

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 23, 2025

Anteris Technologies Global Corp.
(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation)	001-42437 (Commission File Number)	99-1407174 (I.R.S. Employer Identification No.)
Toowong Tower, Level 3, Suite 302 9 Sherwood Road Toowong, QLD Australia (Address of Principal Executive Offices)		4066 (Zip Code)
Registrant's telephone number, including area code: +61 7 3152 3200		
Not Applicable (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	AVR	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 3.02. Unregistered Sales of Equity Securities.

On or about October 23, 2025 (October 24, 2025 AEST), Anteris Technologies Global Corp. (the “Company”) entered into (i) subscription agreements (the “Subscription Agreements”) with certain investors, pursuant to which we agreed to sell 2,244,896 shares (the “Shares”) of the Company’s common stock, par value \$0.0001 per share (“Common Stock”), and accompanying five-year warrants (the “Common Stock Warrants”) to purchase 2,244,896 shares of Common Stock at a price of US\$4.90 per share of Common Stock and accompanying Common Stock Warrant (the “Common Stock Offering”), and (ii) confirmation letters (the “Confirmation Letters”) with certain investors, pursuant to which we agreed to sell 2,788,064 CHESS Depositary Interests (“CDIs”) and accompanying five-year warrants (the “CDI Warrants”) to purchase 2,788,064 CDIs at a price of A\$7.50 per CDI and accompanying CDI Warrant (the “CDI Offering”, and together with the Common Stock Offering, the “Offering”). The Common Stock Offering is expected to close on or around October 27, 2025, subject to customary closing conditions. The CDI Offering is expected to settle on or around October 30, 2025, subject to customary closing conditions. The Offering is expected to result in aggregate gross proceeds of approximately US\$25 million. Evolution Capital Pty Ltd acted as lead manager for the CDI Offering, and will be issued 250,000 CDI Warrants.

Each of the Common Stock Warrants and the CDI Warrants are exercisable commencing six months following the date of issuance. The exercise price of the Common Stock Warrants is \$7.50 per share, and the exercise price of the CDI Warrants is A\$11.50 per CDI.

As part of the Subscription Agreements and the Confirmation Letters, the Company is required to prepare and file a registration statement (the “Registration Statement”) with the Securities and Exchange Commission (the “Commission”) under the Securities Act of 1933, as amended (the “Securities Act”), covering the resale of the Shares, the shares of Common Stock issuable upon exercise of the Common Stock Warrants, the shares of common stock underlying the CDIs issued in the CDI Offering, and the shares of Common Stock underlying the CDIs issuable upon exercise of the CDI Warrants.

The securities to be sold in the Offering will be issued and sold without registration under the Securities Act, in reliance on the exemption provided by Section 4(a)(2) of the Securities Act, including under Rule 506 of Regulation D promulgated thereunder, with respect to the Shares and accompanying Common Stock Warrants in the Common Stock Offering, and Regulation S with respect to the CDIs and accompanying CDI Warrants in the CDI Offering.

Item 7.01. Regulation FD Disclosure.

Attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference is a form of corporate presentation used by the Company in discussions with certain of its securityholders and other persons.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or incorporated by reference into any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the expected closing dates of the offering, the expected gross proceeds from the offering and the expected cash of the Company following the Offering. Forward-looking statements include all statements that are not historical facts. Forward-looking statements generally are identified by the words “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “budget,” “target,” “aim,” “strategy,” “plan,” “guidance,” “outlook,” “may,” “should,” “could,” “will,” “would,” “will be,” “will continue,” “will likely result” and similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described under “Risk Factors” in the Company’s Annual Report on Form 10-K for the fiscal period ended December 31, 2024 that was filed with the Securities and Exchange Commission. Readers are cautioned not to put undue reliance on forward-looking statements, and except as required by law, Anteris does not assume any obligation to update any of these forward-looking statements to conform these statements to actual results or revised expectations.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed with this Current Report on Form 8-K:

Exhibit No.	Description
99.1	Corporate Presentation, dated October 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Anteris Technologies Global Corp.

Date: October 24, 2025

By: /s/ Wayne Paterson
Name: Wayne Paterson
Title: Vice Chairman and Chief Executive Officer

ANTERIS[®]
TECHNOLOGIES

October 2025

NASDAQ: **AVR** | ASX: **AVR**





Disclaimer

This presentation has been prepared by Anteris Technologies Global Corp. ("Anteris," the "Company," "we" or "us" or "our"). This presentation, and its contents and the accompanying discussion with management are confidential and may not be further copied, distributed or passed on, directly or indirectly, to any other person or published or reproduced directly or indirectly, in whole or in part, by any medium or in any form for any purpose without the Company's prior written consent. The recipient should not construe the contents of this presentation as legal, tax, accounting, investment advice or recommendation or business, financial or related advice. The recipient should consult its own counsel and tax and financial advisors as to legal and related matters concerning the matters described in this presentation. This presentation does not purport to be all-inclusive or to contain all of the information that the recipient may require. To the maximum extent permitted by law, none of the Company, its representatives, nor any other person accepts any liability, including, without limitation, any liability arising out of fault or negligence for any loss arising from the use of the information contained in this presentation.

Forward-Looking Statements

This presentation (including oral commentary that accompanies this presentation) contains forward-looking statements, including statements related to our business, products and the PARADIGM Trial. Any statements about our expectations, beliefs, plans, predictions, forecasts, objectives, assumptions, or future events or performance are not historical facts and may be forward-looking. In some cases, you can identify forward-looking statements through the use of words such as "believes," "expects," "may," "will," "should," "would," "seeks," "intends," "plans," "pro forma," "estimates," "contemplates," "aims," "continues," "anticipates" and similar expressions. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements are not guarantees of future performance and involve risks and uncertainties which are subject to change based on various important factors, some of which are beyond our control. Among the factors that could cause actual results to differ materially from those suggested by forward-looking statements are: our current and future research and development activities, including clinical testing and manufacturing and related costs and timing; sufficiency of our capital resources; our product development and business strategy, including the potential size of the markets for our products and future development and/or expansion of our products in our markets; our ability to commercialize products and generate product revenues; our ability to raise additional funding when needed; any statements concerning anticipated regulatory activities, including our ability to obtain regulatory clearances; our research and development expenses; and risks facing our operations and intellectual property; and the other risks described in our Annual Report on Form 10-K for the year ended December 31, 2024 and the other filings we make with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize or should any of these assumptions prove to be incorrect, our actual future results, performance and events and circumstances may differ in material respects from the performance projected in these forward-looking statements. The forward-looking statements included in this presentation are made only as of the date hereof. The Company does not undertake any obligation to update any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in the Company's expectations, except as may be required by law. Accordingly, the Company cautions you not to place any undue reliance on any forward-looking statements.

