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): March 13, 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. 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 8.01 Other Events.

The Company considers its exposure to Silicon Valley Bank ("SVB") as *de minimis*, given that less than one percent of its total cash, cash equivalents and marketable securities are held at SVB.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Investor Presentation.

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 P. Hochman
Name: David P. Hochman
Title: Chief Executive Officer

Date: March 13, 2023

Exhibit 99.1


Orchestra BioMed
Orchestra BioMed
Corporate Presentation
Q1 2023
Bringing medical innovation to life

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.

This presentation contains forward-looking statements within the meaning of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws, including, without limitation, statements relating to our expected financial runway, 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 often identified by the use of words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words, or similar expressions or variations, although not all forward-looking statements contain these words. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those identified under the heading "Risk Factors—Risks Related to Orchestra's Business and New Orchestra Following the Business Combination" in the definitive proxy statement/prospectus of Health Sciences Acquisitions Corporation 2 (Orchestra BioMed's predecessor) filed with the U.S. Securities and Exchange Commission pursuant to Rule 424(b)(3) on December 16, 2022 and in our other filings with the SEC. These risks are not exhaustive. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date hereof and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Orchestra BioMed Executive Summary

Partnership-enabled business model designed to **accelerate innovation** to patients, drive strong partner and shareholder value and yield **exceptional future profitability**

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 H1 2023

Strategic collaboration

TERUMO

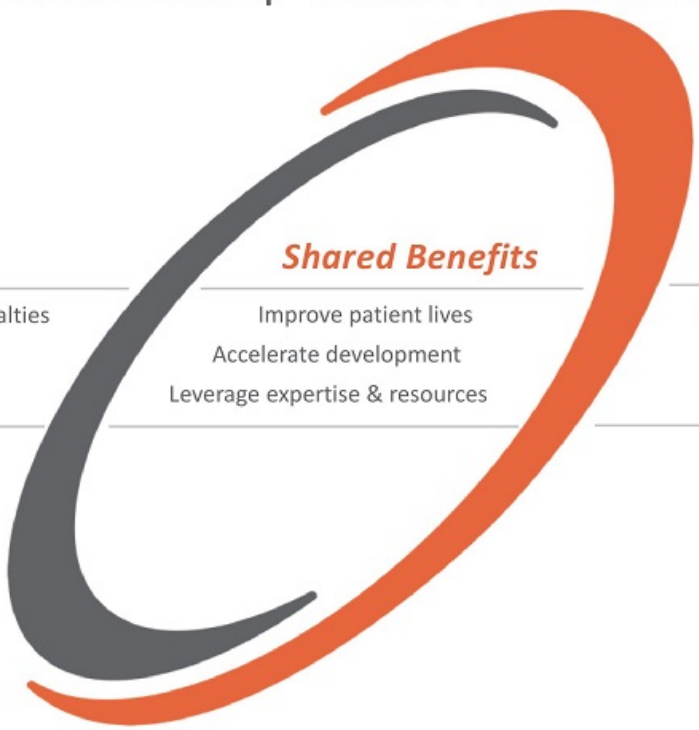
Double-digit revenue share

Strong balance sheet and outstanding investors

Medtronic rtw PERCEPTIVE ADVISORS TERUMO

Orchestra BioMed

Orchestra BioMed's Partnership-enabled Model Benefits All



Orchestra BioMed

Development

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

Shared Benefits

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

Strategic Partners

Commercialization

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

Orchestra BioMed

Highly Accomplished Executive Team & Board

David Hochman
Chairman, CEO, Co-Founder

Darren R. Sherman
President, COO, Director, Co-Founder

Michael Kaswan
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

Juan Lorenzo
VP, Product Dev., Focal Therapies

Executive Team: >250 Years of Experience, ~25 Avg Industry Years, >100 Product Approvals & >600 Authored Patents

