

### **Edwards Lifesciences 2023 Investor Conference**

# **2023 Investor Conference**

### **Mark Wilterding**

Senior Vice President Investor Relations



### **Cautionary Statement**

Presentations and comments made today by management of Edwards Lifesciences Corporation (the "Company") will include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements can sometimes be identified by the use of words, such as "may," "will," "should," "anticipate," "believe," "plan," "project," "estimate," "potential," "predict," "unstoppable," "early clinician feedback," "expect," "intend," "guidance," "outlook," "optimistic," "aspire," "confident" or other forms of these words or similar expressions and include, but are not limited to, the Company's financial goals or expectations for 2023, 2024 and beyond (including, but not limited to, sales, underlying growth, foreign exchange impact on sales, gross profit, earnings per share and its key components, free cash flow, SG&A, R&D, tax rate, operating margin, diluted shares outstanding, and other financial expectations); expectations for our products (including, but not limited to, headwinds and tailwinds, growth drivers, expected global opportunity, the timing and results of clinical trials, regulatory approvals, and reimbursement coverage); industry growth projections; the Company's rate of penetration in individual and global markets; forecasted trends in patient treatment and demographics; strategies for the Company's new and existing products; continued development of future innovations and statements regarding the intention to spin-off the Critical Care business at the end of 2024.

Statements of past performance, efforts, or results about which inferences, or assumptions may be made can also be forward-looking statements and are not indicative of future performance or results. Forward-looking statements are based on estimates and assumptions made by management of the Company and are believed to be reasonable, though they are inherently uncertain, difficult to predict, and may be outside of the Company's control. The Company's forward-looking statements speak only as of the date on which they are made, and the Company does not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. If the Company does update or correct one or more of these statements, investors and others should not conclude that the Company will make additional updates or corrections.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Factors that could cause actual results to differ from that expressed or implied by the forward-looking statements are detailed in the Company's periodic reports filed with the U.S. Securities and Exchange Commission.

The opinions expressed by our guest clinicians are their own and do not necessarily reflect the views of the Company.

### **Use of Non-GAAP Financial Measures**

Unless otherwise indicated, all figures are GAAP financial measures.

The Company uses the term "underlying" or "organic" or "constant currency" growth rate when referring to non-GAAP sales information, which excludes foreign exchange rate fluctuations, the conversion to a consignment inventory system for surgical structural heart, the positive impact of transcatheter aortic valve replacement ("TAVR") stocking sales in Germany and the negative impact of de-stocking, sales return reserves associated with TAVR product upgrades, and includes the prior year proforma sales results of a business acquisition. The Company uses the term "adjusted" to also exclude intellectual property litigation income and expenses, amortization of intangible assets, fair value adjustments to contingent consideration liabilities arising from acquisitions, impairments of long-lived assets, and the purchase of intellectual property.

A reconciliation of non-GAAP historical financial measures to the most comparable GAAP measure is available on the "Investors" page at www.edwards.com

Guidance for sales and sales growth rates is provided on an "underlying basis," and projections for diluted earnings per share, net income and growth, gross profit margin, taxes, and free cash flow are also provided on a non-GAAP basis as adjusted for the items identified above due to the inherent difficulty in forecasting such items. The Company is not able to provide a reconciliation of the non-GAAP guidance to comparable GAAP measures due to the unknown effect, timing, and potential significance of special charges or gains, and management's inability to forecast charges associated with future transactions and initiatives.

### **Opening Remarks**

### **Bernard Zovighian**

Chief Executive Officer



### **Entering a new era of Structural Heart innovation**



### Sharpened Focus on SHD



# Expanding **Opportunity**



### Sustainable **Growth**

#### **Our Credo**

At Edwards Lifesciences, we are dedicated to providing innovative solutions for people fighting cardiovascular disease.

Through our actions, we will become **trusted partners** with customers, colleagues, and patients – creating a community unified in its mission to improve the quality of life around the world. Our results will benefit customers, patients, employees and shareholders.

