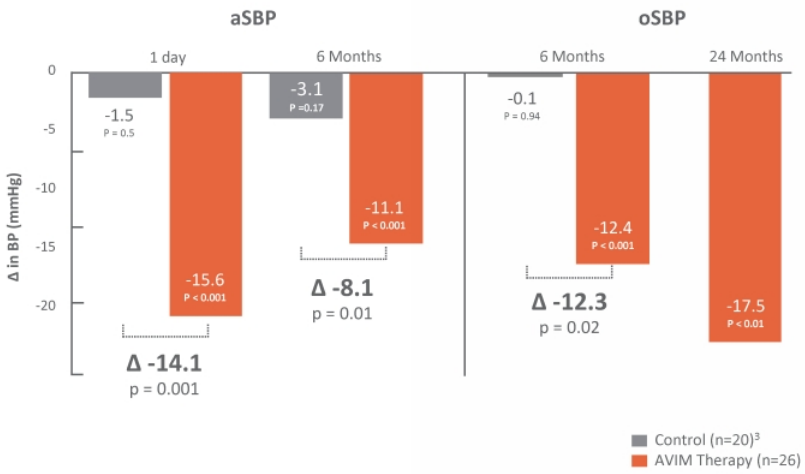
Existing Body of Clinical Data Supporting Efficacy and Safe



MODERATO II Randomized, Double-Blind Results

BackBeat CNT™ (AVIM therapy) showed encouraging results in MODERATO II, a prospective, multi-center, randomized, (BackBeat CNT + medical therapy vs. continued medical therapy), controlled, double-blind, pilot study of pacemaker patients with persistent hypertension

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



-11.1 m
in 24-Hou
at 6 mon

0%
MACE vs.
group at

-17.5 m
in oSBP
at 2 years

85%
of patien
reductior

[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)

BACKBEAT Study Summary

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

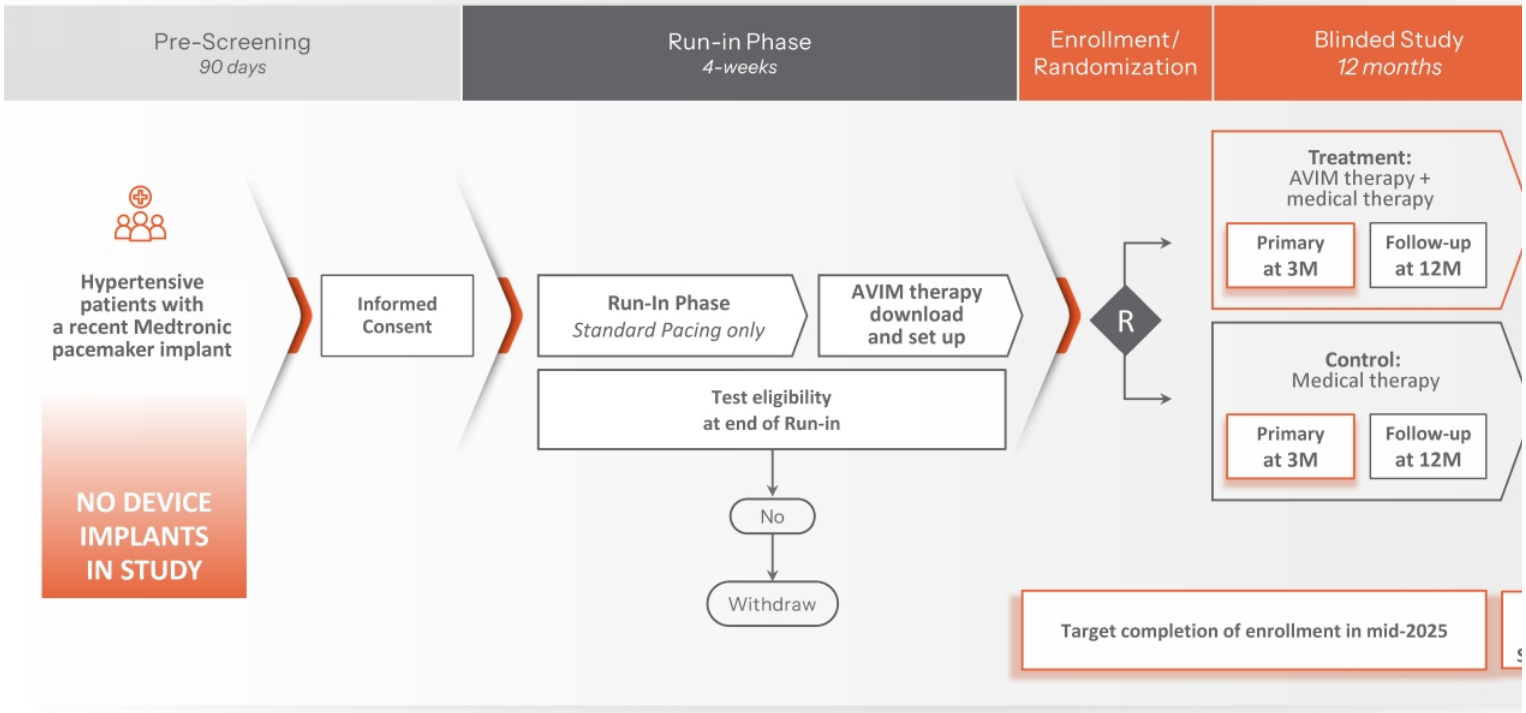
Randomize approximately **500 patients across ~80 study sites** globally