Industry Data

This presentation also includes data, forecasts and information obtained from industry publications and other information available to us. Some data is also based on our good faith estimates, which are derived from management's knowledge of the industry and independent sources. We have not independently verified any of the data from third-party sources, nor have we ascertained the underlying assumptions relied upon therein. While we are not aware of any misstatements regarding the industry data presented herein, estimates and forecasts involve uncertainties and risks and are subject to change based on various factors.

Milestones

This presentation contains various milestones. These milestones are not projections and instead are forward-looking goals that are subject to significant business, economic, regulatory and competitive uncertainties and contingencies, many of which are beyond the control of the Company and its management and are based upon assumptions with respect to future decisions, which are subject to change. Actual results will vary, and those variations may be material. Nothing in this presentation should be regarded as a representation by any person that these milestones will be achieved and the Company undertakes no duty to update these milestones.

No Offer or Solicitation

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful. Before you invest, you should read the documents we file with the SEC for more complete information about us. You can obtain these documents for free by visiting EDGAR on the SEC's website at www.sec.gov.





Anteris Technologies – Executing on strategy

Building commercial readiness for a new class of TAVR that mimics a healthy aortic valve

- 1 | Successfully priced U.S. IPO and listed on Nasdaq in December 2024**
 - Enhancing liquidity and visibility in the world's largest healthcare investment market
- 2 | Total of 130 DurAVR® THV patients, 49 patients treated YTD**
 - Building momentum, 38% of all patients enrolled in 6 months (Jan-Jun 2025)
- 3 | Data showcased by global KOLs at leading cardiovascular conferences**
 - CRT (Mar), Sydney Valves (Mar), Euro PCR (May), CSI Frankfurt (Jun), New York Valves (Jun)
- 4 | First-in-human DUAL valve-in-valve success with DurAVR® THV**
 - DurAVR® successfully implanted in both aortic (Mar) and mitral ViV procedures (May)
- 5 | Hosted global investigator meeting to launch pivotal PARADIGM Trial**
 - Setting the foundation for accelerated site activation and patient enrollment (Jun)





Investment Highlights

DurAVR®
TRANSCATHETER HEART VALVE

The only **biomimetic balloon expandable TAVR**
with 130 treated patients

Poised to disrupt a high value, growth market



Proprietary, First-in-Class TAVR

DurAVR® THV is the **only balloon expandable** aortic valve to deliver **curative, pre-disease hemodynamics**^{1,2}.



Multi-billion-dollar global TAVR market

Forecasted **US\$9.9bn** by 2028 (US\$12.5bn with Valve-in-Valve)³. **Underpenetrated** with 80-85% of severe aortic stenosis patients untreated⁴.

Path to Commercialization



Clinical Validation

130 patients. Strong performance at 30 days & 1 year. **PARADIGM Pivotal trial targeted 4Q25***, 50% DurAVR® vs. 50% SAPIEN or Evolut.



Commercial Readiness

Potential pathway to **FDA & CE Mark approval**. Scaled manufacturing, engaged global KOLs, early adopter site identification.



Commercial Launch

Compact market allows a **capital-efficient launch** with lean, scalable field force. Established TAVR reimbursement pathways.

*Subject to regulatory approval

1. Gagg, P., Morik, M., Saffaripour, J. et al. Restoration of flow in the aorta: a novel therapeutic target in aortic valve intervention. *Nat Rev Cardiol* 21, 264-273 (2024). <https://doi.org/10.1038/s41569-023-00940-6>.
2. Gagg, P. DurAVR® TAVI: biomimetic design restores flow and leads to significant LV mass regression. MR study. Oral presentation at PCR London Valves Nov 2024, London, England.
3. Future Market Insights, Transcatheter Heart Valve Replacement (TAVR) Market: Global Industry Analysis 2016 - 2023 and Opportunity Assessment 2024 - 2034. Future Market Insights, 2024. Available from: <https://www.futuremarketinsights.com/reports/transcatheter-heart-valve-replacement-tavi-market>
4. Gohl B, Gelik M, Head SJ, et al. Natural History of Asymptomatic Severe Aortic Stenosis and the Association of Early Intervention With Outcomes: A Systematic Review and Meta-analysis. *JAMA Cardiol*. 2025;10(1):102-112. doi:10.1001/jamacardio.2020.2497.



Highly Experienced Leadership – Clinical, Operational, Commercial



Wayne Paterson

VICE CHAIRMAN & CEO

Mr. Paterson has served as CEO since March 2017 and was appointed Vice Chairman in March 2025. He held global positions in big pharma incl. Merck KGaA ("Merck") from 2005-2013, and Roche (1995-2005). His roles included Global Head of CV Medicine, President of Europe, Israel, Canada & Australia, President of Emerging Markets incl. Russia & LATAM, CEO of Japan, Head of Commercial Operations in China, Head of Korea, and Product Manager. He also sat on a NASDAQ board (CHPD) and led a \$5B sale of that business. He has launched global healthcare products 36 times totaling billions in revenue and driven dozens of acquisitions, in-licensing and out-licensing deals globally.



David St Denis

PRESIDENT & DIRECTOR

Mr. St Denis has served as COO since July 2017 and was appointed President and Director in March 2025. From 2008-2017 he held senior positions at Merck including Head of Commercial Operations for Europe and Canada, and Head of Operations for Emerging Markets. From 1996-2006, he held senior roles at Millennium Pharmaceuticals Inc.