We will celebrate our successes, thrive on discovery, and continually expand our boundaries. We will act boldly, decisively, and with determination on behalf of people fighting cardiovascular disease.

Helping patients is our life's work, and



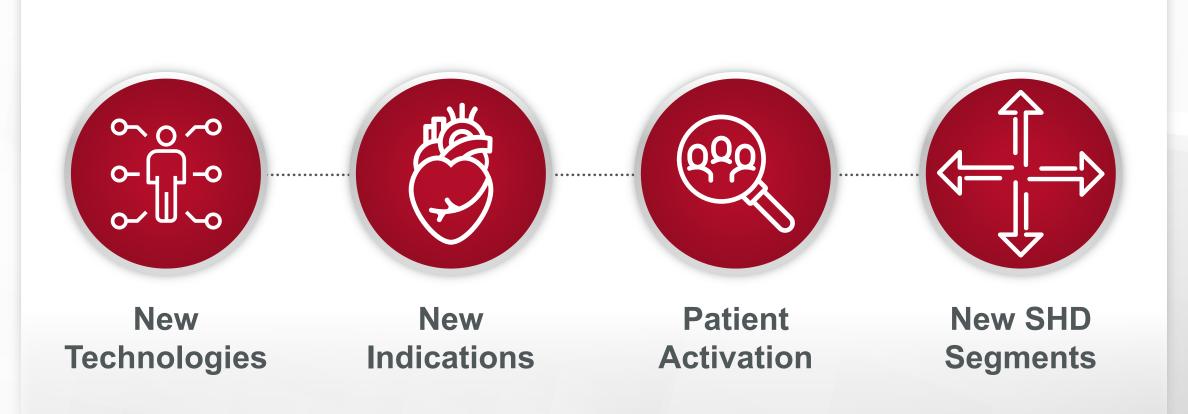
#### **Patient-Focused Culture**



#### **Unique Innovation Strategy**



### Sustainable growth achieved through key investments



### Edwards is uniquely positioned to transform patient care

### **Structural Heart Disease:**

a leading driver of cardiovascular death



### every 33 seconds

One person in the US dies from cardiovascular disease

Enabling a world where structural heart patients are diagnosed earlier, are treated routinely, live longer and enjoy a better quality of life without frequent hospitalizations



### **Expanded opportunities to increase treatment of SHD patients**

#### **Structural Heart Disease**

### **Aortic**



- New Indications
  Asymptomatic, moderate
- New Technology

#### **Mitral**



Portfolio of Technologies
 Mitral Repair (TEER)
 Mitral Replacement (TMVR)

### **Tricuspid**



Portfolio of Technologies
 Tricuspid Repair (TEER)
 Tricuspid Replacement (TTVR)

### **Expanded opportunities to increase treatment of SHD patients**

**Structural Heart Disease** 

### Valvular

### **Aortic**



- **New indications**Asymptomatic, moderate
- New Technology

#### **Mitral**



Portfolio of Technologies
 Mitral Repair (TEER)
 Mitral Replacement (TMVR)

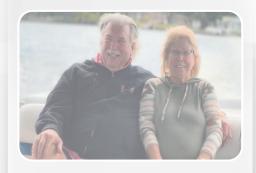
### **Tricuspid**



Portfolio of Technologies
 Tricuspid Repair (TEER)
 Tricuspid Replacement (TTVR)

### Non-Valvular

### **Heart Failure**



- 1 in 4 will develop HF in their lifetime<sup>1</sup>
- **75%**5-year mortality<sup>2</sup>



