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): September 8, 2026

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 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/ Andrew Taylor
Name: Andrew Taylor
Title: Chief Financial Officer

Date: September 8, 2026

Exhibit 99.1


Orchestra BioMed™
Accelerating high-impact technologies to patients through risk-reward sharing partnerships
Nasdaq: OBIO
Corporate Overview | September 2026

LEGAL NOTICE

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 enrollment and timing of our pivotal trials and reporting of top-line results, the timing of regulatory submissions, expected market sizes for our product candidates, the ability of our partnerships to accelerate clinical development, the benefits of Breakthrough Device Designation and the Company's projected cash runway. 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 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; 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 annual report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 12, 2026 as updated by any risk factors disclosed under the heading "Item 1A. Risk Factors" in Part II of 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 presentation. The Company does not plan and undertakes no obligation to update any of the forward-looking statements made herein, except as required by law.

INVESTMENT SUMMARY

Accelerating innovation to patients through partnerships

CAPITAL-EFFICIENT ROYALTY PARTNERSHIP MODEL

We drive R&D through pivotal trials in strategic collaboration with **partners that can optimize global commercialization**

TWO PIVOTAL-STAGE PROGRAMS TARGETING LARGE MARKETS

Our flagship technologies, **AVIM Therapy & Virtue SAB,** target significant needs in **large, established cardiovascular markets**

WELL-FUNDED & BACKED BY INDUSTRY LEADERS

Medtronic, Terumo and **Ligand** have provided **>$185M** of **strategic capital** with our current cash providing **runwa through 2027**[1]

MAJOR UPCOMING CATALYSTS

- Complete BACKBEAT Pivotal Trial enrollment
- Present BACKBEAT primary endpoint data
- Potential FDA approval of AVIM Therapy
- Complete Virtue Pivotal Trial enrollment
- Medtronic AVIM Therapy commercial launch*
- Present Virtue primary endpoint data

*Assuming FDA approval. [1] Strategic capital reflects total amounts invested in and paid to OBIO by its partners.

Orchestra BioMed

OUR MODEL

Our partnership model optimizes execution and capital efficiency

WE FOCUS ON BEING GREAT AT:

- **High-impact innovation**
  differentiated technology with strong IP
- **Expert clinical execution**
  global pivotal trials that support regulatory approvals and optimized reimbursement
- **Value-creating partnerships**
  capital-efficient collaborations that create growth opportunities

WE RELY ON GREAT PARTNERS FOR:

- **Global commercialization**
  established sales, distribution, and support
- **Market leadership**
  trusted relationships, and deep field expertise
- **Operational & financial scale**
  proven manufacturing & strong balance sheets

We develop & prove novel therapies
We secure high-margin royalties without the cost structure

They commercialize at global scale
They secure significant revenue upside without R&D burden on their P&L

OUR MODEL IN ACTION

How we are actively bringing high-impact innovation to life

AVIM THERAPY

Atrioventricular Interval Modulation

Therapy for uncontrolled hypertension, the #1 comorbidity in the **$4 billion pacemaker market**[1]

Patented therapy delivered by a pacemaker that can **immediately, substantially and persistently lower blood pressure**

Medtronic

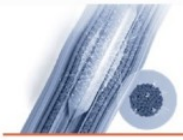
Global strategic collaboration

FOCUSED STRATEGIC APPROACH

We target unmet needs within large, established markets

We build powerful new therapies based on proven technologies

We find novel ways to share risks and rewards with global leaders



VIRTUE SAB

Sirolimus AngioInfusion Balloon

Superior "leave nothing behind" treatment for the **$7.5 billion coronary artery disease market**

Liquid delivery of submicron-encapsulated SirolimusEFR™ directly into artery during angioplasty

TERUMO

Coronary ROFR agreement, strategic optionality preserved

[1]Global Market Insights, Pacemakers Market Report (2024)

Orchestra BioMed

OUR PRODUCT PIPELINE

Our product pipeline targets large immediate and future opportunities

AVIM THERAPY

Atrioventricular Interval Modulation

LAUNCH MARKET | PIVOTAL TRIAL STAGE

Hypertension + Pacemaker

up to **$6B**
global annual total addressable market (TAM)

FDA Breakthrough Device Designation

- Uncontrolled hypertension in pacemaker patients
- Randomized pivotal trial primary results targeted for Q2 2027

EXPANSION MARKET

Hypertensive Heart Disease

up to **$16B**
global annual TAM

FDA Breakthrough Device Designation*

- Hypertensive heart disease in high-risk non-pacemaker patients
- BACKBEAT Trial creates clinical evidence foundation

VIRTUE SAB

Sirolimus AngioInfusion Balloon & SirolimusEFR

LAUNCH MARKET | PIVOTAL TRIAL STAGE

Coronary

$7.5B
global annual TAM

FDA Breakthrough — ISR & Small Vessel

- ISR (in-stent restenosis), small vessel de novo, and other coronary indications
- Randomized pivotal ISR trial targeting 2027 full enrollment

EXPANSION MARKET

Peripheral

$2.5B
global annual TAM

FDA Breakthrough Device Designation — BTK

- Below-the-knee (BTK) & Superficial Femoral Artery (SFA) indications
- Novel devices to leverage liquid SirolimusEFR delivery in longer, larger arteries