Jason Aryeh
Board Member

Pamela Connealy
Board Member

Eric S. Fain, M.D.
Board Member

Eric A. Rose, M.D.
Board Member

Geoffrey W. Smith
Board Member

Advancing a High-Impact Pipeline

Product Platforms	Target Indications	Preclinical	Clinical Feasibility	Clinical Pivotal	Partner	Study Sponsor	Next Milestones & Expected Timing[6]
BackBeat Cardiac Neuromodulation Therapy (CNT™)	*Hypertension (HTN) (pacing patients; HTN+P)*				Medtronic	Orchestra BioMed	Global Pivotal Study Start H2 2023
	High-Risk HTN (non-pacing patients)				Medtronic ROFN		Will Seek to Leverage Data from HTN+P[2]
CNT - HF	*Heart Failure*						Acute Clinical Data 2023 Potential Chronic Study Start 2024
Virtue® Sirolimus AngioInfusion™ Balloon (SAB)	*Coronary In-Stent Restenosis (ISR)*	FDA Breakthrough[3]			TERUMO	Orchestra BioMed	US Pivotal Study Start H1 2023 Japan Pivotal Study Start H1 2024
	Coronary Small Vessel (SV)[1]	FDA Breakthrough[4]			TERUMO	TERUMO	Japan Pivotal Study Start H1 2024 US Pivotal Study Start 2024
	Below-the-Knee (BTK)[1]	FDA Breakthrough[5]			TERUMO	TERUMO	Global BTK Study Start 2024/2025
SirolimusEFR™ / Microporous Balloon	*Urethral Strictures & BPH Osteoarthritis*						Preclinical Development Milestones 2023/2024

[1]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. [2]Will 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 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 discussions with the FDA or a comparable foreign regulator in this regard. [3]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; [4]Virtue SAB has received Breakthrough Device Designation for 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; [5]Virtue SAB has received Breakthrough Device Designation for the balloon dilatation of the stenotic portion (up to 18 mm length) of an infrapopliteal artery (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 IDE approvals or Japan PMDA regarding CTN 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 for approval in the second half of 2023. A 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 necessary for IDE approval and Orchestra expects 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 30 days following formal submissions; clinical study enrollment is expected to begin 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 from enrollment with the exception of Japan Coronary ISR & SV studies, which are expected to be at 6 months from enrollment.

Orchestra BioMed

BackBeat Cardiac Neuromodulation Therapy (CNT™)

Orchestra BioMed™

BackBeat CNT™ Overview

Opportunity

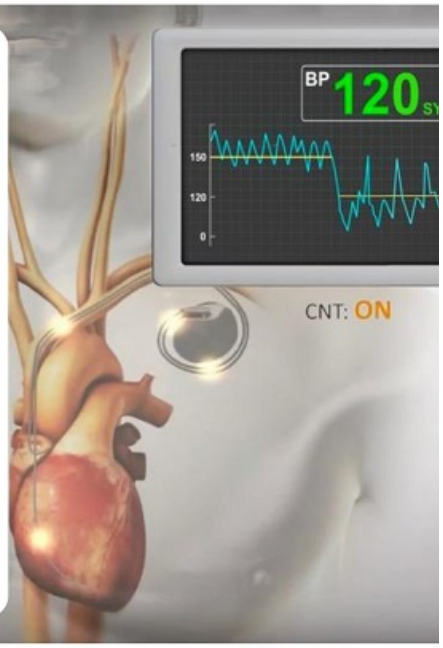
- ***Hypertension is #1 comorbidity in pacemaker population affecting over 70% of patients***[1]
- Older population at ***increased risk for major events*** & challenges with drug compliance

Innovation

- Bioelectronic therapy ***designed to substantially & persistently lower blood pressure***
- ***Compatible with standard pacemaker device*** & 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[2,3]

Collaboration with Medtronic

- Global pacemaker leader providing technology and development/clinical/regulatory support for Orchestra BioMed-sponsored global pivotal trial
- Following regulatory approval, Medtronic has exclusive global rights to commercialization in the pacemaker-indicated patient population with ***double-digit revenue sharing for Orchestra BioMed*** of BackBeat CNT-enabled pacemaker sales