**Prevalent Population** 

~20M patients suffer from Structural Heart Disease

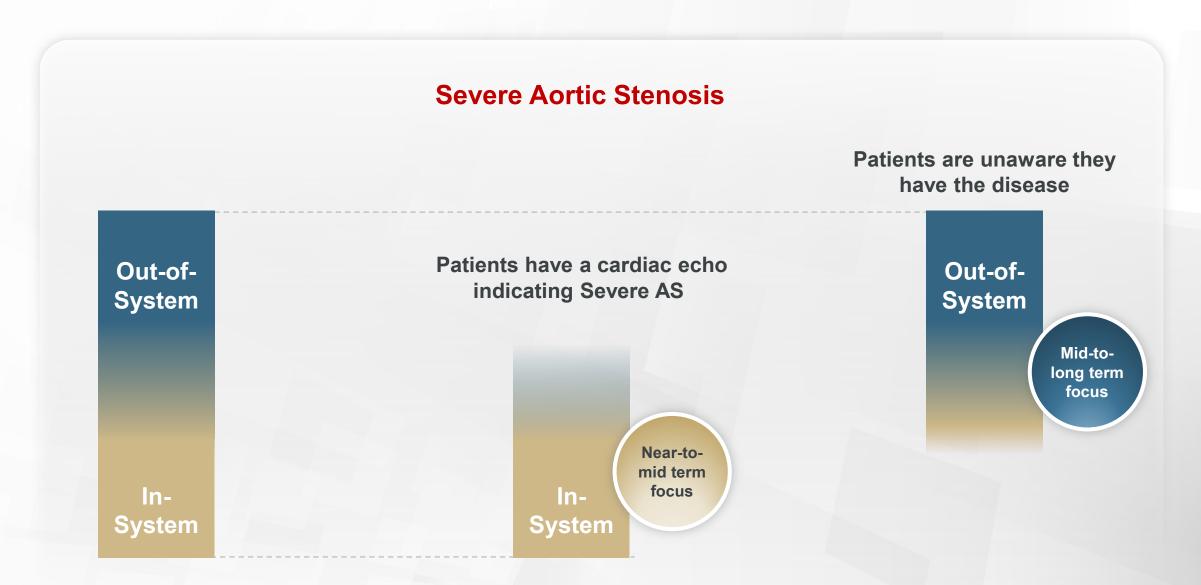
# Technology advancements and evidence have doubled AS treatment rates, yet significant undertreatment remains



Patients with AS have high mortality risk ... aortic valve replacement rates remain low<sup>1</sup>

Many patients with AS are currently undertreated even in experienced centers<sup>2</sup>
– Eugene Braunwald, MD, 2023

### Patient activation is central to our TAVR growth strategy



# Leading innovator

Innovating premium technology for patients best treated with surgery



# Revolutionizing AS treatment

Accelerating the transformation of care for millions of AS patients still untreated



### Pioneering breakthroughs

Reaching inflection point with a therapy portfolio to treat millions of MR and TR patients



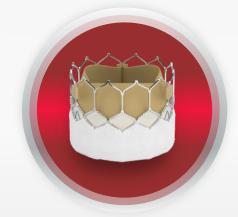
### **Leading** innovator



### Surgical

Innovating premium technology for patients best treated with surgery

### Revolutionizing AS treatment



### TAVR

Accelerating the transformation of care for millions of AS patients still untreated

### Pioneering breakthroughs



### TMTT

Reaching inflection point with a therapy portfolio to treat millions of MR and TR patients