*Global annual TAM figures are Company estimates. FDA Breakthrough Device Designations as granted to date. Launch & Expansion indications are not approved and are subject to clinical, regulatory and reimbursement outcomes. *Breakthrough Device Designation applies to patients with preserved left ventricular systolic function (EF>50%) and uncontrolled hypertension with increased high ten-year ASCVD risk (>20%), despite the use of anti-hypertensive medications or in patients who may have intolerance to anti-hypertensive medications*

Orchestra BioMed

STRATEGIC CAPITAL

Strategic investments & payments from industry leaders

> $185M total strategic capital
invested in & paid to OBIO by its partners

~21%** owned by strategic partners*
led by Medtronic at ~15%**

Medtronic
$81.6M
Equity & $20M strategic capital

LIGAND
$40M
$35M for revenue participation right
plus $5M equity investment

TERUMO
$65M
Payments & equity investments

LARGE, LONG-TERM EQUITY HOLDERS

rtw ~18% Ownership**

PERCEPTIVE ADVISORS ~10% Ownership**

*Strategic capital reflects total amounts invested in and paid to OBIO by its partners. Ownership per public 13D/13G filings and Company records. **Ownership percentages in this presentation assume all pre-funded warrants have been exercised for common stock and are otherwise calculated in accordance with SEC beneficial ownership disclosure rules.

Orchestra BioMed

AVIM THERAPY

A potent hypertension therapy delivered by a pacemaker

*Designed to **lower blood pressure** and **improve cardiac function** through well-characterized mechanisms*

IMMEDIATE

Short AV delays reduce blood pressure

Short AV intervals reduce ventricular filling and cardiac preload, **driving an immediate, substantial drop in systolic pressure**

SUSTAINED

Longer AV delays maintain BP reduction

Interspersed longer AV intervals engage the baroreceptor reflex to modulate autonomic tone and reduce afterload, **maintaining the blood pressure reduction over time**

KEY ADVANTAGES

- Delivered on a **standard dual-chamber pacemaker** *(no additional procedure)*
- Programmable & **not dependent on patient adherence**

Orchestra BioMed

Hypertension is leading cardiovascular risk factor, affecting ~1.4B adults WW[1]

*Every 20 mmHg increase in systolic blood pressure approximately **doubles risk of death** from cardiovascular disease[2]*

#1 Modifiable risk factor for death worldwide[3]

47% of ischemic heart disease attributable to elevated systolic BP[4]

54% of stroke attributable to elevated systolic BP[4]

Lower blood pressure benefits every major endpoint

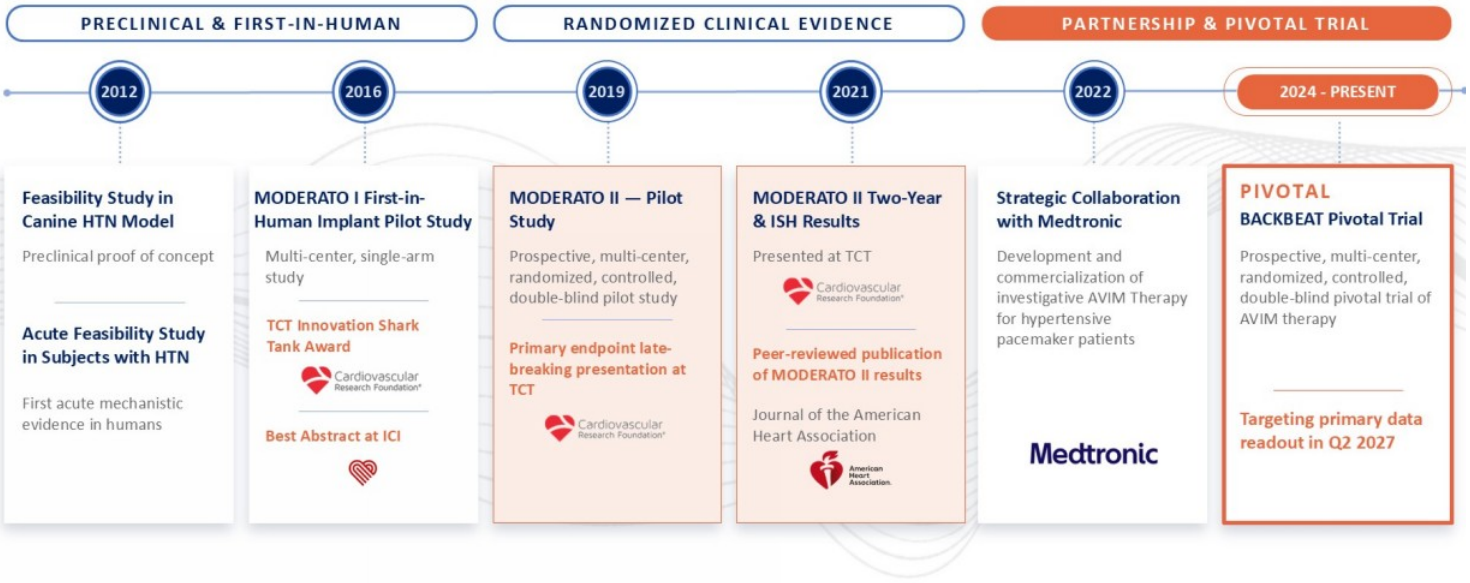
RELATIVE RISK REDUCTION PER 10 MMHG DECREASE IN OFFICE SYSTOLIC BP

-20%	-27%	-28%	-17%	-13%
Major CV events	Stroke	Heart failure	Coronary HD	Mortality