[1]Company estimates based on published sources, including National Inpatient Survey (NIS) and National Health and Nutrition Examination Survey (NHANES); [2]Kalaras et al. Journal of the American Heart Association. ahajournals.org/doi/10.1161/JAHA.120.020492; [3]Burkhoff. MODERATO II Study 2-Year Results TCT 2021;. ***Definitions:*** Ambulatory Systolic Blood Pressure (aSBP) and Office Systolic Blood Pressure (oSBP)

Orchestra BioMed™

Large Global Opportunity for Treating Hypertension in Target Populations

>$10 Billion Potential Annual Global Market Opportunity*

HTN + Pacemaker

- Over 70% of pacemaker patients have HTN[1]
- Older, co-morbid population at increased risk of major events[2]

High Risk HTN (Non-pacemaker)

- Older patients with isolated systolic hypertension (ISH) and comorbidities

>3.1 M Addressable HTN Patients

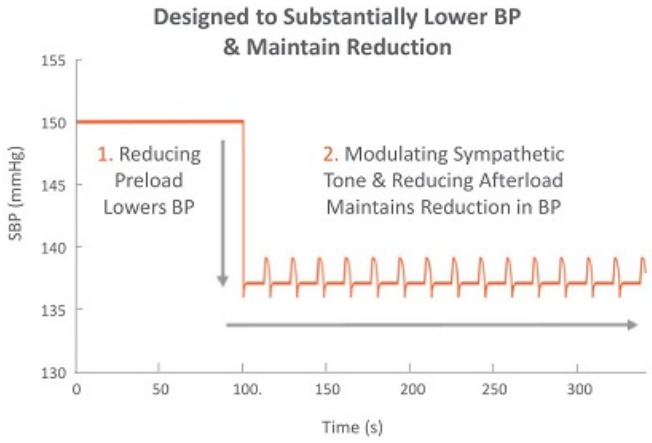
*Total addressable market in 2025 based on company estimates; [1]Company estimates based on published sources, including National Inpatient Survey (NIS) and National Health and Nutrition Examination Survey (NHANES); [2]Known and well-characterized population, multiple references available; ***Definition:*** Hypertension (HTN)

Orchestra BioMed™

BackBeat CNT™

Designed to Substantially and Persistently Lower Blood Pressure

- Bioelectronic therapy designed to leverage standard rhythm management device procedures (dual-chamber pacemaker)
  - Same implant procedure and lead positions
  - Large trained physician pool
  - Same target patient population
  - Leverageable existing reimbursement
- 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



Orchestra BioMed™

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

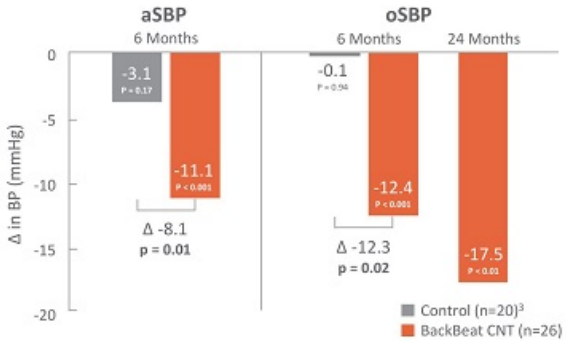
-11.1 mmHg in 24-Hour aSBP at 6 months

-17.5 mmHg in oSBP at 2 years

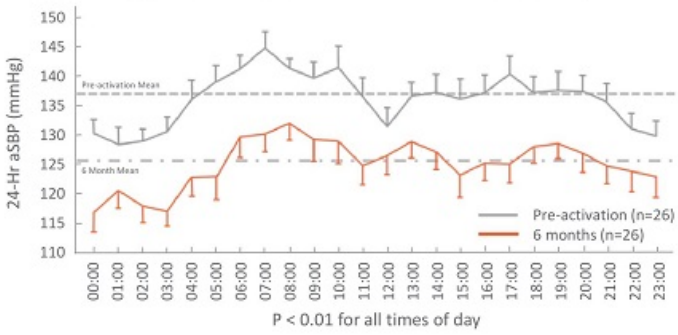
0% MACE vs. 9.5% in control group at 6 months