Matthew McDonnell

CHIEF FINANCIAL OFFICER

Mr. McDonnell has served as CFO since November 2018. Prior to his appointment he worked at KPMG for over 24 years, where Mr. McDonnell held several senior positions including 10 years as a partner. He has experience in restructurings, acquisitions, divestments, privatizations and other significant financial transactions.



Dr. Chris Meduri

CHIEF MEDICAL OFFICER

Dr. Meduri has served as Anteris' CMO since August 2021. Dr. Meduri is a practicing Interventional Cardiologist at Stem Cardiovascular Foundation, Memphis, TN and a recognized global leader in the field of valvular heart disease with over 3,500 career structural heart procedures and over 300 annually. He has served as global head of many TAVR, mitral and tricuspid trials.



Board of Directors



John Seaberg

CHAIRMAN

Mr. Seaberg has been Chairman since March 2017 and a director since October 2014. He has served as Board Chair of Preceptis Medical Inc since 2016 and Phraxix Medical Inc since 2009. He was Executive VP at Cedar Point Capital from 2015-2023. He was Chair of Synovis Inc., a manufacturer of medical devices and tissue products from 2008-2012.



Wayne Paterson

VICE CHAIRMAN & CEO

Mr. Paterson has served as CEO since March 2017 and was appointed Vice Chairman in March 2025. He held global positions in big pharma incl. Merck KGaA ("Merck") from 2005-2013, and Roche (1995-2005). His roles included Global Head of CV Medicine, President of Europe, Israel, Canada & Australia, President of Emerging markets incl. Russia & LATAM, CEO of Japan, Head of Commercial Ops in China. He sat on a NASDAQ board (CHPD) and led a \$5B sale of that business. He has launched 36 global healthcare products totaling billions in revenue.



Stephen Denaro

DIRECTOR & COMPANY SECRETARY

Mr. Denaro has been a director and Company Secretary since October 2018. Mr. Denaro serves as director and sole shareholder of Trio Business Intermediaries Pty Ltd. He has over 25 years of experience in mergers and acquisitions, business valuations, accountancy services, and income tax compliance.



Dave Roberts

NON-EXECUTIVE DIRECTOR

Mr. Roberts joined LeMaitre Vascular (NASDAQ: LMAT) in 1997 as its twelfth employee and has served as a Board Director since 2001 and as President since 2007. Mr. Roberts has also served as a Board Director of Lexington Medical since 2023 and of Parasole Restaurant Holdings since 2013.



Greg Moss

NON-EXECUTIVE DIRECTOR

Mr. Moss serves as Chief Business and Legal Officer, as well as Corporate Secretary and Chief Compliance Officer of Evommune, Inc. Prior to Evommune, he served as Executive Vice President, General Counsel, and Corporate Secretary, Chief Compliance Officer at Kadmon, culminating in Kadmon's \$1.9 billion acquisition in 2021.



David St Denis

PRESIDENT & DIRECTOR

Mr. St Denis has served as COO since July 2017 and was appointed President and Director in March 2025. From 2008-2017 he held senior positions at Merck including Head of Commercial Operations for Europe and Canada, and Head of Operations for Emerging Markets. From 1996-2006, he held senior roles at Millennium Pharmaceuticals Inc.



Global Manufacturing Footprint

Purpose-built infrastructure designed for efficient scale-up and commercial readiness

Malaga, Western Australia



Minneapolis, USA

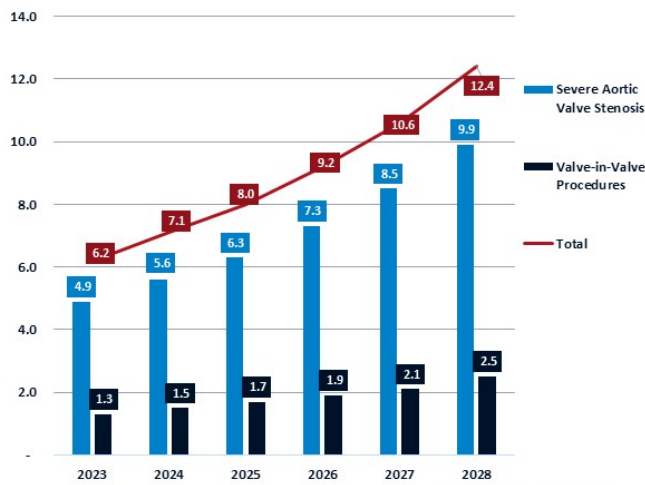




TAVR market opportunity expected to reach US\$9.9bn in 2028

Underpenetrated patient population with only 15-20%¹ of severe aortic stenosis cases treated today

TAVR Aortic Stenosis & Valve-in-Valve Market²



Potential for further significant growth

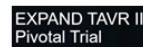
Currently 3 industry trials in progress, anticipated to be completed in 2025



Edwards Lifesciences: SAPIEN 3 platform FDA approved for asymptomatic severe AS patients based on EARLY TAVR Trial (May 2025)



Edwards Lifesciences: will examine the TAVR procedure in patients who are > 65 years, have moderate AS, and have at least one additional risk factor



Medtronic: to explore the treatment of moderate AS with early TAV implantation (TAVI) before AS becomes severe

¹ Galis B, Çelik M, Head SJ, et al. Natural History of Asymptomatic Severe Aortic Stenosis and the Association of Early Intervention With Outcomes: A Systematic Review and Meta-analysis. *JAMA Cardiol*. 2020;5(10):1102-1112. doi:10.1001/jamacardio.2020.2487.
² Future Market Insights. Transcatheter Heart Valve Replacement (TAVR) Market: Global Industry Analysis 2016-2033 and Opportunity Assessment 2024-2034. Future Market Insights 2024. Available from: <https://www.futuremarketinsights.com/reports/transcatheter-heart-valve-replacement-tavr-market>.