[1]World Health Organization, Global Report on Hypertension 2025 (an estimated 1.4B adults aged 30–79 with hypertension in 2024, 33% of that age group; ~23% controlled). [2]Lewington et al., Lancet 2002;360:1903–13 (each 20 mmHg higher usual systolic BP associated with approximately two-fold higher vascular mortality). [3]WHO Global Report on Hypertension; GBD Risk Factor analyses (leading modifiable risk factor for death worldwide). [4]Lawes et al. / WHO, Lancet 2008 (attributable fractions for ischemic heart disease and stroke). [5]Ettehad et al., Lancet 2016;387:957–67 (123 trials, 613,815 patients; relative risk reductions per 10 mmHg lower systolic BP). Phillips et al., J Am Coll Cardiol 2018;71:1601–10.

Orchestra BioMed

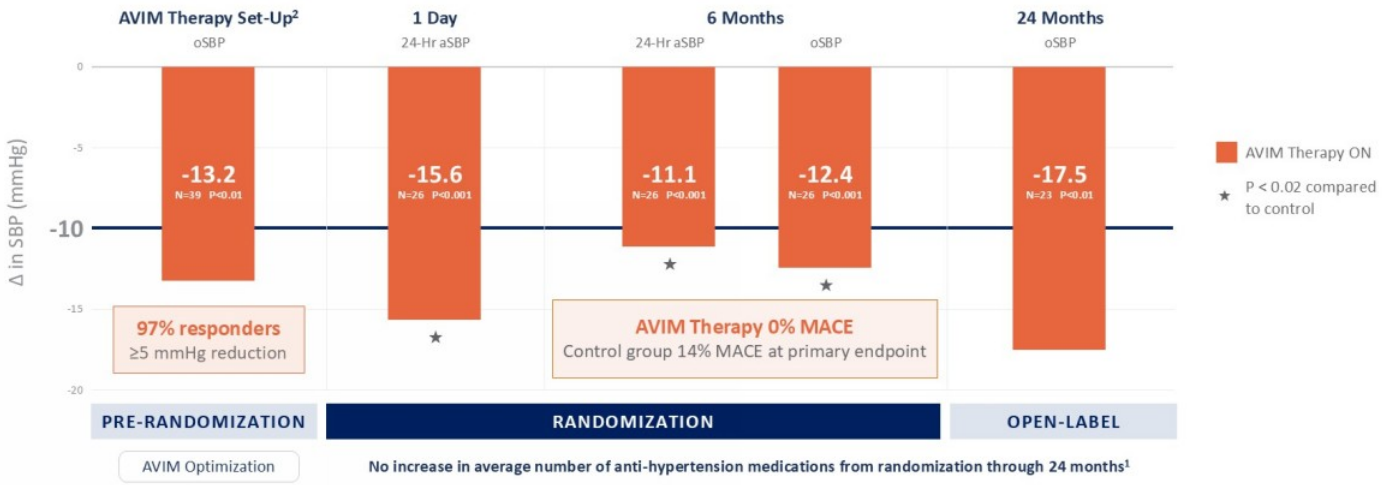
More than a decade of evidence supporting AVIM Therapy



Orchestra BioMed

MODERATO II demonstrated immediate, substantial and sustained BP reduction

*AVIM Therapy **significantly reduced systolic blood pressure** compared to control with no medication changes & low MACE[1]*



[1]Kuck, AVIM Therapy as a Treatment for Hypertensive Heart Disease, HRS 2026. [2]Includes AVIM therapy and control patients at pre-randomization using BACKBEAT Trial set-up methodology. Definitions: MACE (Major Adverse Cardiac Events), oSBP (ambulatory Systolic Blood Pressure), oSBP (office Systolic Blood Pressure), Hr (Hour).

Orchestra BioMed

AVIM is designed to address the needs of high-risk, comorbid, older patients

*MODERATO II results show AVIM Therapy offers **disease-modifying potential benefits** for hypertensive heart disease*

ALWAYS-ON BLOOD PRESSURE CONTROL

70% of treated patients age 65+ remain above BP goal; non-adherence is the principal driver[1]. AVIM Therapy is programmable, adjustable and not dependent on patient adherence

REDUCED PULSE PRESSURE IN ISH

In Isolated Systolic Hypertension patients (ISH), **AVIM Therapy significantly reduced pulse pressure**, an independent risk factor for heart failure and stroke[2,3]

IMPROVED DIASTOLIC FUNCTION

AVIM Therapy demonstrated **improved myocardial relaxation & diastolic compliance** in patients with echocardiographic markers of Diastolic Dysfunction[4]

INDUCED POSITIVE REVERSE REMODELING

In 12-month echocardiographic follow up, AVIM Therapy **induced positive reverse remodeling**[5]

[1]Adapted from CDC, Estimated Hypertension Prevalence, Treatment, and Control Among US Adults: Tables, 2023. [2]Burkhoff, MODERATO II Study 2-Year Results, TCT 2021. [3]Vaccarino et al., Am J Cardiol 2001. [4]Fudim et al., JACC: Advances 2025;4(7):101896. [5]Chovanec et al., JACC Clin Electrophysiol 2025;11:2493–2504. ISH = isolated systolic hypertension.