85% of patients with reduction in aSBP

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



Significant Reduction in aSBP 24 Hours a Day



[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 CNT™ Medtronic Collaboration

Aligned with Global Market Leader in Pacemakers and Device-based Hypertension Treatment

- Medtronic is the global leader in pacemakers
  - >$1.5 billion annual pacemaker revenues[1]
- Key Terms: (Hypertension + Pacemaker population)
  - Orchestra BioMed drives and finances development as sponsor of global pivotal trial
  - Medtronic provides certain development/clinical/regulatory resources funded by Orchestra to support integration into a Medtronic pacemaker and execution of the pivotal trial
  - Medtronic has exclusive global rights for commercialization upon regulatory approval
  - Orchestra is expected to receive between $500 and $1,600 per BackBeat CNT enabled device sold based on a formula of the higher of (1) a fixed dollar amount per device (amount varies materially on a country-by-country basis) or (2) a percentage of sales.
  - BackBeat CNT enabled devices expected to be ***sold under existing reimbursement codes***.
  - Medtronic has a right of first negotiation to expand its global rights to BackBeat CNT for the treatment of HTN patients not indicated for a pacemaker
- $50 million equity investment in Orchestra BioMed

Medtronic

Orchestra BioMed™

[1]Based on MDTs consolidated financial results for the fiscal year ended April 29, 2022

BackBeat CNT™ Pivotal Trial Design

Current anticipated trial design:

- Randomization of ~650-750 patients with uncontrolled HTN despite medical therapy 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 the BackBeat CNT-with continued antihypertensive drug treatment **or** to standard pacing-only with continued antihypertensive drug therapies
- 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:*** Non-inferiority between the treatment and control groups comparing Major Adverse Cardiovascular Events (MACE) at 12 months post randomization
- Enroll patients across ~80 study sites planned for United States, Europe and, potentially, Japan

Orchestra BioMed™

Virtue® Sirolimus AngioInfusion™ Balloon (SAB)

Orchestra BioMed™

Virtue® SAB Overview

Opportunity

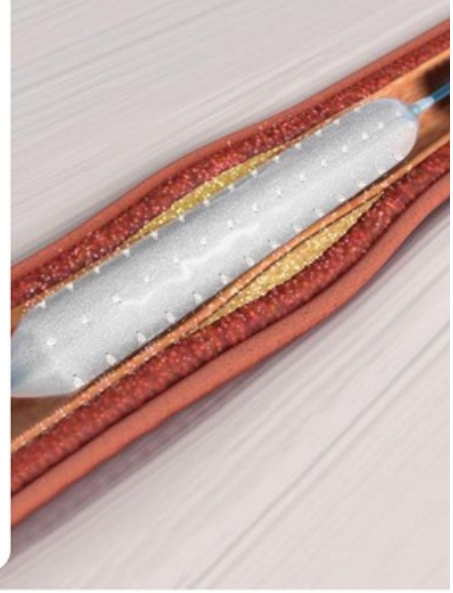
- Significant need for "leave nothing behind" treatment for coronary and peripheral indications representing an ***>$3B global market opportunity***[1]
- Drug-eluting stents (DES) carry risks of long-term restenosis and late thrombosis; require extended dual antiplatelet therapy; not effective/approved for select patients/lesions

Innovation

- ***Highly-differentiated, non-coated drug/device combination*** product candidate designed to enable angioplasty with protected delivery of extended release sirolimus
- ***Compelling clinical results in multi-center coronary ISR clinical trial*** with 3-year follow-up[2]
- ***FDA Breakthrough Device Designation*** received for indications in coronary ISR[3], coronary SV[4] and BTK[5]

Partnership with TERUMO

- ***Global commercial leader*** with >$2.5B annual interventional cardiology revenue responsible for commercializing ***Virtue SAB as flagship therapeutic offering***
- Collaboration driving multi-indication pivotal trial program starting with coronary ISR
- ***Orchestra BioMed to receive double-digit royalties and per unit drug payments***