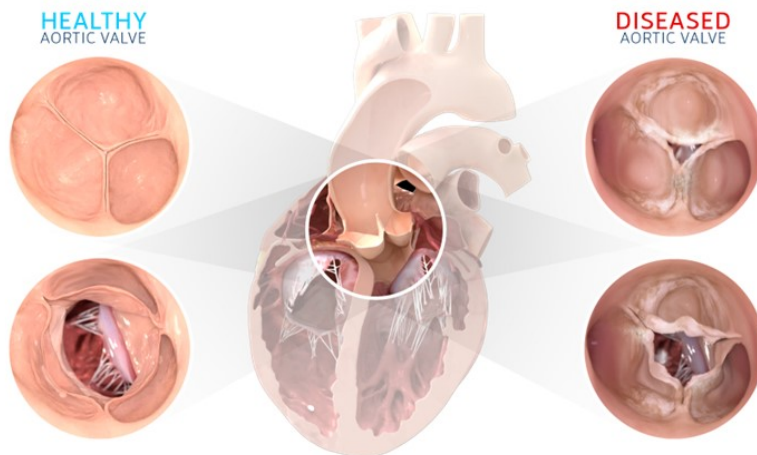


A New Class of TAVR

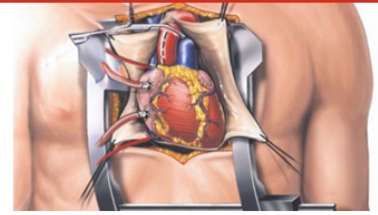
anteristech.com

Aortic Stenosis (AS) - Current Treatment Options

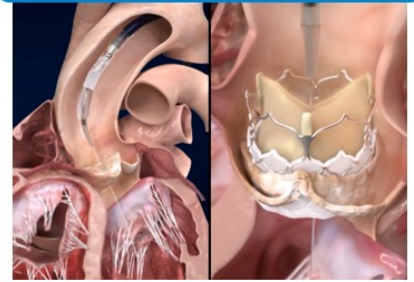
A life-threatening condition caused by narrowing of the aortic valve
Patients with severe AS have a 50% risk of dying within 2 Years¹



SAVR – Invasive, open-heart surgery



TAVR - Minimally invasive procedure



¹ Leon MB, Smith CR, Mack M, et al. Transcatheter Aortic Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery. N Engl J Med. 2010;363(17):1597-1607. doi:10.1056/NEJMoa1008232.
SAVR, Surgical aortic valve replacement; TAVR, Transcatheter aortic valve replacement



Yesterday's TAVRs were not developed for today's patients

DurAVR® was deliberately designed for younger and more active patients

Patients need a safer alternative to open heart surgery

First & second generation TAVRs

~85 yrs

2011-2013 average patient age was 84¹



Patients need a valve that restores an active lifestyle for the rest of their life

Third generation TAVRs

~73 yrs

2016-2017 average patient age is 73 & declining²



¹ STS/ACC TVT Registry of Transcatheter Aortic Valve Replacement J Am Coll Cardiol 2016;117:2492-2516
² N Engl J Med 2017; 376:1695-1705



Anteris set out to address the needs in TAVR by asking different questions

How does a healthy aortic valve perform?



How can we mimic a native valve?



How can we put that valve in a frame?



How do we deliver the valve?



Our expert panel of physicians advised the Company what they wanted in a next generation valve:

- **Balloon-expandable delivery**
Drives clinical adoption - Controlled expansion, predictable placement, commissure alignment
- **Clinically better**
For younger and more active patients
Curative, pre-disease hemodynamics, laminar flow



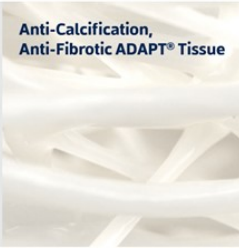


DurAVR®: A New Class of TAVR

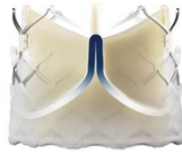
Single-piece, native-shaped biomimetic design built to mimic the performance of a healthy aortic valve.



Anti-Calcification,
Anti-Fibrotic ADAPT® Tissue



Long Coaptation
To Reduce Stress



Balloon Expandable
Precision



Commissure Alignment
Technology



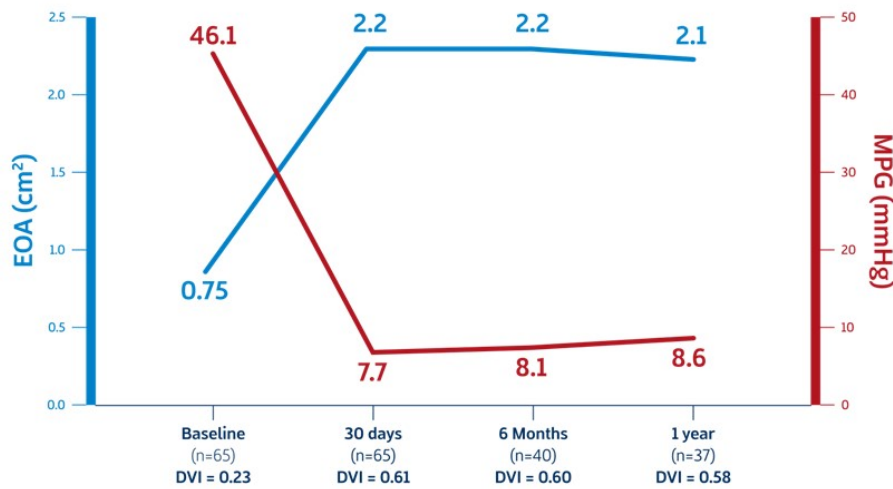
Coronary
Access





DurAVR® Sustained hemodynamic performance to 1 year

Mean Annular Diameter: 22.4 mm



MPG 8.6
(Mean Pressure Gradient mmHg)

EOA 2.1
(Effective Orifice Area cm²)

DVI 0.58
(Doppler Velocity Index)

Mean Pressure Gradient (MPG)

- The average pressure across the aortic valve between the left ventricle and aorta
- Patients with severe AS have MPG ≥ 40 mmHg

Effective Orifice Area (EOA)