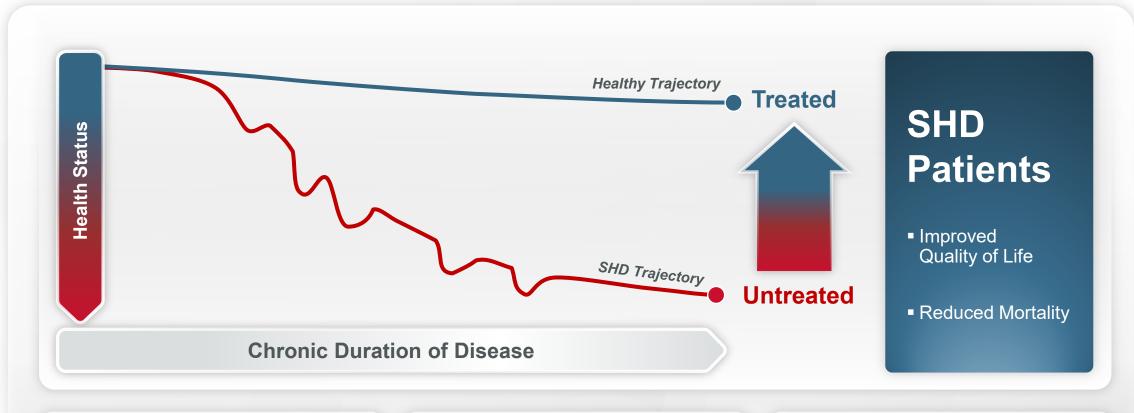
### Natural progression



### Interventional HF

Investing in early-stage technology solutions

### With the common goal of transforming the patient experience





SAPIEN 3 THV
"I got my life back."



EVOQUE Tricuspid
"I am able to walk long
distances, resume yoga,
gardening."



PASCAL
"I'm glad to be here,
waking up in the morning
and seeing my family.
Now I can drive them all
crazy!"

### Exiting 2023 in a position of strength



### Achieved Clinical and R&D Milestones

- Rapidly enrolling ALLIANCE pivotal trial for groundbreaking next-generation TAVR,
   SAPIEN X4
- Completed enrollment in ENCIRCLE pivotal trial for first ever transfemoral mitral valve replacement, SAPIEN M3
- Presented 1-year CLASP IID pivotal trial data for PASCAL, our differentiated edgeto-edge mitral repair system



### **Obtained Important Regulatory Approvals**

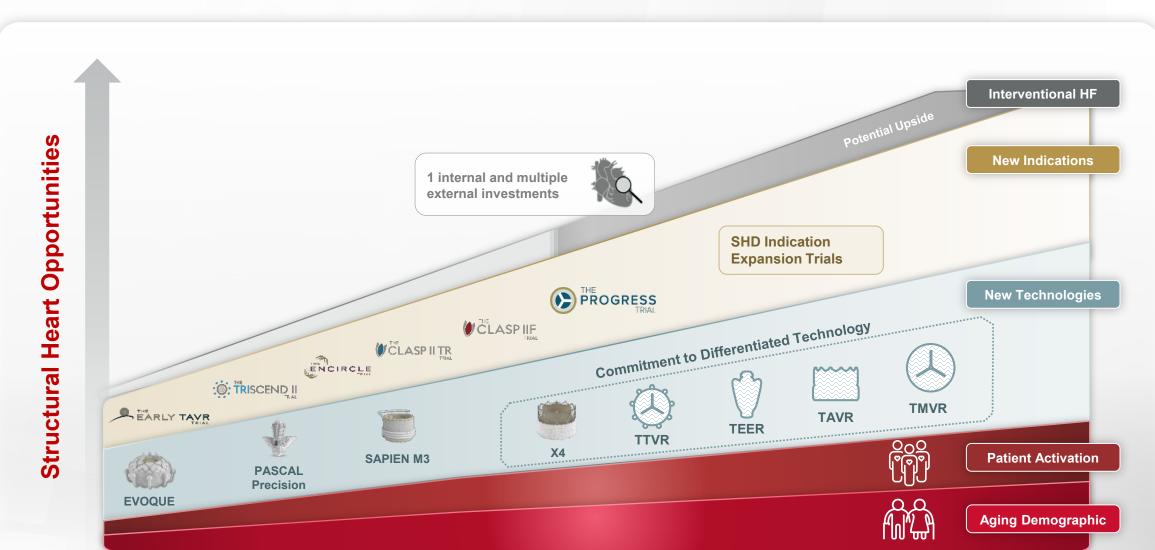
- CE Mark approval for EVOQUE, world's first transcatheter tricuspid valve
- CE Mark approval for MITRIS RESILIA, our differentiated surgical mitral valve
- Initiated enrollment of HF patients with APTURE in ALT-FLOW II, a randomized, sham controlled trial



### **Maintained Durable Financial Profile**

- Expect total company sales growth of 10-13% in-line with guidance \$5.9 - \$6.1 billion
- \$2.47 \$2.53 Adjusted EPS
- Strategic investments in R&D and fieldbased resources for TAVR and TMTT

