

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): July 12, 2023

**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.**

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. Additionally, the Company has posted the 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.

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a> 104	<a href="#">Investor Presentation</a> 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: July 12, 2023

# Orchestra BioMed

Corporate  
Presentation  
Q2 2023



# 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 timing of our planned pivotal trials, 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 probability. Actual events and circumstances may be different from those stated or implied in the forward-looking statements. Actual events and circumstances are beyond the control of the Company. Forward-looking statements are subject to a number of risks and uncertainties, including: (i) domestic and foreign business, market, financial, political, and economic conditions; (ii) the ability to realize the anticipated benefits of the business combination; (iii) the timing of regulatory approval of the Company’s product candidates; (iv) the Company’s ability to achieve expected regulatory and business development milestones; (v) the success of competitive products and product candidates; and (vi) the risk factors disclosed under the heading “Item 1A. Risk Factors” in the Company’s quarterly reports filed with the U.S. Securities and Exchange Commission on May 12, 2023, and 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 market. New risks emerge from time to time. Given these risks and uncertainties, we caution against placing undue reliance on these forward-looking statements, which only speak as of the date of this press release. The Company undertakes no obligation to update any of the forward-looking statements contained herein, except as required by law.

# Orchestra BioMed Executive Summary

## Partnership-enabled business model designed to:

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

### BackBeat CNT™

targets >\$10B annual hypertension markets  
Firmware upgrade to existing pacemaker

Statistically significant double-blind,  
randomized preliminary trial efficacy data

Plan to initiate pivotal trial H2 2023

Strategic  
collaboration

**Medtronic**

Double-digit revenue share



### Virtue® SAB

targets >\$3B annual artery disease markets  
Protected sirolimus delivery, non-coated balloon

Strong 3-year multi-center preliminary trial  
safety and efficacy data

Plan to initiate pivotal trial H2 2023

Strategic  
collaboration

**TERUMO**

Double-digit revenue share

## Strong balance sheet and outstanding investors:

**Medtronic**

**rtw**

**PERCEPTIVE  
ADVISORS**

**TERUMO**

# Orchestra BioMed's Partnership-Enabled Model Benefits



## Orchestra BioMed *Development*

Secure substantial  
long-term royalties

Outsource  
commercialization

Multiple pipeline  
opportunities



## Shared Benefits

Improve  
patient lives

Accelerate  
development

Leverage expertise  
& resources



## Strategic Partnership *Commercialization*

Enable new growth  
opportunities

Outsource  
development

Minimize  
P&L dilution

# Strong Collaborations Position Us for Long-term Success

in collaboration with  
**Medtronic**

## BackBeat CNT

Global market leader in pacemakers:  
**>\$1.5B** in annual revenues

Providing leading device plus clinical & regulatory resources

Exclusive global commercial rights for HTN+Pacemaker market

**\$50M equity investment** in Orchestra BioMed

Right of first negotiation to expand global rights  
for the treatment of non-pacemaker HTN patients

### Role and Revenue Share

Sponsor for BackBeat CNT HTN + Pacemaker global pivotal study

**\$500 - \$1,600** per BackBeat CNT-enabled device sold<sup>1</sup> under existing  
reimbursement codes

## Virtue SAB

Global leader in interventional cardiology:  
**>\$2.5B** in annual revenues<sup>2</sup>

**\$30M upfront payment** and potential future milestones

\$5M equity investment in Orchestra BioMed

Responsible for clinical and regulatory expenses, excluding  
study, as well as device supply chain and commercialization

Positioned to become Terumo's flagship therapeutic offering

### Role and Revenue Share

Sponsor for Virtue ISR-US pivotal study

**10-15% royalty PLUS per unit payments** for SirolimusEFR

Retains rights to Virtue SAB for clinical applications outside  
of coronary and vascular interventions



# Advancing High-Impact Pipeline

Product Platforms	Target Indications	Preclinical	Clinical Feasibility	Clinical Pivotal	Partners
BackBeat Cardiac Neuromodulation Therapy (CNT™)	Hypertension (HTN) (pacing patients; HTN+P)				Medtronic
	High-Risk HTN (non-pacing patients)				Medtronic ROFN
	CNT - HF				
Virtue® Sirolimus AngioInfusion™ Balloon (SAB)	Coronary In-Stent Restenosis (ISR)				TERUMO
	Coronary Small Vessel (SV) <sup>1</sup>				TERUMO
	Below-the-Knee (BTK) <sup>1</sup>				TERUMO
SirolimusEFR™ / Microporous Balloon	Urology, orthopedics, oncology & other				