- The cross-sectional area of the aortic valve opening that is available for blood flow
- Patients with severe AS have an EOA of ≤ 1 cm²

Doppler Velocity Index (DVI)

- An index that expresses EOA as a proportion of valve area
- DVI represents the physical ratio of a patient's aortic valve area to the left ventricular outflow tract area

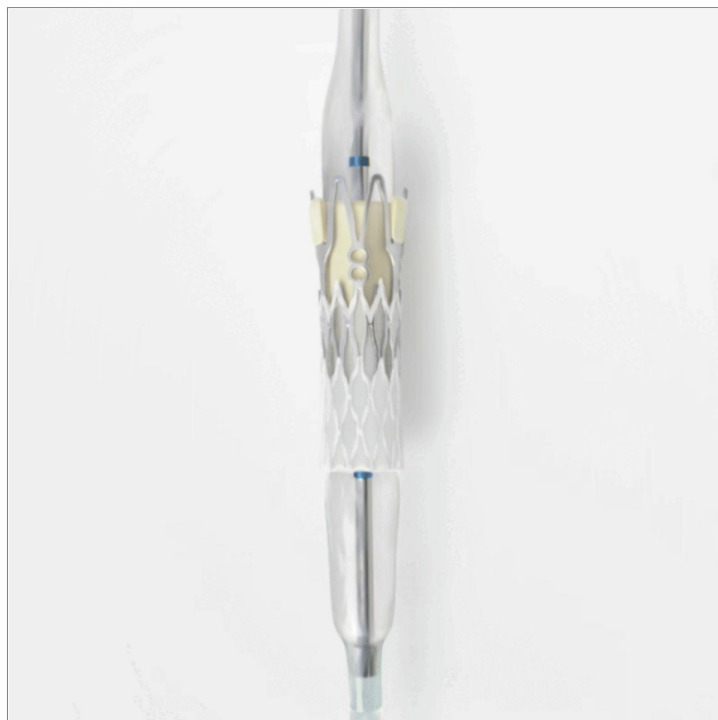
DurAVR[®]

TRANSCATHETER HEART VALVE

" A balloon expandable valve with self-expanding hemodynamics is like the holy grail. "

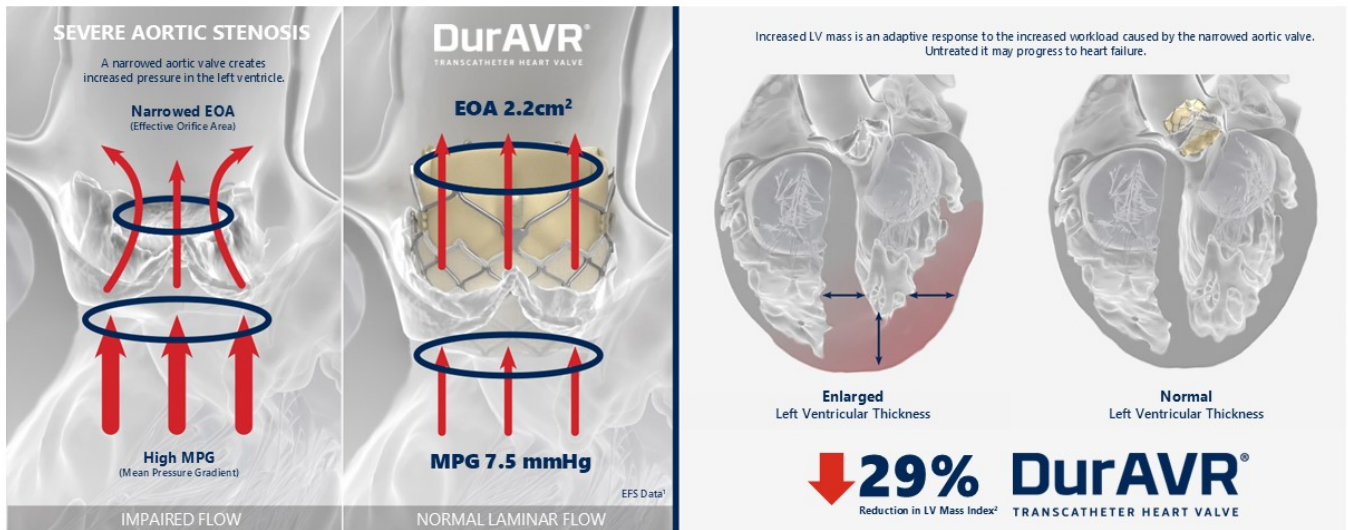


Dr Michael Reardon
Professor of Cardiothoracic Surgery, Allison Family
Distinguished Chair of Cardiovascular Research
Methodist DeBakey Heart & Vascular Center





Restores flow dynamics, significantly reducing left ventricular (LV) mass



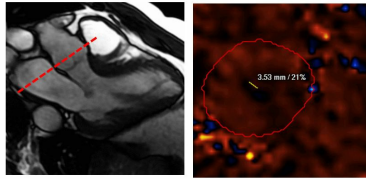
1. Waggoner T. DurAVR® Biomimetic Transcatheter Heart Valve: Early Feasibility Study (EFS) Update. Oral Presentation at: CRT Conference, March 2024, Washington, USA.
2. Caraculante J. Biomimetic Design Restores Flow and Hemodynamics and Leads to Significant LV Mass Regression: update from First-in-Human (FHI) Study with novel DurAVR® Transcatheter Heart Valve. Oral Presentation at: New York Valves, June 2024, New York, New York, USA.