Orchestra BioMed

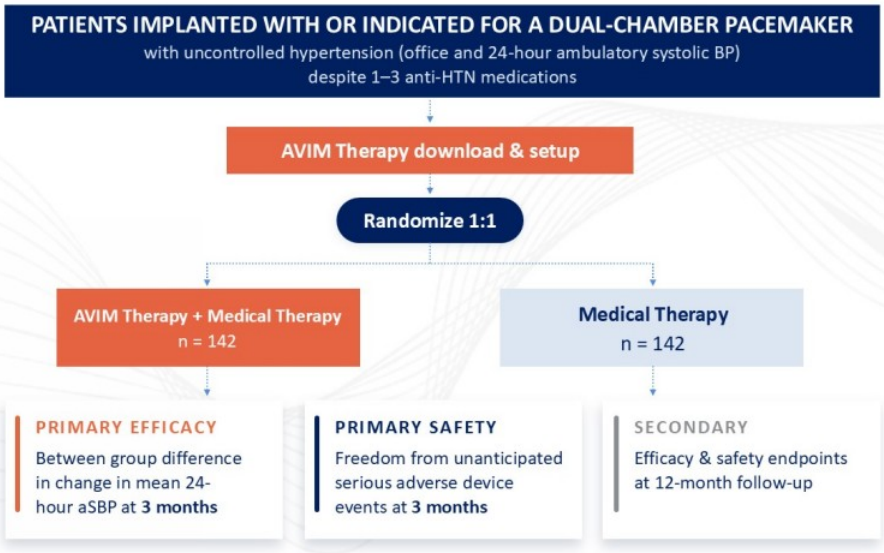
The BACKBEAT Global Pivotal Trial nearing completion

BACKBEAT
GLOBAL PIVOTAL STUDY

- Double-blind, randomized, 1:1
- 284 evaluable randomized patients target
- ~120 sites globally
- >90% statistical power (safety & efficacy)
- Actively enrolling trial participants

Orchestra BioMed Medtronic

Sponsored by Orchestra BioMed in collaboration with Medtronic



Orchestra BioMed

The global market leader will drive commercialization

Orchestra BioMed

DEVELOPMENT & CLINICAL EXECUTION

- Invented AVIM Therapy; owns 120+ HTN patents plus more in heart failure
- Executed MODERATO I & II pilot studies along with all mechanistic studies
- Sponsoring & funding the BACKBEAT pivotal trial

OBIO earns an uncapped, double-digit royalty-based revenue share of every AVIM Therapy-enabled device sold

Medtronic

MANUFACTURING & COMMERCIALIZATION

- Exclusive global rights to pacemaker-indicated patients; global leader in pacemakers
- Incorporating AVIM Therapy in next-gen transvenous device (and in potential future leadless technology)
- Responsible for regulatory approvals, manufacturing and global sales, marketing & support

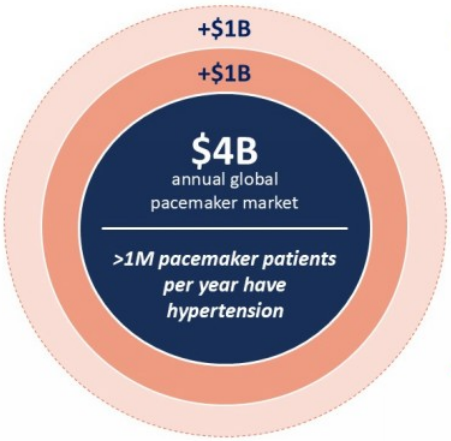
$81.6M invested in Orchestra BioMed
Right of First Negotiation for non-pacemaker HTN

[1]Global Market Insights, Pacemakers Market 2024; 'Medtronic led with over 54% market share in 2024' (global); U.S.-specific share: IData Research U.S. Cardiac Rhythm Management report / Medtronic data. Per-device economics per OBIO 10-K (FY2025).

Large, established market of pacemaker patients with hypertension

*Substantial **uncapped royalties** can drive significant OBIO topline growth and accelerated profitability*

AVIM CAN GROW THE COMMERCIAL VALUE OF THE PACEMAKER MARKET



- **Existing market: $4B**
  ~1.4M pacemaker implants per year; >1M addressable patients with HTN
- **+$1B: AVIM premium positioning[1]**
- **+$1B: potential U.S. enhanced reimbursement**

~ $6B potential annual global market

Medtronic benefits include potential increased revenue + profit growth and increased market share

OBIO ROYALTY OPPORTUNITY

$500M+
Annual potential global royalties[2]

$500-$1,600
Estimated royalty per device (uncapped)[3]

- Assumes existing reimbursement structures
- $500 minimum per device royalty outside the U.S.
- Materially higher minimums in U.S., Japan and China

Significant potential upside with enhanced US reimbursement

Market sizes are Company estimates; existing market reflects ~1.4M global pacemaker implants per year. [1]Target ASP supportable by NTAP (inpatient) and TPT (outpatient); eligibility follows from FDA Breakthrough Device Designation and is not guaranteed. [2]Royalty per device company estimate based on current license terms. Royalty opportunity figures are based on $500 per device minimum (lowest minimum for outside the US excluding Japan and China) multiplied by 1M estimated patients per year getting pacemakers that also have hypertension.