<sup>1</sup>Plan to leverage existing coronary ISR data to support potential Pivotal Study, although there have only been limited discussions with the FDA or a comparable foreign regulator in this regard. <sup>2</sup>Will seek to leverage data from HTN+P pilot and pivotal trials to support clinical and regulatory development for High-Risk demographic factors of the target population are expected to be similar, the type of hypertension treated will likely be isolated systolic hypertension which is predominant in the HTN+P population, and other co-morbidities are also expected to be common to both target populations. However, there have been no foreign regulator in this regard. <sup>3</sup>Virtue 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; <sup>4</sup>Virtue SAB has the balloon dilatation of the de novo 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; <sup>5</sup>Virtue SAB has received Breakthrough Device Designation for the balloon dilatation of the stenotic portion (P-3 segment or distal, below the knee, with reference vessel diameter (RVD) 2.25 - 4.0 mm), for the purpose of improving lumen diameter. All references to clinical study initiations for HTN+P, Coronary ISR and Coronary SV indications are based on ongoing interactions with US FDA regarding approvals, which are required to start clinical studies. With respect to BackBeat CNT for HTN, Orchestra and Medtronic have had initial interactions with the FDA regarding IDE approval and expect to continue interactions regarding clinical trial design and submission requirements ahead of submitting documentation. Pre-CTN discussion with the PMDA is planned for December 2022 with submission for CTN approval anticipated in the second half of 2023. With respect to Virtue SAB for Coronary ISR, Orchestra has been working on IDE approval with the FDA under the breakthrough designation program to define all of the elements to complete the agreed upon work and submit documentation for approval in Q1 of 2023. Orchestra and Terumo have had initial interactions with the PMDA and expect to submit for CTN approval for Coronary ISR and SV studies in the second half of 2023. FDA and PMDA responses are expected approximately 6-8 weeks after regulatory approvals; study enrollment timelines are currently estimated to be 12-18 months for all referenced studies although actual study enrollment timeframes may be longer; final primary endpoint results for all studies are at 12 months. Japan Coronary ISR & SV studies, which are expected to be at 6 months from enrollment.

# 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



**J.C. Simeon**  
SVP, Quality



**Inessa R. Wheeler**  
VP, Marketing



**Bob Laughner**  
VP, Regulatory Affairs



**Stephen A. Zielinski**  
VP, Product Dev.,  
Bioelectronic Therapies



**Ziv Belsky**  
VP, Research,  
Bioelectronic Therapies



Executive Team: | >350 Years of Experience | ~25 Avg Industry Years | >100 Product Approvals | >600 Autho

## Board members

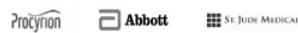
**Jason Aryeh**



**Pamela Connealy**



**Eric S. Fain, M.D.**



**Eric A. Rose, M.D.**



# BackBeat Cardiac Neuromodulation Therapy™ (CNT™)





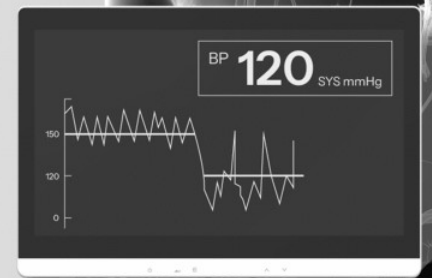
## Unmet Need

- Hypertension is the leading global risk factor for death and #1 comorbidity in pacemaker population, affecting over 70% of patients<sup>1</sup>
- Older population at increased risk for major events & challenges with drug compliance
- Additional opportunity to treat high-risk patients not indicated for a pacemaker



## Innovation

- Bioelectronic therapy **designed to substantially & persistently lower blood pressure**
- **Compatible with standard pacemaker devices** & leverages existing treatment paradigm
- **Compelling clinical data from double-blind randomized study:** significant 8.1 mmHg net reduction in 24-Hr aSBP at 6 months & 17.5 mmHg reduction in oSBP at 2 years<sup>2,3</sup>



# Large Global Opportunity for Treating Hypertension in Target Populations



HTN + Pacemaker

**750,000 patients**

~70% of pacemaker patients

**>\$2 Billion**



High Risk HTN

**2,400,000 patients**

~0.2% of HTN patients

**>\$8 Billion**



**>\$10 Billion Potential Annual Global Market Opportunity**

**>3.1 M Addressable HTN Patients**

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

Medtronic owns **over 50%** of the pacemaker market

\*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); 2Known and well-characterized population, multiple references available; Definition: Hypertension (HTN)