DurAVR[®] is the first aortic valve to restore normal aortic flow

Normal Aortic Flow

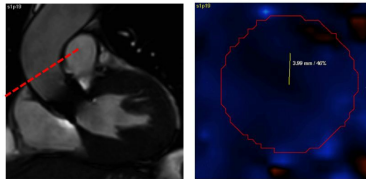
When compared to a healthy aortic valve, DurAVR[®] THV showed **no significant difference** in flow ($p > 0.05$)

Healthy Aortic Valve



FD = **10%**
FRR = **1%**
(n=5)

Post DurAVR[®] THV implant

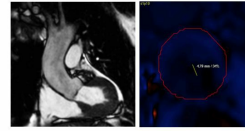


FD = **14%**
FRR = **4%**
(n=5)

Impaired Aortic Flow

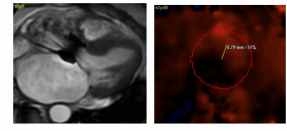
Normal Valve (n=5) vs: TAVR (n=4) $p < 0.05$ | SAVR (n=8) $p < 0.01$

Severe AS



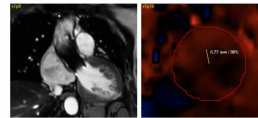
FD = **46%** FRR = **23%**

Sapien 3



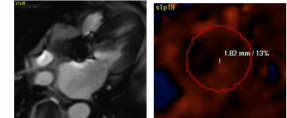
FD = **48%** FRR = **35%**

Evolut R



FD = **25%** FRR = **4%**

CEP Magna Ease



FD = **27%** FRR = **30%**

FD = Flow Displacement | FRR = Flow Reversal Ratio

1. Garg P. DurAVR[®] TAVI novel leaflet design restores ascending aortic flow haemodynamics on cardiac MRI: First-in-human study. Oral presentation at PCR London Valves, November 2022, London, England.
2. Garg P. DurAVR[®] TAVI: biomimetic design restores flow and leads to significant LV mass regression. MRI study. Oral presentation at PCR London Valves, November 2024, London, England.
3. Cavalcante J. Biomimetic Design Restores Flow and Hemodynamics and Leads to Significant LV Mass Regression: update from First-in-Human (FIH) Study with novel DurAVR[®] Transcatheter Heart Valve. Oral presentation at New York Valves, June 2024, New York, New York, USA.
Controls with no known aortic valve disease assessed and age-height-weight matched to reduce bias. Limitations: Small sample size. Control n=5, DurAVR[®] n=5, Other TAVR n=4, SAVR n=8.

Valve in Valve (ViV) expanding TAVR market – US\$2.5bn by 2028

Existing bioprosthetic valves fail and patients need retreatment

- **ViV Challenges**

Preserving coronary access, providing good hemodynamic result

- **Solution – DurAVR® THV**

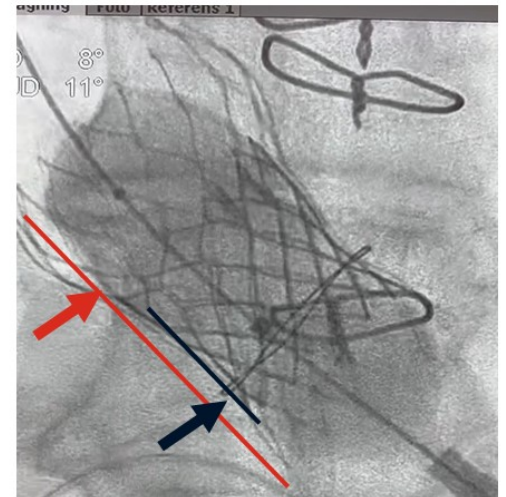
Short-frame valve, paradigm-shifting hemodynamic performance and large open cell geometry to maintain coronary access

- **Case Study (Valve-in-Valve-in-Valve)**

77-year-old patient, too high risk for repeat surgery with failure of his valve-in-valve

Compassionate use approved by Swedish Regulatory Authority

Date	Vmax ao m/s	MPG mmHg	DVI
2011 Surgical Valve	3.1	23	0.4
2018 Evolut in Surgical Valve	3.7	31	0.34
2024 Max stress	4.0	41	0.15
Post DurAVR®	3.0	20	0.33–0.40



 **Failed Evolut**

 **Surgical Valve**

1. Setberg, M. DurAVR® THV ViV case: How to achieve optimal gradients in limited space. Oral Presentation at PCR London Valves, November 2024, London, England.
Vmax ao: The maximum velocity of blood flow across the aortic valve during systole. In healthy individuals, the Vmax ao is typically 1.0 m/s. As AS progresses, the valve narrows, and the blood flows through the smaller opening at a higher velocity.



Path to Commercialization



anteristech.com



130 DurAVR[®] patients – support pivotal trial launch (PARADIGM Trial)

49 patients treated YTD (2025)

2021

2022

2023

2024

2025

First-in-human
("Embark") Study

FPI Nov 2021

Early Feasibility Study
("EFS") - DurAVR[®]

FDA submission

FDA approval

Ongoing monitoring

Valve-in-Valve
Compassionate use



Patient recruitment
targeted 4Q 2025*

*Subject to regulatory approval

FPI: First patient in Embark Study

21



PARADIGM

TRIAL





The first all-risk, head-to-head TAVR registration trial



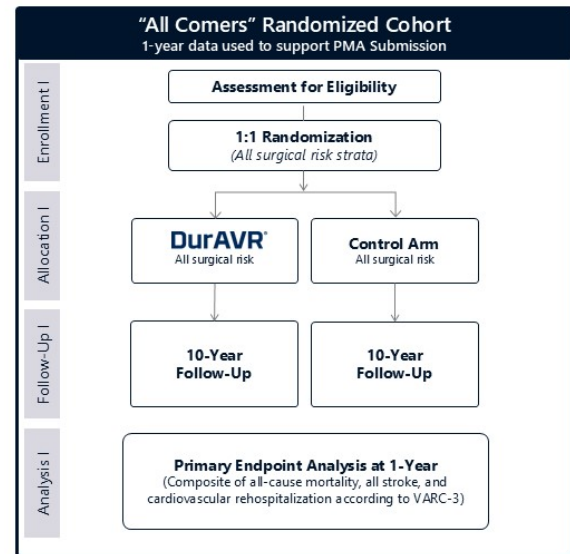
Study Co-Chairs: Dr. Michael J. Reardon, Professor Stephan Windecker