# Our sharpened focus and investments will significantly expand the SHD opportunity through 2028 and beyond

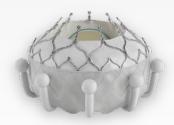


### **Entering 2024 with strong momentum**



#### **TAVR**

- Moderate AS trial enrollment complete in Q1, 2 years early
- Asymptomatic pivotal trial results expected at TCT
- SAPIEN 3 Ultra RESILIA approval expected in Europe in early 2024
- Actively enrolling SAPIEN X4 trial
- Patient activation momentum



#### **TMTT**

- Launching EVOQUE transcatheter valve in Europe; planning U.S. launch mid-2024
- PASCAL new markets and global momentum
- After completion of M3 pivotal trial expect Europe launch end of 2025
- CLASP IITR year-end completion



### Surgical

- Continuing to extend leadership in Surgical
- Launching MITRIS RESILIA in Europe
- Presenting clinical data on MITRIS and KONECT



#### **Critical Care**

- Advancing the next generation of smart, predictive sensors
- Driving Smart Recovery adoption with clinical evidence
- Spin-off creates industry-leading company

### Guidance

2024

8-10%
Sales growth\*

\$2.70 - \$2.80

9-11% EPS growth

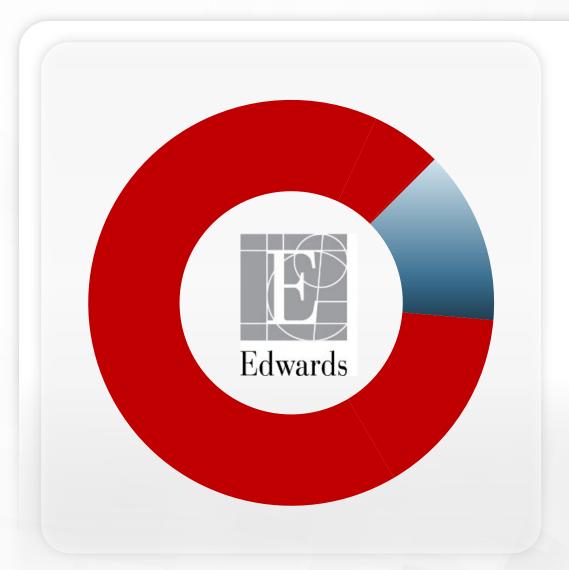
2025 And Beyond

10%+
Sales growth\*

Double-digit

EPS growth

# Strategic spin-off of Critical Care creates industry-leading advanced monitoring company



- Starting from a position of strength as a
   ~\$1 billion global market leader, with more
   than 4,000 talented employees dedicated to
   helping patients
- Enables increased focus and flexibility to improve the quality of care for millions of patients around the world
- Platform for organic growth, acquisitions, and strategic collaborations

### Edwards' executive leadership team



Bernard
Zovighian
Chief Executive Officer



**Don Bobo, Jr.** Strategy & Corporate Development



Todd Brinton, M.D. Chief Scientific Officer



Daveen
Chopra
Transcatheter Mitral
& Tricuspid Therapies



Dirksen Lehman Public Affairs



Jean-Luc Lemercier EMEA, Canada, Latin America



Dan Lippis JAPAC



Wayne Markowitz Surgical Structural Heart



Christine McCauley Human Resources



Joe Nuzzolese Global Supply Chain



Arnold
Pinkston
General Counsel



Gary Sorsher
Quality & Regulatory
Compliance



Katie Szyman Critical Care



Scott Ullem
Chief Financial Officer



Larry Wood
Transcatheter Aortic
Valve Replacement &
Surgical Structural Heart

Long-tenured healthcare executives

Deep expertise implementing our unique innovation strategy

Incentives aligned with shareholders

### Edwards' Board is accomplished and engaged

Leading governance practices

Highly experienced leaders

### **Active engagement**

- Strategy
- Incentive alignment
- Shareholder engagement
- Ompliance and risk oversight





# **Transcatheter Aortic Valve Replacement**

### **Larry L. Wood**

Corporate Vice President and Group President Transcatheter Aortic Valve Replacement and Surgical Structural Heart