# BackBeat CNT™

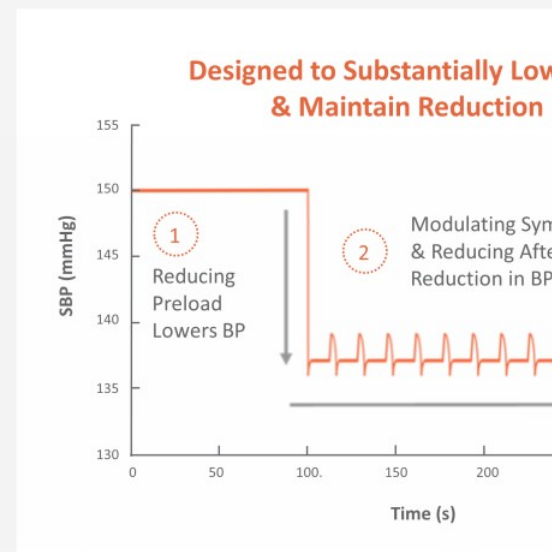
## Designed to Substantially and Persistently Lower Blood Pressure

### Bioelectronic therapy designed to leverage standard dual-chamber pacemaker

- Same implant procedure and lead positions
- Large trained physician pool that already implant pacemakers
- Same target patient population that already need pacemakers
- Leverageable existing reimbursement with robust payment opportunity for novel devices with novel capabilities

### Mechanism of action

- Designed to substantially reduce blood pressure by reducing preload through programmed pacing with short AV delays
- Designed to maintain reduction by modulating sympathetic tone and reducing afterload through programmed variable pressure patterns





# MODERATO II Double-Blind, Randomized Results

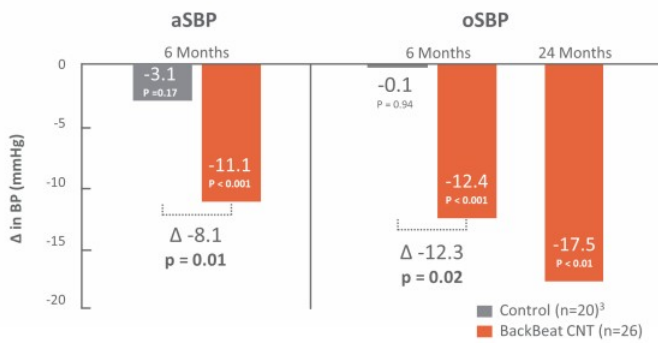
BackBeat CNT™ showed encouraging results in MODERATO II, a prospective, multi-center, randomized, (BackBeat CNT + Medical Therapy vs. Continued Medical Therapy), double-blind, pilot study of pacemaker patients with persistent hypertension

**-11.1 mmHg**  
in 24-Hour  
aSBP at 6  
months

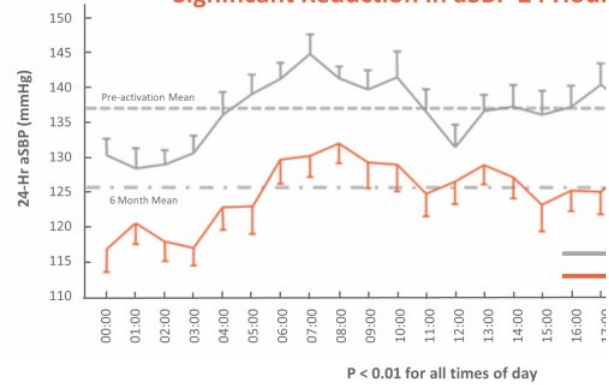
**-17.5 mmHg**  
in oSBP at  
2 years

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

## Significant Reduction in 24-Hr aSBP and oSBP<sup>1,2</sup>



## Significant Reduction in aSBP 24 Hour



<sup>1</sup>Kalaras et al. Journal of the American Heart Association. 2021;10:e020492. doi:10.1161/JAHA.120.020492; <sup>2</sup>Burkoff MODERATO II Study 2-Year Results TCT 2021; <sup>3</sup>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 CNT™ Pivotal Trial Design

## Current anticipated trial design:

Prospective, multi-center, double-blind study investigating the efficacy of BackBeat CNT™ in patients with uncontrolled hypertension (HTN) despite the use of antihypertensive medications, who are indicated for a dual-chamber pacemaker