Clinical Trial Snapshot

- **Sample size**
~1,000 patients, all surgical risk groups
- **Sites**
Up to 85 centers in the U.S., Europe & Canada
- **Primary end point**
Non-inferiority at 1-year (DurAVR® THV vs. SAPIEN or Evolut series THV)

Regulatory & Commercial Pathway

- **PMA Submission**
1-year clinical data potentially supports U.S. FDA Premarket Approval
- **CE Mark**
European regulatory submission anticipated to progress in parallel
- **Commercialization**
Launch to commence following PMA or CE Mark approval



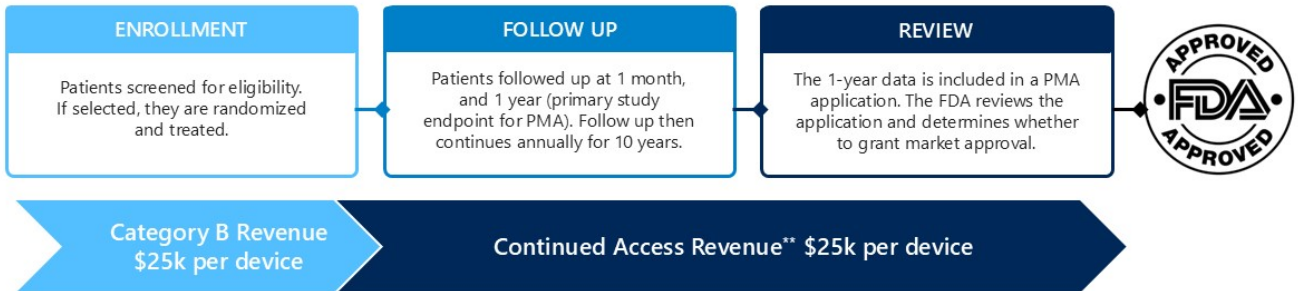
Premarket Approval (PMA) is required for commercialization of the DurAVR® THV in the United States.
CE Mark approval is required for commercialization of the DurAVR® THV in the European Economic Area (EEA).



PARADIGM Trial – Planned enrollment and revenue*

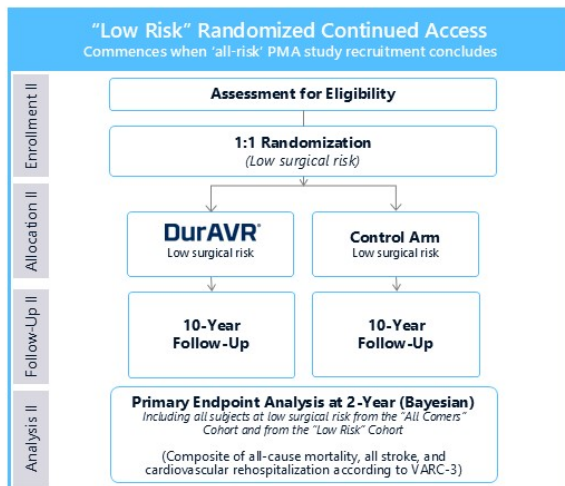


Category B Medicare coverage of US\$25k per device*

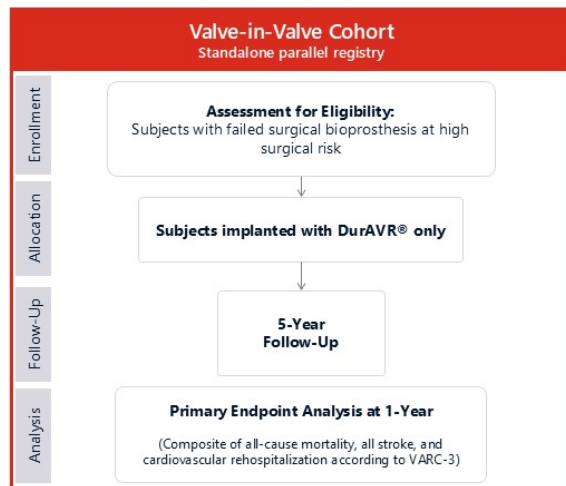


*US Medicare coverage: An approval for a Category B (Nonexperimental/investigational) IDE study will allow coverage of the Category B device and the routine care items and services in the trial. Medicare Coverage Related to Investigational Device Exemption (IDE) Studies (CMS) - coverage is subject to FDA IDE approval.
** Anters will seek FDA approval for continued access.

Supplementary studies not expected to be required for all-risk TAVR approval*



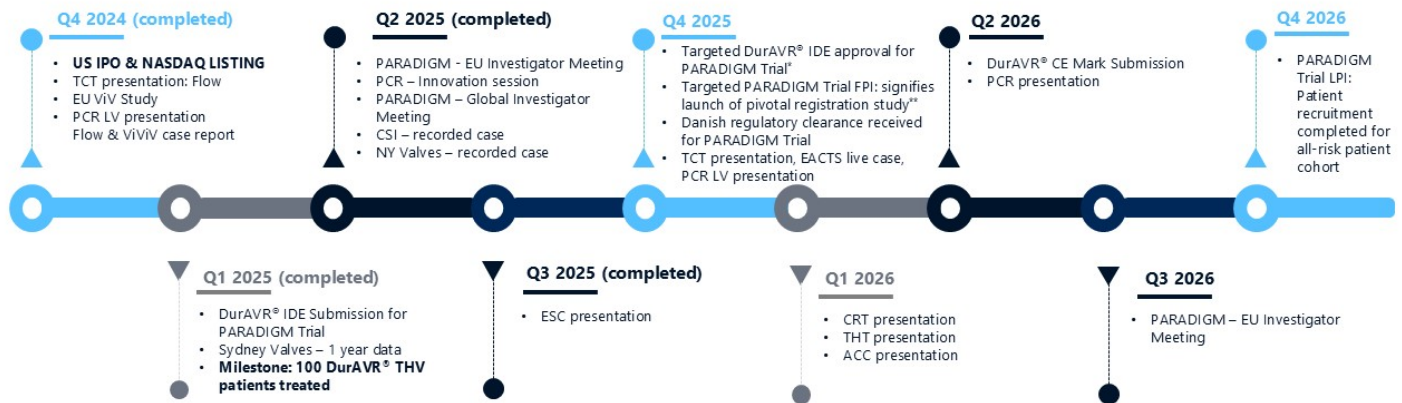
Low-risk data are not required to support the regulatory submission, whether PMA or CE Mark, for an all-risk TAVR indication for severe aortic stenosis