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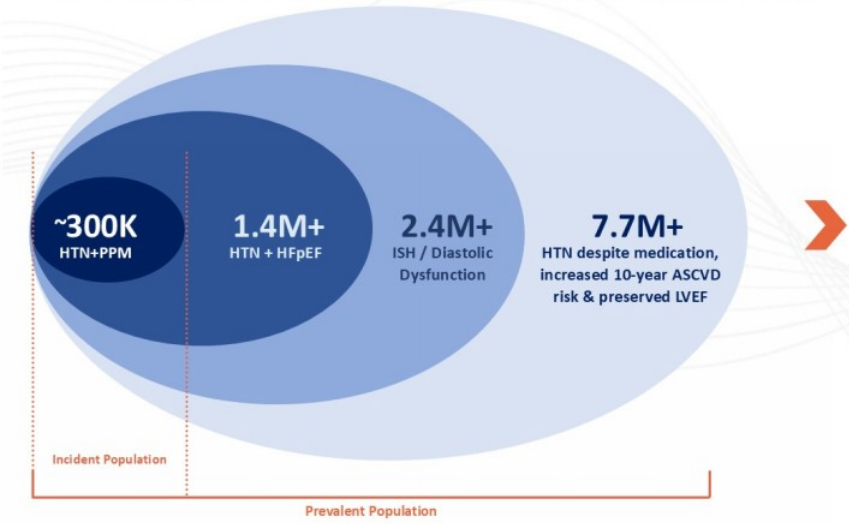
Significant expansion opportunity beyond the pacemaker market

*Second FDA BDD highlights **AVIM potential to treat hypertensive heart disease** in high-risk, non-pacemaker patients*

U.S. patient population meeting FDA Breakthrough Designation criteria[1]



ANNUAL ESTIMTED ADDRESSABLE EXPANSION POPULATION[2]

~1.1M in the US | ~2.6M OUS

ANNUAL ESTIMATED EXPANSION MARKET SIZE[3]

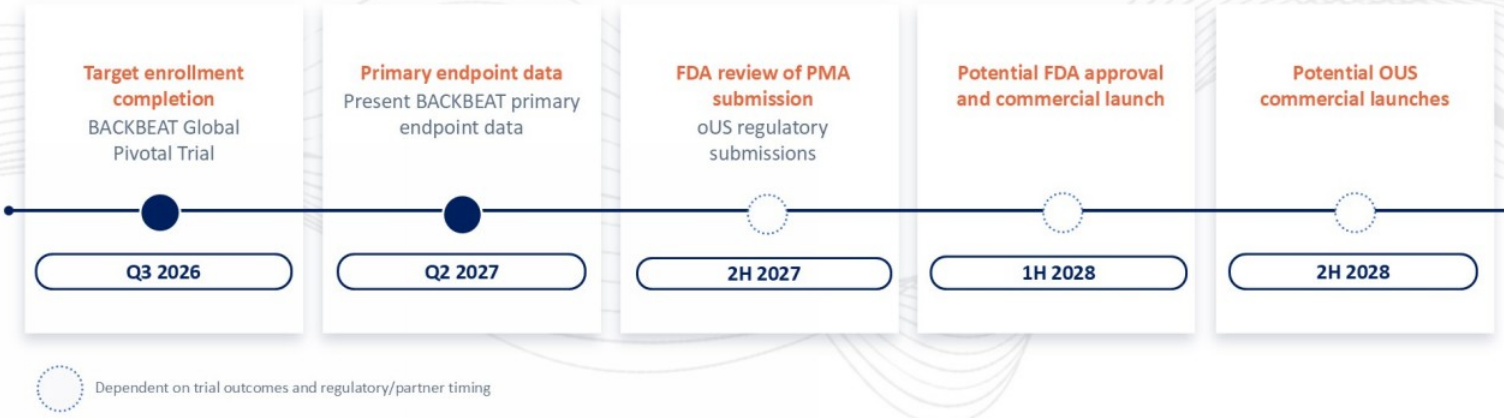
~$7.5B in the US | ~$8.5B OUS

- Leverages existing pacing clinical expertise and infrastructure
- Potential to utilize existing reimbursement coding and payment
- Coverage to be based on clinical evidence and regulatory labeling
- BACKBEAT Trial designed to provide clinical evidence foundation

[1]U.S. patient population estimates based on company analysis; populations are nested, not additive. Second FDA Breakthrough Device Designation granted April 22, 2025. [2]Annual Addressable Expansion Population reflects estimated patients per year meeting Breakthrough Designation criteria who could be addressable with an AVIM-enabled device; [3]Annual Expansion Market Size reflects the estimated annual revenue opportunity ($) associated with treating that population. PPM = permanent pacemaker; HFpEF = heart failure with preserved ejection fraction; ISH = isolated systolic hypertension; ASCVD = atherosclerotic cardiovascular disease; LVEF = left ventricular ejection fraction.