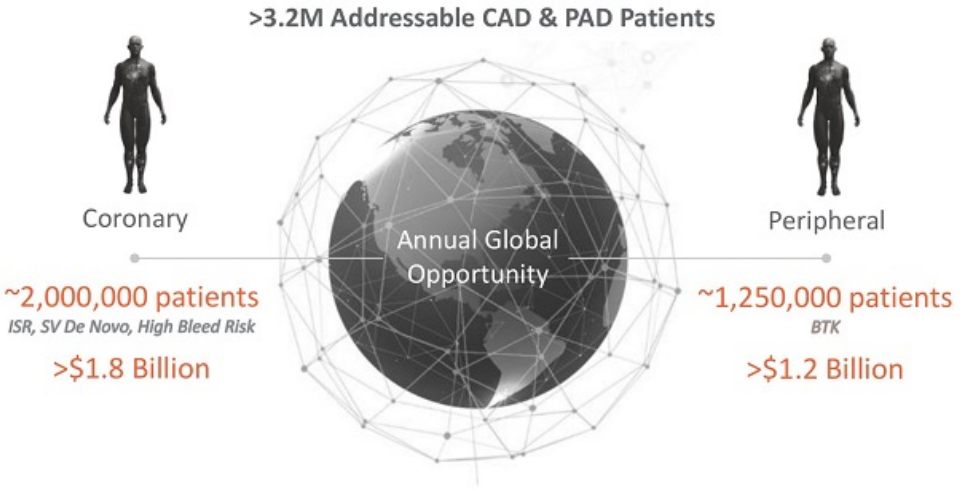
[1]Total addressable market is 2025 market data based on company estimates; [2]von Birgelen et al. JACC Vol. 59, No. 15, 2012 April 10, 2012:1350–61; Virtue SAB has received Breakthrough Device Designation for: [3]The balloon dilatation of the stenotic portion (up to 26 mm length) of a stented coronary artery (in-stent restenosis (ISR)) that is 2.25 to 4.0 mm in diameter, for the purpose of improving lumen diameter; [4]The balloon dilation 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; [5]The balloon dilatation of the stenotic portion (up to 18 mm length) of an infrapopliteal artery (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.

Orchestra BioMed™

Large Opportunity for Leave Nothing Behind Solution

>$3 Billion Annual Global CAD & PAD Market Opportunity*

- Artery disease is the primary cause of death worldwide
- Large mature market with significant unmet need
  - Suboptimal treatments for coronary ISR, coronary SV *de novo* and BTK
- Designed to leverage existing treatment paradigm & established technologies: sirolimus and balloon angioplasty



*Total addressable market in 2025 based on company estimates; ***Definitions:*** Coronary Artery Disease (CAD), Peripheral Artery Disease (PAD), In-stent Restenosis (ISR), Small Vessel (SV, ≤2.5mm), High bleeding Risk De Novo (>2.5mm), Below-the-Knee (BTK, Rutherford 3-6, w/out severe comorbidities).

Orchestra BioMed™

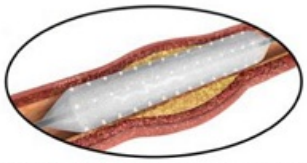
Virtue® SAB

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

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

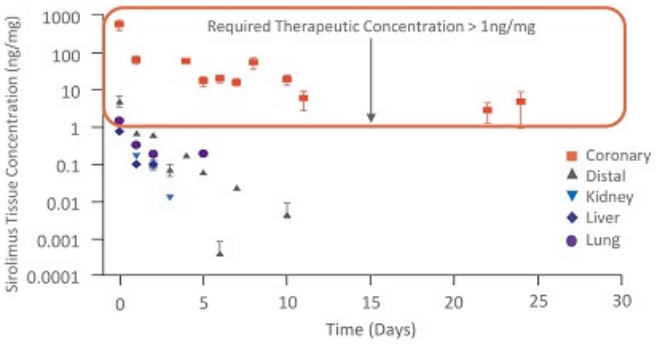
Protected Delivery/No Drug Coating

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



Inflated to deliver dose through micropores

SirolimusEFR™ Formulation provided extended focal release of therapeutic levels of sirolimus through critical healing period (≈30 days)[1]



