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): October 10, 2023

ORCHESTRA BIOMED HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39421**	**92-2038755**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

150 Union Square Drive
New Hope, Pennsylvania 18938
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (215) 862-5797

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.0001 per share	**OBIO**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On October 10, 2023, Orchestra BioMed Holdings, Inc. (the "Company," "we," or "our") filed a registration statement on Form S-1 (the "Registration Statement") to register under the Securities Act of 1933, as amended, the resale of certain shares of its common stock, par value $0.0001 per share ("Common Stock"), the resale of certain warrants to purchase Common Stock and the issuance of certain shares of Common Stock underlying warrants, as required by the terms of the Amended and Restated Registration Rights and Lock-Up Agreement it entered into on January 26, 2023 with certain investors. The Company did not file the Registration Statement as part of an effort to raise capital and is not seeking to raise additional capital at this time.

The Registration Statement includes, among other things, the following updated information:

As previously disclosed, the Company, on the one hand, and Terumo Corporation and its U.S. subsidiary, Terumo Medical Corporation (collectively, "Terumo"), on the other hand, have been negotiating mutually agreeable adjustments to the Company's distribution agreement with Terumo (the "Terumo Agreement") that could serve to restructure milestone payments as well as make other potential material modifications to the Terumo Agreement. Until we gain clarity on the likely outcome of such ongoing negotiations, our current expectation is that the initiation of the Virtue ISR-US pivotal study evaluating the efficacy and safety of our Virtue Sirolimus AngioInfusion Balloon ("Virtue SAB") will be postponed until 2024. If negotiations are not completed to our satisfaction or to the satisfaction of Terumo, clinical study, product development, and commercialization plans for Virtue SAB may continue to be adversely impacted.

An updated copy of the slide presentation that the Company uses at investor and industry conferences and presentations is attached to this Current Report on Form 8-K (this "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.

Forward-Looking Statements

Certain statements included in this Current Report 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 timing of the Virtue ISR-US pivotal study. These statements are based on various assumptions, whether or not identified in this Current Report, and on the current expectations of the Company's management and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as and must not be relied on as a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and may differ from assumptions. Many actual events and circumstances are beyond the control of the Company. These forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political, and legal conditions; failure to realize the anticipated benefits of the business combination; risks related to regulatory approval of the Company's product candidates; the timing of, and the Company's ability to achieve, expected regulatory and business milestones; the impact of competitive products and product candidates; and the risk factors discussed under the heading "Item 1A. Risk Factors" in the Company's quarterly report on Form 10-Q filed with the U.S. Securities and Exchange Commission on May 12, 2023, as updated by any risk factors disclosed under the heading "Item 1A. Risk Factors" in the Company's subsequently filed quarterly reports on Form 10-Q.

The Company operates in a very competitive and rapidly changing environment. New risks emerge from time to time. Given these risks and uncertainties, the Company cautions against placing undue reliance on these forward-looking statements, which only speak as of the date of this Current Report. The Company does not plan and undertakes no obligation to update any of the forward-looking statements made herein, except as required by law.

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: October 10, 2023


Orchestra
BioMed
Corporate
Presentation
Q4 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 circums impossible to predict and may differ from assumptions. M circumstances are beyond the control of the Company. statements are subject to a number of risks and uncertaintie domestic and foreign business, market, financial, political, and to realize the anticipated benefits of the business combin regulatory approval of the Company's product candidates; t Company's ability to achieve expected regulatory and business of competitive products and product candidates; and the risk the heading "Item 1A. Risk Factors" in the Company's quarterl filed with the U.S. Securities and Exchange Commission on May any risk factors disclosed under the heading "Item 1A. Risk Fac subsequently filed quarterly 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 press release. The Compa undertakes no obligation to update any of the forward-loo 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

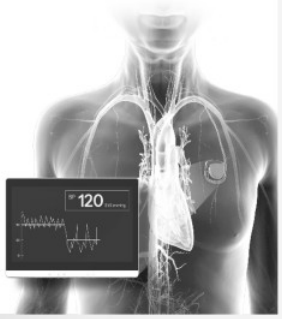
Firmware upgrade to existing pacemaker

Statistically significant double-blind, randomized preliminary trial efficacy data

Plan to initiate pivotal study by end of 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 study in 2024

Strategic collaboration TERUMO

Double-digit revenue share

Strong balance sheet and outstanding investors:

Medtronic rtw PERCEPTIVE ADVISORS TERUMO

Orchestra BioMed's Partnership-Enabled Model Benef

Orchestra BioMed
Development

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

Shared Benefits

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

Strategic Pa
Commercia

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

Strong Collaborations Position Us for Long-term Succes

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

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
study, as well as device supply chain and commercializatio

Positioned to become Terumo's flagship therapeutic offeri

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 outsid
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	Partne
BackBeat Cardiac Neuromodulation Therapy (CNT™)	Hypertension (HTN) (pacing patients; HTN+P)				Medtron
	High-Risk HTN (non-pacing patients)				Medtron ROFN
CNT - HF	Heart Failure				
Virtue® Sirolimus AngioInfusion™ Balloon (SAB)	Coronary In-Stent Restenosis (ISR)	FDA Breakthrough[3]			TERUM
	Coronary Small Vessel (SV)[1]	FDA Breakthrough[4]			TERUM
	Below-the-Knee (BTK)[1]	FDA Breakthrough[5]			TERUM
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-Ris 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. [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 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 sten 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 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 documentat 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 elem 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 approxim 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 m 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 ™)

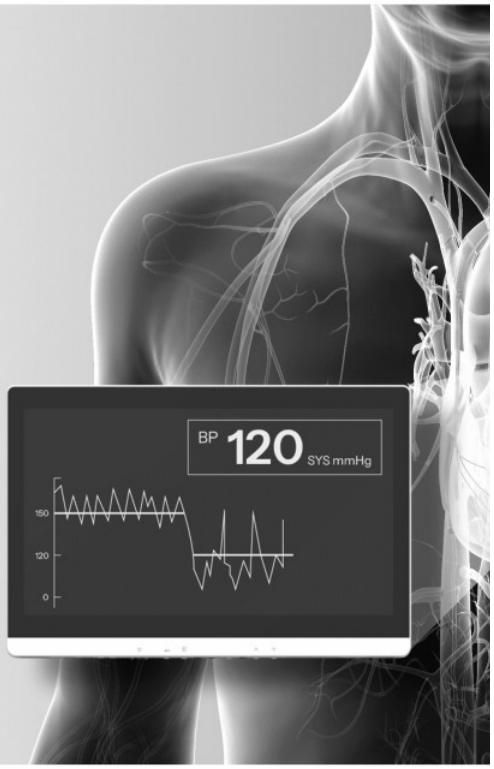
BackBeat CNT™ Overview

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)

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 Annu
Global Market Opportunity

>3.1M Addressable HTN P

High Risk HTN (Non-pacemake
patients with isolated systolic
hypertension (ISH) and comorb

Medtronic is the global pacem
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); Definition: Hypertension (HTN)

BackBeat CNT™

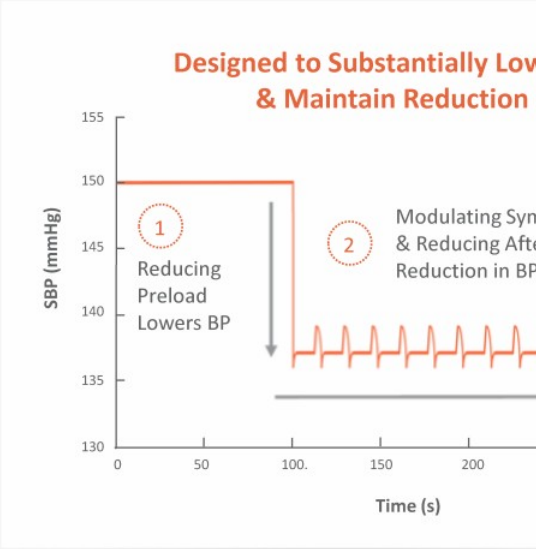
Designed to Substantially and Persistently Lower Blood Pressure

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

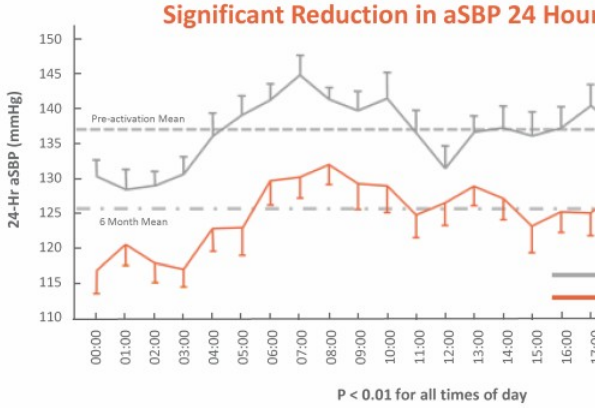
-11.1 mmHg in 24-Hour aSBP at 6 months

-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[1,2]