Orchestra BioMed

BACKBEAT Trial & AVIM Therapy Catalysts



Dependent on trial outcomes and regulatory/partner timing

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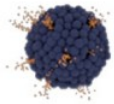
Virtue SAB: designed to optimize sirolimus dosing, uptake and release

SUBMICRON PARTICLE-ENCAPSULATED SirolimusEFR™

Proven gold standard sirolimus
The anti-restenotic and anti-inflammatory, cytostatic drug with a broad safety margin[1]



Designed to Optimize Sustained Sirolimus Delivery

- **Rapidly infuses** particles transmurally
- **Sustains** sirolimus release through the critical healing period[2,3]
- Saturates binding sites **to inhibit proliferation & modulate inflammation**

SirolimusEFR formulation

NON-COATED, MICROPOROUS ANGIOINFUSION™ BALLOON

Protected large liquid volume infusion
for rapid intramural distribution

NO drug loss in transit
NO rapid navigation
NO large particulate

[1]Xinlin Zhang, et al. PLOS ONE 2014 May 20;9(5):e97934. [2]Granada et al. EuroIntervention 2016;12:740-747. [3]Virtue SAB Mechanism of Action Note to File. [4]Instructions For Use

Orchestra BioMed

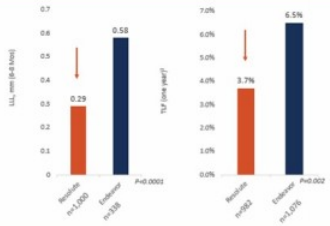
Why there is a compelling opportunity for Virtue SAB

1 SIROLIMUS IS THE GOLD STANDARD FOR RESTENOSIS, PACLITAXEL IS INFERIOR AND DISAPPEARS FROM DES

Superior safety and efficacy over paclitaxel
across 76 DES studies, including 26 RCTs[1]

45%	26%
lower TLR risk	lower MACE risk

2 SIROLIMUS NEEDS A HIGH ENOUGH DOSE IN THE ARTERY WALL, FOR ENOUGH TIME, TO WORK



Fast elution (<15 days) **Endeavor drug-eluting stent (DES) inferior to Standard elution** (30+ day) **Resolute DES**[2]

3 PACLITAXEL RESURFACED ON COATED BALLOONS BECAUSE IT IS EASIER, NOT BETTER

The **majority of DCBs** available worldwide are **paclitaxel-coated**

Boston Scientific's paclitaxel-coated **AGENT** is the first DCB approved in U.S. for coronary use

Medtronic's paclitaxel-coated **PREVAIL** is in a U.S. IDE pivotal coronary study

4 ...BUT EVERY COATED BALLOON CARRIES THE SAME THREE CONSTRAINTS

Dose is limited ~1–4 µg/mm² — capped by balloon surface area and coating integrity[3]

Drug is lost Up to ~80% lost before reaching the lesion[4]

Embolic risk Coating particulate in up to 36% of downstream sections[5]

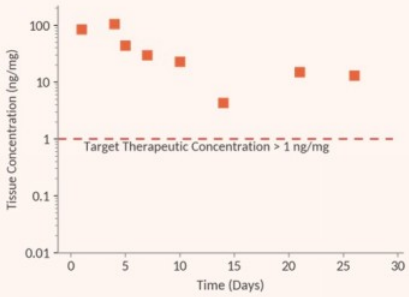
[1]Zhang et al., PLoS ONE 2014 (network meta-analysis of 76 DES studies including 26 RCTs). [2]Tada et al., Am Heart J 2013; Leon et al., ACC 2011 (Endeavor vs. Resolute). [3]Based on Company review of published dose concentration of commercially available DCBs worldwide. [4]Brodmann; EuroPCR 2015. [5]Kowai et al. Catheterization and Cardiovascular Interventions, 2025; 105:1434–1444.
Definitions: Drug-Coated Balloon (DCB)

Orchestra BioMed

In published PK study, Virtue delivered/maintained more sirolimus than DES and DCB

Virtue achieved high drug concentrations in tissue through critical healing period, ***exceeding published levels of proven DES (Xience) and leading Sirolimus-coated balloons***