Inclusion and exclusion criteria for enrollment in the BackBeat CNT Pivotal Study will be similar to the criteria used in the MODERATO II study

Patients will be randomized 1:1 in a double-blinded manner to either active treatment with BackBeat CNT with continued antihypertensive medications or standard pacing only with continued antihypertensive medications

Anticipated primary efficacy and safety endpoints:

- **Efficacy endpoint:** Superiority of treatment as compared to control based on mean change in 24-hour aSBP at 3 months post randomization
- **Safety endpoint:** Safety assessment will include evaluation of differences in composite cardiovascular adverse events (CCAЕ) between groups at 12 months

Enroll patients across ~80 study sites planned for United States, Europe and, potentially, Japan



# Virtue<sup>®</sup> Sirolimus AngioInfusion<sup>™</sup> Balloon (SAB)





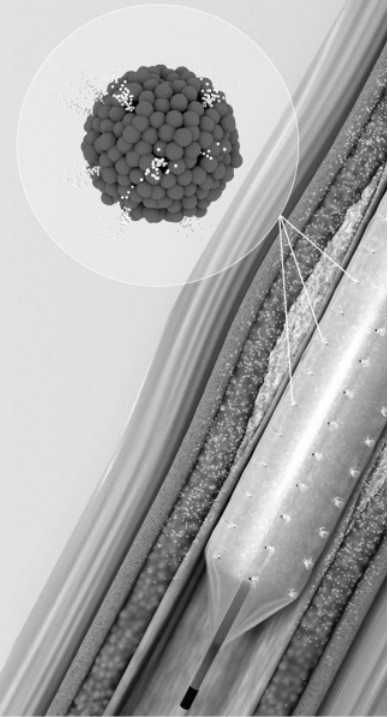
## Unmet Need

- Artery disease is **the leading cause of death** in the U.S. and worldwide
- **Global paradigm shift toward drug-eluting balloons away from stents** for the treatment of coronary indications
- Current treatment options are suboptimal and are associated with long-term risks and complications



## Innovation

- **Highly-differentiated, non-coated drug/device combination** product candidate designed to reduce long-term complications by enabling angioplasty with protected delivery of extended release sirolimus
- **Compelling clinical results in multi-center coronary ISR clinical trial with 3-year follow-up<sup>1</sup>**
- **FDA Breakthrough Device Designation** received for indications in coronary ISR<sup>2</sup>, coronary SV<sup>3</sup> and BTK<sup>4</sup>



# Large Opportunity for Novel AngioInfusion Balloon



## Coronary

**~2,000,000 patients**

ISR, SV De Novo, High Bleed Risk

**>\$1.8 Billion**



## Peripheral

**~1,250,000 patients**

BTK

**>\$1.2 Billion**



**>\$3 Billion**

Annual Global CAD & PAD Market Opportunity

**>3.2M**

Addressable CAD & PAD Patients

Artery disease is the primary cause of death worldwide

Large mature market with suboptimal treatment options for coronary ISR, coronary SV de novo and BTK

Designed to leverage existing treatment paradigms and technologies: sirolimus and balloon angioplasty

# Virtue<sup>®</sup> SAB

Designed to Enable Angioplasty with Protected Sirolimus Delivery while Leaving No Metal Behind

## AngioInfusion<sup>™</sup> Balloon

designed to enable angioplasty with protected drug delivery to dilate vessel, to consistently deliver intended dose and to leave no metal behind

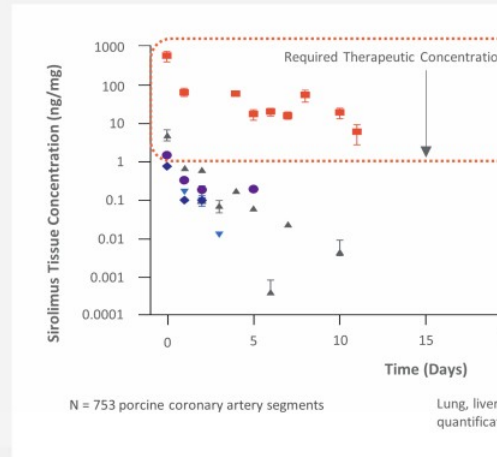


## Protected Delivery/No Drug Coating

- No drug loss in transit
- No time limits on delivery
- No drug coating particulates

