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

FORM 8-K/A

Amendment No. 1

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	**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. ☐

Explanatory Note

This Current Report on Form 8-K/A amends the Current Report on Form 8-K previously filed by Orchestra BioMed Holdings, Inc. on July 12, 2023 (the "Original 8-K") to correct the investor presentation filed as Exhibit 99.1 (the "Investor Presentation"). The revised Investor Presentation is attached hereto as Exhibit 99.1 and supersedes Exhibit 99.1 to the Original 8-K in its entirety. No other changes to the Original 8-K have been made.

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.

Exhibit No.	Description
99.1	Investor Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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

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 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 are difficult impossible to predict and may differ from assumptions. Many actual events circumstances are beyond the control of the Company. These forward-look statements are subject to a number of risks and uncertainties, including change domestic and foreign business, market, financial, political, and legal conditions; fai to realize the anticipated benefits of the business combination; risks related regulatory approval of the Company's product candidates; the timing of, and Company's ability to achieve expected regulatory and business milestones; the imp of competitive products and product candidates; and the risk factors discussed un the heading "Item 1A. Risk Factors" in the Company's quarterly report on Form 1 filed with the U.S. Securities and Exchange Commission on May 12, 2023 as updated any risk factors disclosed under the heading "Item 1A. Risk Factors" in the Compa subsequently filed quarterly reports on Form 10-Q.

The Company operates in a very competitive and rapidly changing environment. N risks emerge from time to time. Given these risks and uncertainties, the Comp cautions against placing undue reliance on these forward-looking statements, wh only speak as of the date of this press release. The Company does not plan undertakes no obligation to update any of the forward-looking statements m 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 profitability

BackBeat CNT™

targets >$10B annual hypertension markets

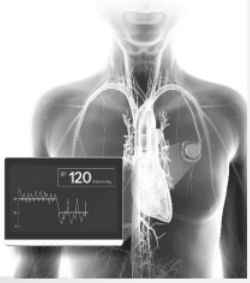
Firmware upgrade to existing pacemaker

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

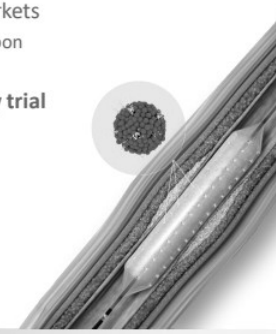
Protected sirolimus delivery, non-coated balloon

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

Plan to initiate pivotal trial 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 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

Strong Collaborations Position Us for Long-term Success

BackBeat CNT

in collaboration with Medtronic

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[1] under existing reimbursement codes

Virtue SAB

in collaboration with TERUMO

Global leader in interventional cardiology:
>$2.5B in annual revenues[2]

$30M upfront payment and potential future milestones

$5M equity investment in Orchestra BioMed

Responsible for clinical and regulatory expenses, excluding Virtue ISR-US 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

*Total addressable market in 2025 based on company estimates; [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. [2] Based on Terumo's consolidated financial results for the fiscal year ended March 31, 2022

Advancing High-Impact Pipeline

Product Platforms	Target Indications	Preclinical	Clinical Feasibility	Clinical Pivotal	Partner	Study S
BackBeat Cardiac Neuromodulation Therapy (CNT™)	Hypertension (HTN) (pacing patients; HTN+P)				Medtronic	Orche
	High-Risk HTN (non-pacing patients)				Medtronic ROFN	
CNT - HF	Heart Failure					
Virtue® Sirolimus AngioInfusion™ Balloon (SAB)	Coronary In-Stent Restenosis (ISR)	FDA Breakthrough[3]			TERUMO	Orche
	Coronary Small Vessel (SV)[1]	FDA Breakthrough[4]			TERUMO	TERU
	Below-the-Knee (BTK)[1]	FDA Breakthrough[5]			TERUMO	TERU
SirolimusEFR™ / Microporous Balloon	Urology, orthopedics, oncology & other					

[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 oth 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 comparal 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 Designa 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 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 20 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 Orc 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 submissi 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 excepti 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

Bill Little
EVP, Corporate & Strategy

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 Lorenz
VP, Product D
Focal Therapi

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

Board members

Jason Aryeh

Pamela Connealy

Eric S. Fain, M.D.

Eric A. Rose, M.D.