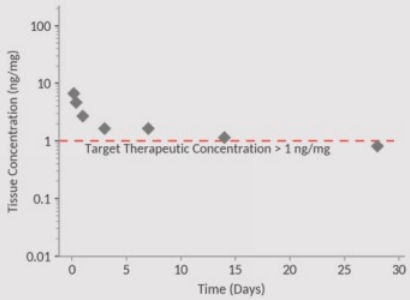
VIRTUE® SAB



N = 15 - 247/time point

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

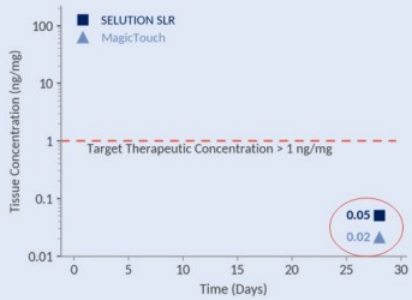
XIENCE™



N = up to 30/time point

Perkins et al. J Int Cardiol 2009; 22(Suppl 1): S28-S40

SIROLIMUS-COATED BALLOONS



N = 3 arteries per device, single 28-day terminal timepoint · medians

Kawai et al. Catheter Cardiovasc Interv 2025;105:1434-1444

5

SIROLIMUS COATED BALLOONS FAIL TO DELIVER/MAINTAIN SUFFICIENT DRUG CONCENTRATION… AND THEIR CLINICAL RESULTS FOLLOW THEIR PHARMACOKINETI

SELUTION SLR

Coronary ISR IDE study showed 12-month TLF outcomes similar to AGENT's coronary ISR IDE results:

Trial	Device	12-month TLF
SELUTION4ISR[1]	**SELUTION SLR** *sirolimus drug eluting balloon*	14.2%
AGENT IDE[2]	**AGENT DCB** *paclitaxel drug-coated balloon*	13.5%

MagicTouch

Failed to demonstrate non-inferiority to paclitaxel-coated balloons in the TRANSFORM I randomized study[3]

[1] Cutlip DE, Mehran R, Sharma S, et al. Sirolimus-Eluting Balloon vs Repeat Drug-Eluting Stent or Balloon Angioplasty for Coronary In-Stent Restenosis. J Am Coll Cardiol. 2026;88(1). doi:10.1016/j.jacc.2026.03.021. Prespecified single-layer ISR analysis. [2] Kirtane AJ, Shlofmitz R, Moses J, et al. Paclitaxel-Coated Balloon for the Treatment of Multilayer In-Stent Restenosis: AGENT IDE Subgroup Analysis. J Am Coll Cardiol. 2025;86(7):502–511. doi:10.1016/j.jacc.2025.05.062. Prespecified stent-layer subgroup. SELUTION4ISR and AGENT IDE are separate randomized studies with different designs, populations and comparators — not a head-to-head comparison. [3]Ninomiya K, et al. JACC Cardiovasc Interv 2023 (TRANSFORM I)

Orchestra BioMed

SABRE pilot trial results showcase opportunity for Virtue SAB

VIRTUE® SAB

Virtue SAB demonstrated encouraging safety and efficacy results in patients with coronary ISR in the prospective, multi-center SABRE trial — **single-layer restenosis with 6 month angiographic follow up**, per-protocol analysis. [1-4]

- Very Low 2.8% TLF at 1 year
- 0% increase in TLR from 1–3 years
- Low 0.12 mm late lumen loss (LLL) at 6 months

AGENT™ DCB - AGENT IDE TRIAL

Boston Scientific's AGENT DCB demonstrated a reduction in TLF versus POBA in patients with **single-layer restenosis** in the randomized IDE trial. [5,6]

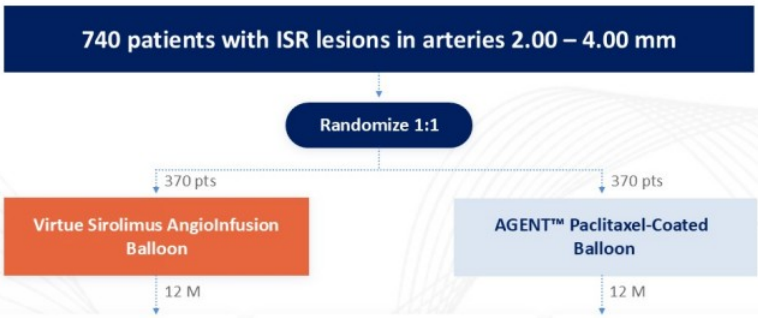
- 13.5% TLF at 1 year, a 93% relative increase in TLF from 1 to 3 years[7]
- No angiographic follow-up in the IDE
- AGENT LLL = 0.397 mm at 6 months[8]

[1]Verheye et al., JACC Cardiovasc Interv 2017;10(20):2029–2037. [2]Revised per-protocol analysis set meets the criteria of the proposed In-Stent Restenosis IDE study population. [3]Granada, SABRE 3-Year Clinical Results, TCT 2018. [4]Cause of death unknown — reported as multiple organ failure, non-cardiac and non-neurological; adjudicated as non-device and non-procedure related. [5]Yeh et al., JAMA 2024;331(12):1015–1024 (AGENT IDE); single-layer subgroup: Kirtane et al., J Am Coll Cardiol 2025. [6]Moses, Two-Year Outcomes from the AGENT IDE Trial, CRT 2025. [7]Relative increase calculated from reported single-layer TLF at 1 and 3 years (13.5% to 26.0%). [8]Boston Scientific AGENT DCB Brochure, 2017. SABRE and AGENT IDE are separate studies with different designs and patient populations — not a head-to-head comparison. . This included independent core lab adjudication with CEC/DSMB.