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 rand
- **Safety endpoint:** Freedom from **unanticipated serious adverse device events at 3 months** post randomiz
- **Secondary/additional endpoints**: Double-blind follow-up will continue **through 12 months** to enable colle of additional clinical results and secondary endpoints

BACKBEAT Study Design



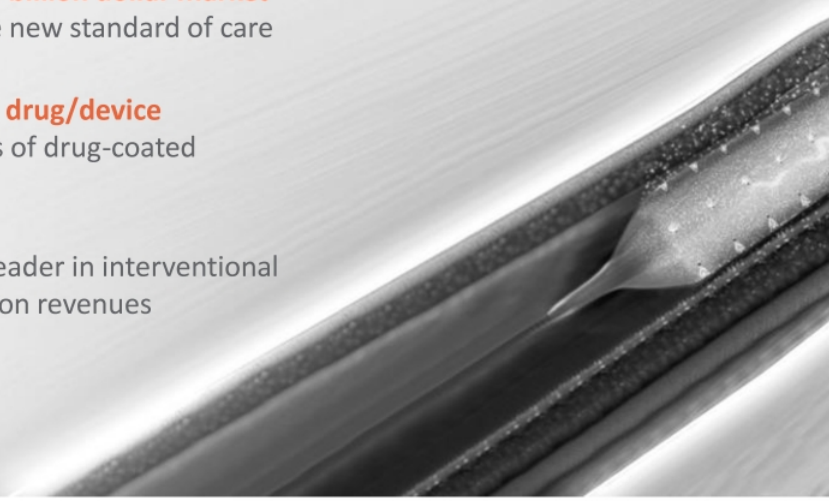
Virtue® Sirolimus AngioInfusion™ Balloon (SAB)

Virtue® SAB overview

Collaboration

Designed to Enable Angioplasty with Protected Delivery of Extended-Release Sirolimus with Nothing Left

- Significant opportunity in an **established multi-billion dollar market migrating toward drug-eluting balloons** as the new standard of care
- Highly-differentiated, best-in-class **non-coated drug/device combination** designed to overcome limitations of drug-coated balloons
- Strategic collaboration with **Terumo**, a global leader in interventional cardiology devices with **>$2.5B** in annual division revenues



Virtue® SAB – Redefining the Class of Drug-Eluting Ball

Microporous AngioInfusion™ Balloon

Angioplasty with Protected Delivery of Extended Release Sirolimus

SirolimusEFR™

1

Precise dose loaded inside balloon system

No coating **= no drug loss in transit**

2

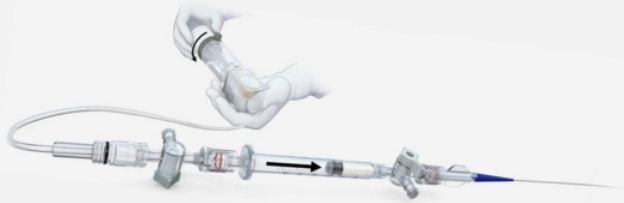
Standard navigation to lesion

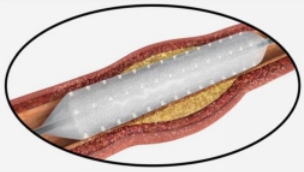
No coating **= no rush to deliver**

3

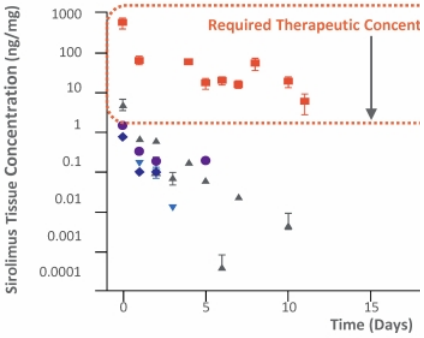
Intended dose delivered during angioplasty