N = 753 porcine coronary artery segments

Lung, liver & kidney below level of assay quantification (0.1 ng/mg) in <1 week

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

Orchestra BioMed™

Compelling SABRE Trial Results in Coronary ISR Patients

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

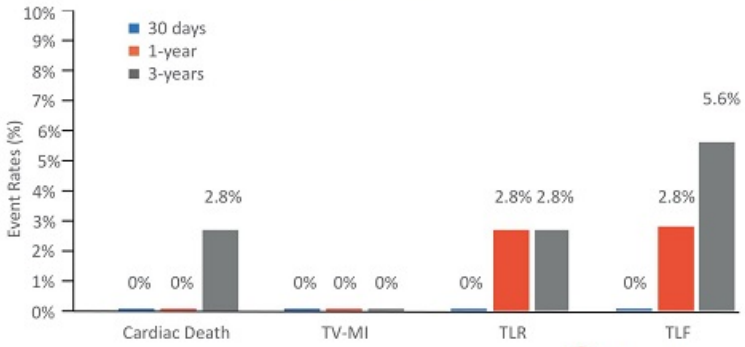
0% New TLR between 1 to 3 years

Preliminary Efficacy Results Showed Low 0.12mm Late Loss

	Per Protocol[4]
n	36
Reference Vessel Diameter (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.

Preliminarily Demonstrated Safety with Low Event Rates Out to 3 Years[2]



[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).