The Virtue Pivotal Trial actively enrolling

Virtue Trial

- FDA IDE approved
- 1:1 RCT vs AGENT DCB
- N = 740
- Primary endpoint: 12-month TLF
- Actively enrolling trial participants



PRIMARY ENDPOINT

Target Lesion Failure (TLF) at 12 months

ANALYSIS

- Non-inferiority comparison
- Superiority test upon confirming non-inferiority

FOLLOW-UP

Clinical follow-up out to 5 years

Orchestra BioMed

Treatment paradigm shift and strong U.S. reimbursement fueling fast-growing opportunity

Virtue SAB product differentiation offers potentially significant, sustainable commercial advantages

THE CORONARY MARKET[1] | "LEAVE NOTHING BEHIND" PARADIGM SHIFT

>$5,000 DCB ASP in U.S. broadly reimbursed[4]

STRATEGIC PARTNERING PATHWAY

TERUMO Coronary Right of First Refusal

- $65M in payments & equity investments to Orchestra[2]
- ROFR does not restrict any strategic activity today and expires 90 days after Virtue Trial data disclosure
  - 30 days to exercise after notice of third-party proposal
  - Expires 90 days after disclosure of primary endpoint data

FUTURE STRATEGIC TRANSACTION OPPORTUNITY

We maintain strategic optionality and opportunity to engage with up to 10 currently identified potential partners

PRECEDENT TRANSACTION

Cordis acquired MedAlliance, developer of the SELUTION SLR sirolimus-coated balloon, in 2023 for up to **$1.135B[3]**

[1]Procedure volumes and market sizes are Company estimates. [2]ROFR terms per agreement filed with the Company's Form 8-K (October 2025). [3]Per MedAlliance/Cordis announcements (October 2023) with the substantial majority of such amount dependent on achievement of certain regulatory and commercial milestones. [4]DCB U.S. reimbursement reflects CMS Transitional Pass-Through payment for coronary DCBs (effective January 1, 2025) and New Technology Add-on Payment (effective October 1, 2025).

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LEADERSHIP & GOVERNANCE

Led by a team with a proven cardiovascular innovation track record

300+ Combined years of industry experience

25+ Average years of experience across the team

100+ Successful product approvals delivered globally

600+ Authored patents shaping the future of healthcare

EXECUTIVE LEADERSHIP

David Hochman
Chairman & CEO, Founder

Managing Partner, Orchestra Medical Ventures; co-founder BackBeat, Caliber, Motus GI, Corbus & PROLOR Biotech; Managing Director, Spencer Trask

Darren R. Sherman
President & COO, Director, Founder

Managing Partner, Orchestra Medical Ventures; CEO/Co-inventor Caliber; co-founder/inventor BackBeat; Cordis Neurovascular (J&J); founder, Revivant

Andrew Taylor
Chief Financial Officer

CFO, Motus GI; CFO & President, Avertix Medical; 20+ yrs medtech finance leadership

Amy Berman
Vice President, Clinical Operations

Clinical operations leadership roles at Optinose, Cordis (J&J), and IlluminOss Medical

Bill Little
EVP, Corporate Development & Strategy

COO, Neovasc (→ Shockwave); Abbott Vascular; St. Jude Medical; Boston Scientific

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

Co-founder & CEO, BackBeat Medical; CTO & CSO, Impulse Dynamics; AVIM therapy inventor; Ph.D., Technion

Mark Pomeranz
EVP & GM, Interventional Therapies

CEO, Motus GI; CEO, Svelte Medical; 30+ yrs medical-device leadership across cardiology & GI; Cordis Neurovascular (J&J); Cardiac Pathways

Heather Buckley
Vice President, Marketing

Marketing leadership roles at Olympus Corporation, Cordis (J&J), and Boston Scientific

BOARD OF DIRECTORS *independent directors*

Jason Aryeh — Ligand; Anebulo

Pamela Connealy — Pyxis Oncology; Genentech

Chris Cleary — Medtronic; GE Capital

Eric S. Fain, M.D. — St. Jude Medical; Abbott; Procyrion

John Mack — Medtronic (30+ yrs)

David Pacitti — Abbott; Siemens Healthineers; Avanos

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THE BOTTOM LINE

We deliver value for patients, partners and shareholders

CAPITAL-EFFICIENT ROYALTY ECONOMICS

High-margin potential royalties on partner-driven sales; no sales, marketing or manufacturing to fund

TWO LARGE, ESTABLISHED TARGET MARKETS

AVIM and Virtue SAB each target **multibillion-dollar annual opportunities** in two of the largest cardio-device markets

MEDTRONIC COLLABORATION FOR AVIM THERAPY

Spans development, regulatory & global commercialization with expansion optionality into hypertensive heart disease

STRATEGIC OPTIONALITY FOR VIRTUE SAB

Free to pursue strategic transaction subject to limited coronary ROFR with Terumo

ALIGNED, BLUE-CHIP STRATEGIC BACKING

$185M+ of strategic capital; ~50% of shares owned by strategic investors and long-term institutional holders

DEFINED, NEAR-TERM CATALYST PATH

BACKBEAT enrollment (Q3 2026) and pivotal data (Q2 2027), funded to end of 2027

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Orchestra BioMed™
BRINGING MEDICAL INNOVATIONS TO LIFE THROUGH PARTNERSHIPS
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