No coating **= no large particulate**





Published Animal Data Demonstrates
Tissue Concentration Through Criti



N = 753 porcine coronary artery segments

Lung, liver quantificati

[1]Granada et al. EuroIntervention 2016;12:740-747

Virtue SAB: Highly Differentiated

	Virtue SAB (SirolimusEFR)	Paclitaxel-coated balloons	Sirolimus ballo
Superior Pharmaceutical Agent for Restenosis Based on 26 DES coronary RCTs	✓	X	✓
Peer-Reviewed Pharmacokinetics Data for >28 days elution	✓	-	X
No Coating No rush to target lesion, no large particulate	✓	X	X
Protected Drug Delivery No drug loss in transit; deliver full/intended dose at time of angioplasty	✓	X	X
No Procedural Time Constraints No limitations in time to deliver balloon to lesion	✓	X	X
Does Not Generate Large Particulates Non-coated drug-eluting balloon	✓	X	X

DES = drug-eluting stents; RCT = randomized control trial

Compelling SABRE Trial Results in Coronary ISR Patient

Virtue® SAB preliminarily demonstrated encouraging safety and efficacy results in patients with coronary in-stent restenosis (ISR) in prospective, multi-center SABRE Trial[1]

0.12mm
LLL at 6-months

2.8%
Target Lesion Failure at 1 year

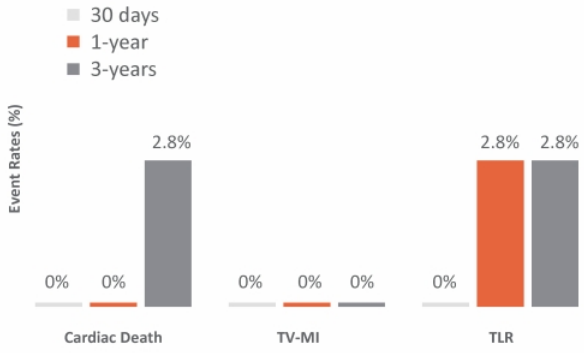
0%
Ne
1 t

Preliminary Efficacy Results Showed Low 0.12mm Late Loss

	Per Protocol[4]
n	36
Reference Vessel Dianeter (RVD) mm[1]	2.52 ± 0.32
Minimum Lumen Diameter (MLD) mm	1.96 ± 0.32
% Diameter Stenosis	22.3 ± 9.4
Change in % Diameter Stenosis	5.2 ± 11.4
Late Lumen Loss (LLL) mm[2]	0.12 ± 0.33
Binary Restenosis[3]	2.8%

[1]RVD reported using Internormal values; [2]Trial primary performance endpoint; [3]Trial secondary performance endpoint (binary restenosis = >50% lumen diameter stenosis). [4]Data is based on per protocol population criteria revised to be consistent with proposed Virtue ISR-US pivotal study population.

Demonstrated Preliminary Safety D with Low Safety Event Rates Out to 3



[1]Verheye et al. JACC Cardiovasc Interv 2017 Oct 23;10(20):2029-2037. DOI: 10.1016/j.jcin.2017.06.021. [2]Granada 3-Year Clinical Results TCT 2018. 3-Year SABRE Trial Clinical Report on file. ***Definitions:*** Target lesion failure (TLF), late lumen loss (LLL), target lesion revascularization (TLR) and Myocardial Infarction (MI).

Key Takeaways and Strategic Priorities

- **Lead program, BackBeat CNT (AVIM therapy) positioned to enter global pivotal trial by end c** strong strategic partner
  - 70% of pacemaker patients also have hypertension, equating to an addressable annual market opportunity of **ap 750,000 patients worldwide valued at over $2 billion**
  - **Medtronic** is the ideal partner as the **global leader in cardiac pacing therapies**
  - Orchestra BioMed has a substantial royalty-based revenue sharing interest in future commercial sales and is expe between **$500-1600 for each AVIM-enabled pacemaker sold**
  - **Significant follow-on market opportunity** in other targeted high-risk populations
- Pipeline program, Virtue SAB represents a **highly differentiated solution for a significant estal market**, with strong strategic partner and an approved IDE for pivotal study in lead coronary ir
- **Novel business model** provides pathway for pipeline expansion and additional strategic collab
- **Expected cash runway into 2H 2026**, beyond target reporting of top-line data readout for BAC

Bringing Medical Innovations to Life Through Partnerships