Orchestra BioMed™

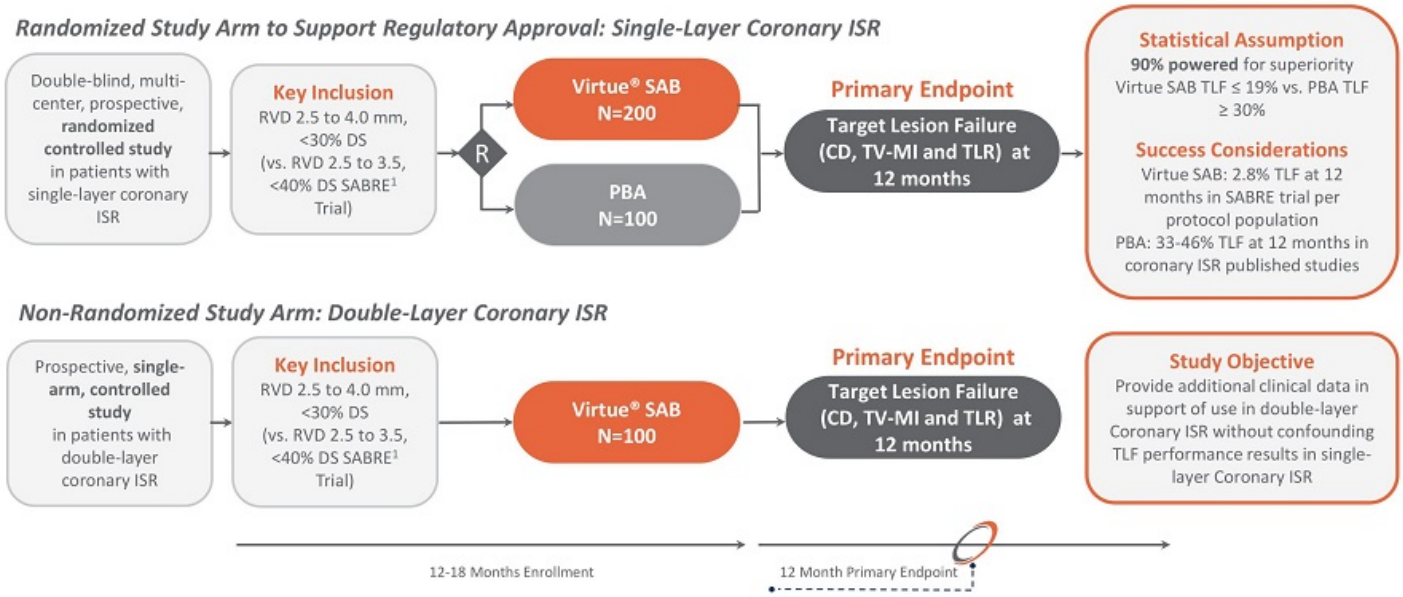
Virtue® SAB Terumo Partnership

Multinational Market Leader Provides Global Commercial Reach and Long-Term Alignment

- Terumo is a global leader with >$2.5 billion annual interventional cardiology revenues[1]
- Virtue SAB positioned to become Terumo's **flagship** therapeutic offering with potential to drive significant future growth
- Key Terms:
  - $30 million upfront and potential future clinical and regulatory milestones
  - $5 million equity investment in Orchestra BioMed
  - Terumo responsible for clinical and regulatory expenses, excluding Virtue ISR-US study which Orchestra BioMed is sponsoring
  - Terumo responsible for device supply chain and commercialization expenses
  - Orchestra BioMed receives 10-15% royalty PLUS per unit payments for SirolimusEFR™ as exclusive supplier
  - Orchestra BioMed retains rights to Virtue SAB in all clinical applications outside of vascular indications

[1]Based on Terumo's consolidated financial results for the fiscal year ended March 31, 2022

Virtue® SAB – Coronary ISR US Pivotal Trial



[1]Verheye S. JACC Cardiovasc Interv. 2017; 10: 2029-37. ***Definitions:*** Coronary In-stent Restenosis (ISR), Diameter Stenosis (DS), Plain Balloon Angioplasty (PBA). Revised per protocol analysis set meets the criteria of the proposed In-Stent Restenosis IDE study population.

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2023 - Anticipated Milestones

H1 2023

Virtue SAB – Coronary ISR

- Virtue ISR-US FDA IDE Approval
- 1st Pt. Enrollment

H2 2023

BackBeat CNT – HTN + Pacemaker

- FDA IDE Approval
- 1st Pt. Enrollment

CNT-HF

- Acute Clinical Results

Virtue SAB – Coronary ISR

- Japan PMDA CTN Approval[1]

Virtue SAB – Coronary SV

- Japan PMDA CTN Approval[1]

SirolimusEFR

- Preclinical Feasibility Results[2]

BackBeat CNT / CNT-HF
Virtue SAB
SirolimusEFR

[1]Timing estimated and subject to Terumo execution since Terumo controls development of Virtue SAB for SV indication and for ISR in Japan
[2]Assumes focus on a device/drug combination balloon-based solution targeting indication such as urethral strictures or BPH

Orchestra BioMed™

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 Balance Sheet and Committed Strategic and Financial Investors