Geoffrey W. Smith

BackBeat Cardiac Neuromodulation Therapy™ (CNT ™)

BackBeat CNT™ Overview

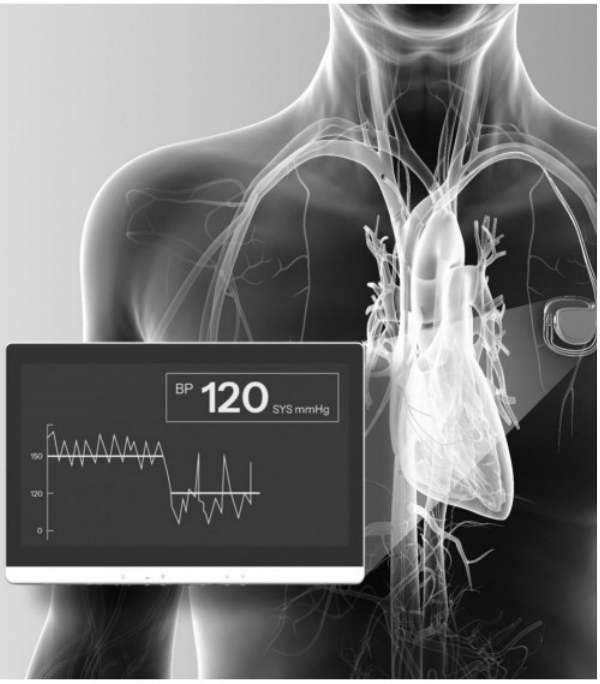
Collaboration with Medtr

Unmet Need

- **Hypertension is the leading global risk factor for death and #1 comorbidity in pacemaker population, affecting over 70% of patients**[1]
- 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[2,3]



[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)

Orches Bio

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*

>3.1M Addressable HTN Patients

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

Medtronic is the global pacemaker leader with >50% of U.S. market share

*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™

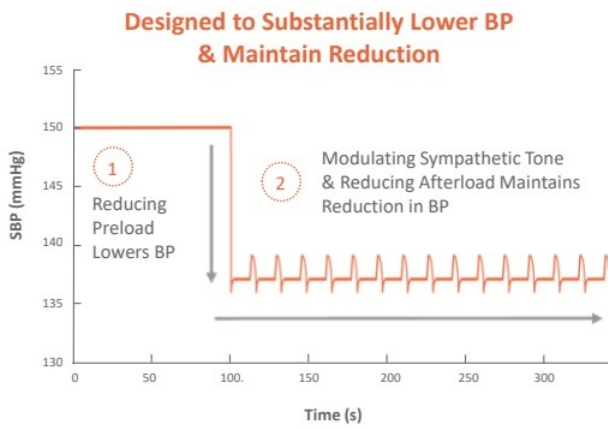
Designed to Substantially and Persistently Lower Blood Pressure

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

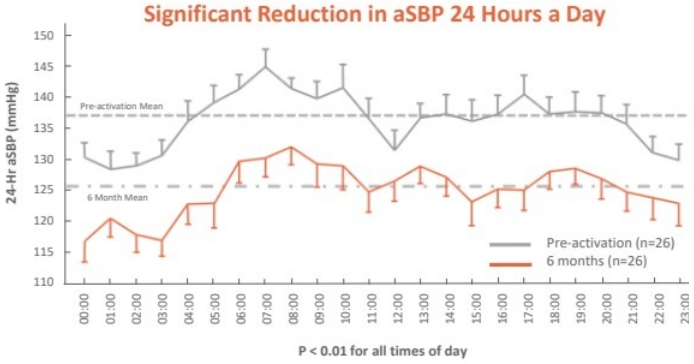
-17.5 mmHg in oSBP at 2 years

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

85% of patients w reduction in aSBP

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

Significant Reduction in aSBP 24 Hours a Day



P < 0.01 for all times of 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)

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 (CCAE) between groups at 12 months

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

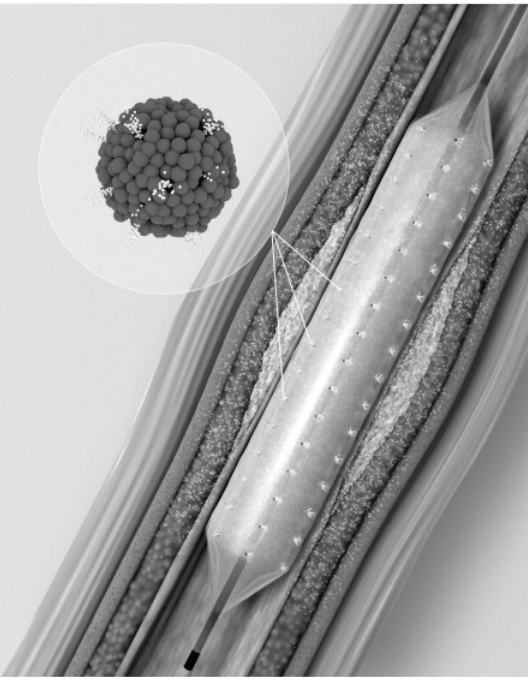
Virtue® Sirolimus AngioInfusion™ Balloon (SAB)

Virtue® SAB Overview

Collaboration with TERUMO

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[1]**
- **FDA Breakthrough Device Designation** received for indications in coronary ISR[2], coronary SV[3] and BTK[4]

[1]von Birgelen et al. JACC Vol. 59, No. 15, 2012 April 10, 2012:1350–61; Virtue SAB has received Breakthrough Device Designation for: [2]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; [3]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; [4]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.