## SirolimusEFR<sup>™</sup> Formulation

provided extended focal release of therapeutic concentration through critical healing period ( $\approx 30$  days)<sup>1</sup>



# 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<sup>1</sup>

**0.12mm**  
LLL at 6-months

**2.8%**  
Target Lesion  
Failure at 1 year

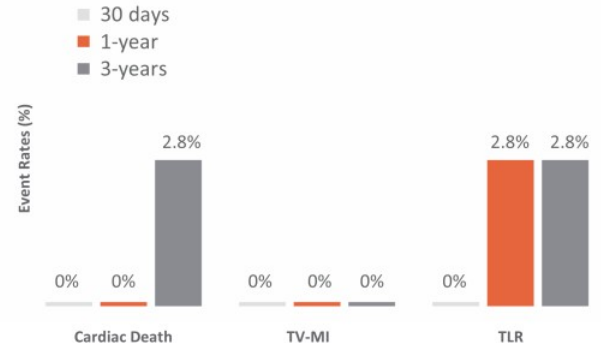
**0%**  
Ne  
11

## Preliminary Efficacy Results Showed Low 0.12mm Late Loss

	Per Protocol <sup>4</sup>
n	36
Reference Vessel Diameter (RVD) mm <sup>1</sup>	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 <sup>2</sup>	0.12 ± 0.33
Binary Restenosis <sup>3</sup>	2.8%

<sup>1</sup>RVD reported using Internal values; <sup>2</sup>Trial primary performance endpoint; <sup>3</sup>Trial secondary performance endpoint (binary restenosis = >50% lumen diameter stenosis). <sup>4</sup>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



# Virtue<sup>®</sup> SAB Coronary ISR US Pivotal Trial

## Randomized Study Arm to Support Regulatory Approval: Single-Layer Coronary ISR

Double-blind, multi-center, prospective, **randomized controlled study** in patients with single-layer coronary ISR

### Key Inclusion

RVD 2.5 to 4.0 mm, <30% DS (vs. RVD 2.5 to 3.5, <40% DS SABRE<sup>1</sup> Trial)

R

Virtue<sup>®</sup> SAB  
N=200

PBA  
N=100

### Primary Endpoint

Target Lesion Failure (CD, TV-MI and TLR) at 12 months

### Statistical Ass

90% powered for s  
Virtue SAB TLF ≤ 15

### Success Consi

Virtue SAB: 2.8% TLF in SABRE trial per p  
PBA: 33-46% TLF at in coronary ISR put

## Non-Randomized Study Arm: Double-Layer Coronary ISR

Prospective, **single-arm, controlled study** in patients with double-layer coronary ISR

### Key Inclusion

RVD 2.5 to 4.0 mm, <30% DS (vs. RVD 2.5 to 3.5, <40% DS SABRE<sup>1</sup> Trial)

Virtue<sup>®</sup> SAB  
N=100

### Primary Endpoint

Target Lesion Failure (CD, TV-MI and TLR) at 12 months

### Study Objectiv

Provide additional i  
of use in double-lay  
without confoundin  
results in single-lay

12-18 Months Enrollment

12 Month Primary Endpoint



# 2023 - Anticipated Milestones

## Planned **Regulatory** Milestones

### BackBeat CNT

- HTN + Pacemaker FDA IDE Approval

### Virtue SAB

- Virtue-ISR US FDA IDE Approval
- Japan PMDA CTN **Coronary ISR** Approval<sup>1</sup>
- Japan PMDA CTN **Coronary SV** Approval<sup>1</sup>

## Planned **Clinical** Milestones

### BackBeat CNT

- HTN + **Pacemaker** 1<sup>st</sup> Pt. Enrollment

### Virtue SAB

- **Virtue-ISR US** 1st Pt. Enrollment

### CNT-HF and SirolimusEFR Program Updates

# Bringing Medical Innovations to Life Through Partnerships

## Partnership-Enabled Business Model & Accomplished Leadership Team

Designed to accelerate innovation to patients, enable pipeline expansion and drive strong partner and shareholder value

Highly experienced team with proven track record of innovation and execution

## Two Programs Targeting Large Markets Supported by Promising Trial Data Entering Pivotal Trials

### BackBeat CNT™

- >\$10 billion annual market
- Randomized, controlled study shows efficacy potential
- Collaboration with **Medtronic**

### Virtue® SAB

- ~\$3 billion annual market
- 3-year pilot study results show potential safety & efficacy
- Partnered with **TERUMO**

Strong & Com Strateg Investc

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