Medtronic

rtw

PERCEPTIVE ADVISORS

TERUMO

Partnership-Enabled Business Model

Orchestra BioMed™

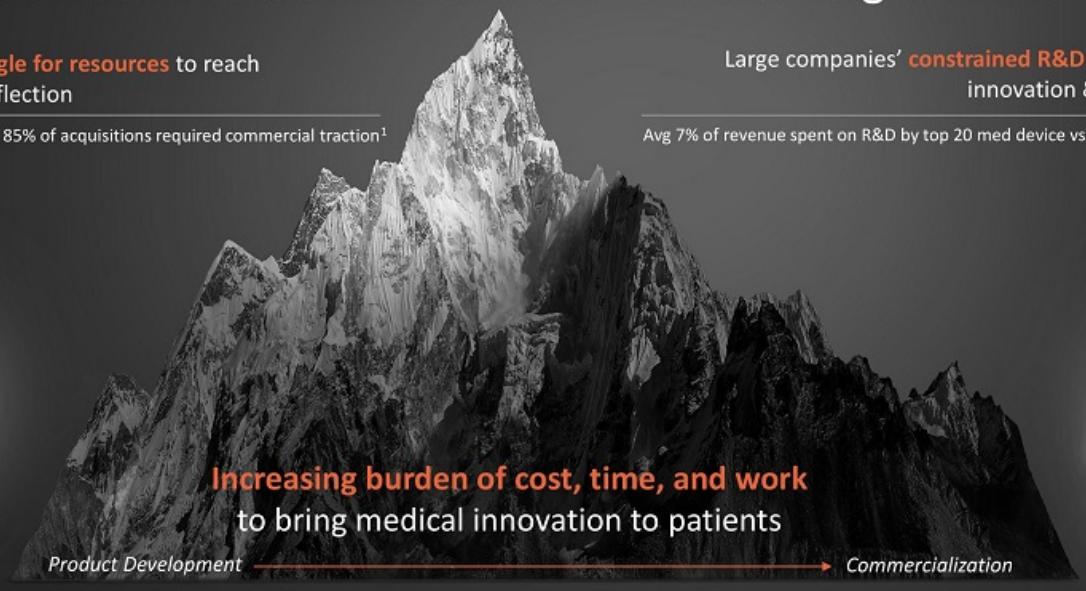
Significant Barriers Prevent Innovation From Reaching Patients

Startups often **struggle for resources** to reach commercial value inflection

Avg $60M funding needed, 85% of acquisitions required commercial traction[1]

Large companies' **constrained R&D budgets** limit innovation & acquisitions

Avg 7% of revenue spent on R&D by top 20 med device vs. 20% in pharma[2,3]



Increasing burden of cost, time, and work
to bring medical innovation to patients

Product Development → *Commercialization*

[1]Pitchbook – Analysis of 430 companies since 2015 that completed at least Series B financing [2]SVB Healthcare Report 2019 [3]Capital IQ

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Orchestra BioMed Can Accelerate Innovation to Patients

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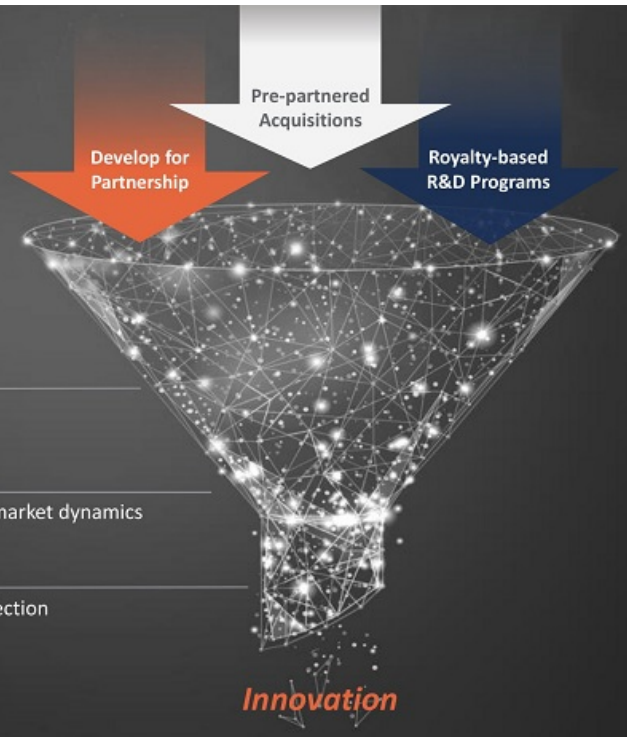
Selecting Optimal Opportunities



Key Pipeline Criteria

Large Market with Unmet Needs

Large market, significant unmet needs, established distribution channels

Potential for High Impact

Designed to improve standard of care, fit existing treatment paradigm, disrupt market dynamics

Favorable for Partnering

Significant differentiation, attractive economics for partnership, durable IP protection

Orchestra BioMed™

Orchestrating Innovation

Accomplished Leadership Team

Created Pipeline, Pioneered Business Model and Established Partnerships

Orchestra BioMed™