ViV registry is a separate registry conducted in parallel and is not required to support the regulatory submission for an all-risk TAVR indication for severe aortic stenosis



Anticipated Milestones



*Following our IDE submission in the first quarter of 2025, the FDA provided us with requests for additional information, which we are working to address. As of the date of this presentation, the FDA has not approved the IDE. We cannot predict whether or to what extent the FDA will have further requests for information or guarantee that the IDE will be approved at all or on any particular timeline. In particular, if prolonged government shutdown or disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions. To the extent the PARADIGM Trial is commenced in a non-U.S. jurisdiction prior to obtaining FDA approval of the IDE, there is a risk that the results of such trial may not be permitted to be used to support a future marketing approval or clearance of the device by the FDA to the extent that the FDA-approved IDE version differs from the version tested in such non-U.S. jurisdiction. **Subject to regulatory approval, as described in the preceding footnote.



Key Takeaways

Building commercial readiness for a new class of TAVR that mimics a healthy aortic valve

- 1 | DurAVR® THV - Proprietary, new class of TAVR for aortic stenosis**
 - Easy, predictable balloon expandable deployment with the function of a healthy, native aortic valve
- 2 | US\$9.9bn global TAVR market forecasted by 2028¹ with many untreated patients**
 - DurAVR® was designed to offer advantages over two TAVR market leaders
- 3 | Clinically validated with 130 patients**
 - 30 day and 1 year data supports strong DurAVR® safety profile and hemodynamics
- 4 | PARADIGM Trial targeted start 4Q 2025* potentially supporting FDA & CE Mark filings**
 - High quality global KOL adoption expected to drive rapid trial enrollment
- 5 | Commercial ready - capital efficient go to market plan**
 - Highly experienced clinical & commercial leadership plus infrastructure in place



1. Future Market Insights: Transcatheter Heart Valve Replacement (TAVR) Market: Global Industry Analysis 2016 - 2023 and Opportunity Assessment 2024 - 2034. Future Market Insights, 2024. Available from: <https://www.futuremarketinsights.com/reports/transcatheter-heart-valve-replacement-tavi-market>.
*Subject to regulatory approval

Appendices





Medical Advisory Board

Anteris is guided by a global team of well-regarded cardiovascular Physician advisors



North America



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Cardiovascular Research
Foundation
New York, NY



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Centre, Adelaide



Dion Stub, MBBS, PhD

The Alfred/ Cabrini
Hospital, Melbourne



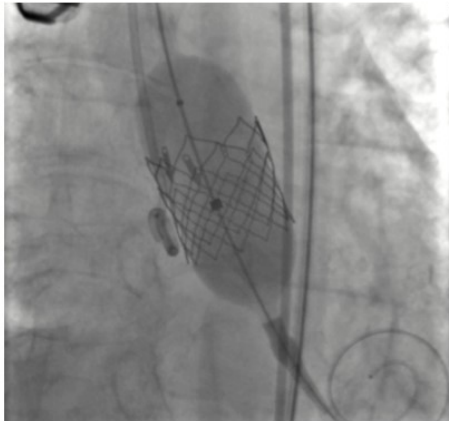
Europe



Australia

Procedural Success Endpoints Across Various Anatomies

Technical Success (VARC 3): 94%
Device Success (VARC 3): 92.3%
n = 65

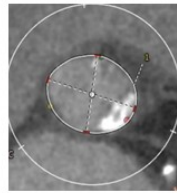


1 patient required 2 valves; 3 patients had vascular access site complications

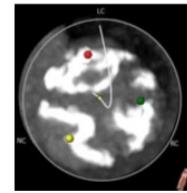
Predictable BE Placement

Challenging anatomies treated
(Baseline MDCT)

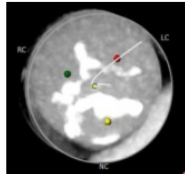
Severe annular calcium



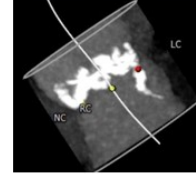
Extreme leaflet calcium



Type 1 bicuspid



Extreme LVOT calcium

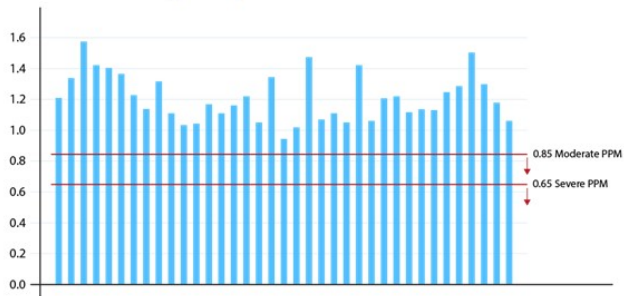


BAV = Balloon Aortic Valvuloplasty
MDCT = Multidetector Computed Tomography



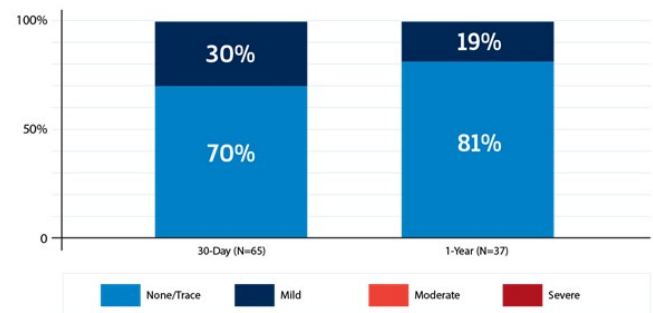
DurAVR® Data Spotlight

Zero Prosthesis Patient Mismatch (PPM) in Small Annuli



Measured at 1-year, n=37

Low Paravalvular Leak



No moderate or severe PVL