Orches Bio

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 treatments for coronary ISR, coronary SV de novo and BTK

Designed to leverage existing treatment paradigm & established technologies: sirolimus and balloon angioplasty

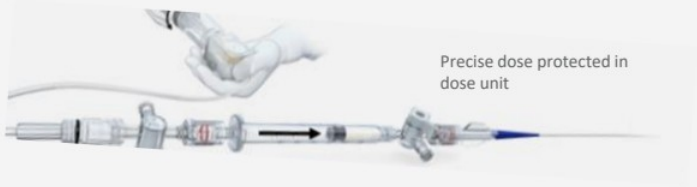
*Total addressable market in 2025 based on company estimates; Definitions: Coronary Artery Disease (CAD), Peripheral Artery Disease (PAD), In-stent Restenosis (ISR), Small Vessel (SV, ≤2.5mm), High bleeding Risk De Novo (>2.5mm), Below-the-Knee (BTK, Rutherford 3-6, w/out severe comorbidities).

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



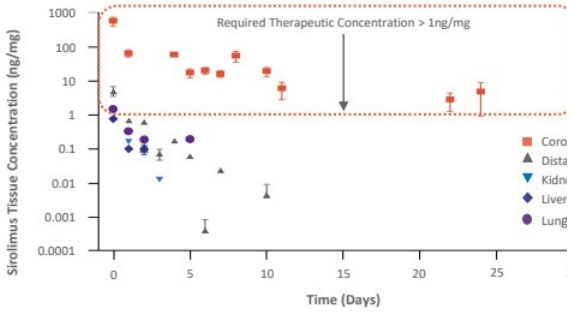
Protected Delivery/No Drug Coating

- 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 siroli through critical healing period (≈30 days)[1]



N = 753 porcine coronary artery segments

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

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

Orches Bio

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

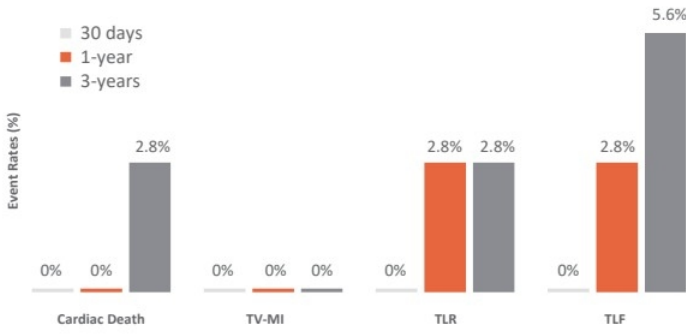
0%
New TLR between 1 to 3 years

Preliminary Efficacy Results Showed Low 0.12mm Late Loss

	Per Protocol[4]
n	36
Reference Vessel 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 Data with Low Safety 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).

Virtue® 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[1] Trial)

R

- Virtue® SAB N=200
- PBA N=100

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

Statistical Assumption
90% powered for superiority
Virtue SAB TLF ≤ 19% vs. PBA TLF ≥ 30%

Success Considerations
Virtue SAB: 2.8% TLF at 12 months in SABRE trial per protocol population
PBA: 33-46% TLF at 12 months in coronary ISR published studies

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[1] Trial)

Virtue® SAB N=100

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

Study Objective
Provide additional clinical data in support of use in double-layer Coronary ISR without confounding TLF performance results in single-layer Coronary ISR

12-18 Months Enrollment

12 Month Primary Endpoint

[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.

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[1]
- Japan PMDA CTN Coronary SV Approval[1]

Planned Clinical Milestones

BackBeat CNT

- HTN + Pacemaker 1st Pt. Enrollment

Virtue SAB

- Virtue-ISR US 1st Pt. Enrollment

CNT-HF and SirolimusEFR Program Updates

[1]Timing estimated and subject to Terumo execution since Terumo controls development of Virtue SAB for SV indication and for ISR in Japan

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 & Committed Strategic & Financial Investors

Medtronic

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PERCEPTIVE ADVISORS

TERUMO