Significant Reduction in aSBP 24 Hour



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 hypertensi (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 antihyp 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

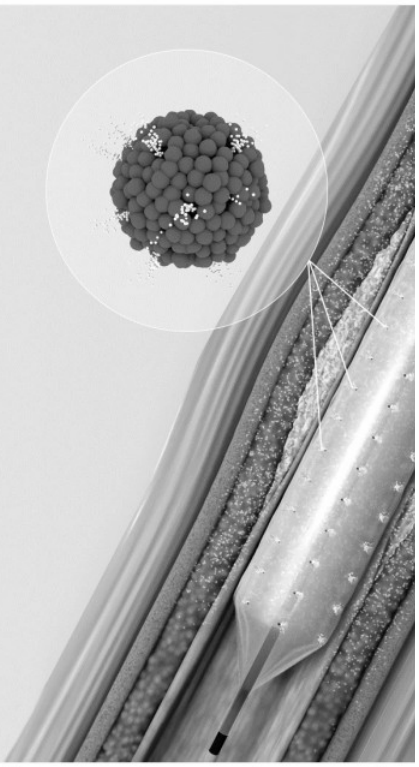
Virtue® Sirolimus AngioInfusion™ Balloon (SAB)

Virtue® SAB Overview

Collaboration wi

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 ste 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) o 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.

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 Opportu

>3.2M
Addressable CAD & PAD Patients

Artery disease is the primary cause of death wo

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

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

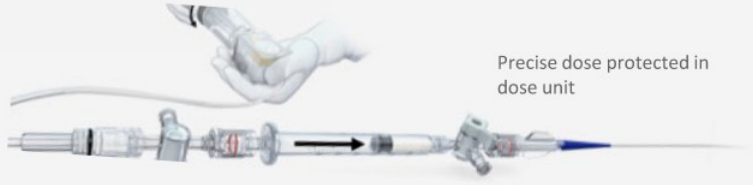
*Total addressable market in 2025 based on company estimates; Definitions: Coronary Artery Disease (CAD), Peripheral Artery Disease (PAD), In-stent Restenosis (ISR), Small Vessel (SV, ≤2.5mm), High bleeding Risk De Novo (>2.5mm), Below-the-Knee (BTK, Rutherford 3-6, w/out severe comorbidities).

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



Precise dose protected in dose unit

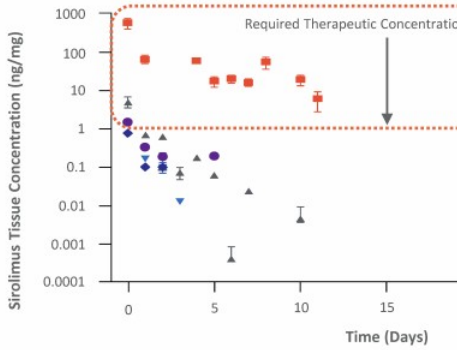
Protected Delivery/No Drug Coating

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



N = 753 porcine coronary artery segments

Lung, live quantifica

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

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

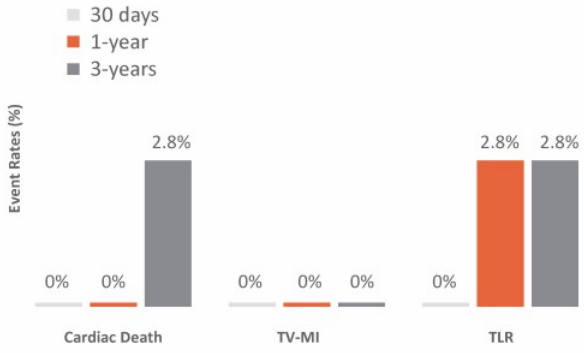
0%
Ne
1 t

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).

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 Ass

90% powered for s
Virtue SAB TLF ≤ 19

Success Consi

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

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 Objecti

Provide additional
of use in double-la
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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.

Upcoming 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; *Initiation of the Virtue ISR-US pivotal study will be postponed until 2024 while Orchestra BioMed and Terumo align on partnership restructuring. If negotiations are not completed to the satisfaction of Orchestra BioMed or to the satisfaction of Terumo, clinical and development efforts, and commercialization plans for Virtue SAB and/or the Orchestra BioMed relationship with Terumo may continue to be adversely impacted.

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 Investo