# We expect the Global TAVR opportunity to exceed \$10B by 2028



The **Severe Aortic Stenosis** (SAS) opportunity remains significant - we are **gaining momentum in patient activation** 



We have made **significant progress in evidence generation**, including within the
Asymptomatic SAS and Moderate AS patient
populations



Our **technology is well positioned** to deliver excellent outcomes to AS patients and enable lifetime management



# Treatment rates of Severe AS patients have more than doubled since the introduction of TAVR



>2X
patients treated & treatment rate

### ~160K patients

Severe AS patients received AVR<sup>1</sup>

### ~70K patients

Severe AS patients received AVR<sup>1</sup> pre-TAVR

Technology, evidence, and efforts in patient activation have advanced treatment rates

US TAVR Launch

2010

2011





### Severe AS is a deadly disease, yet treatment rates remain low

Aortic Stenosis is one of the most common and serious heart valve diseases<sup>1</sup>



1 in 10 may die\*

\*SSAS patients within the first 5 weeks while awaiting treatment<sup>2</sup>

**AVR** treatment remains underutilized

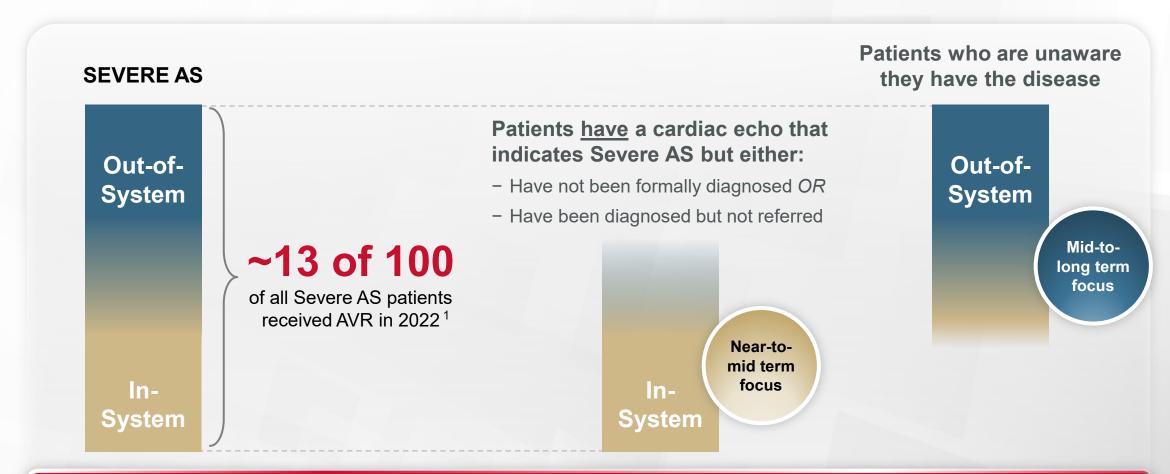


~13 of 100

of all Severe AS patients received AVR in 2022<sup>3</sup>

Our mission is to help unlock this undertreatment, so patients get access to life-saving therapy

# Undertreatment merits a deeper look into the severe AS opportunity



Both in-system and out-of-system opportunities support sustainable TAVR growth

# Research supports that undertreatment of in-system SAS patients specifically is significant



# The complexity of diagnosis and referral helps explain the undertreatment rate

Diagnosis of Severe AS starts with Echo



Several key criteria to assess degree of valve constriction

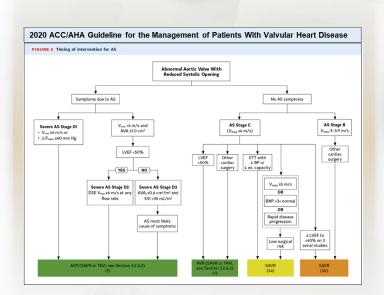


- Diameter (AVA)
- Pressure\* (mean gradient)
- Blood flow (Peak velocity)



**Guidelines are complex** 





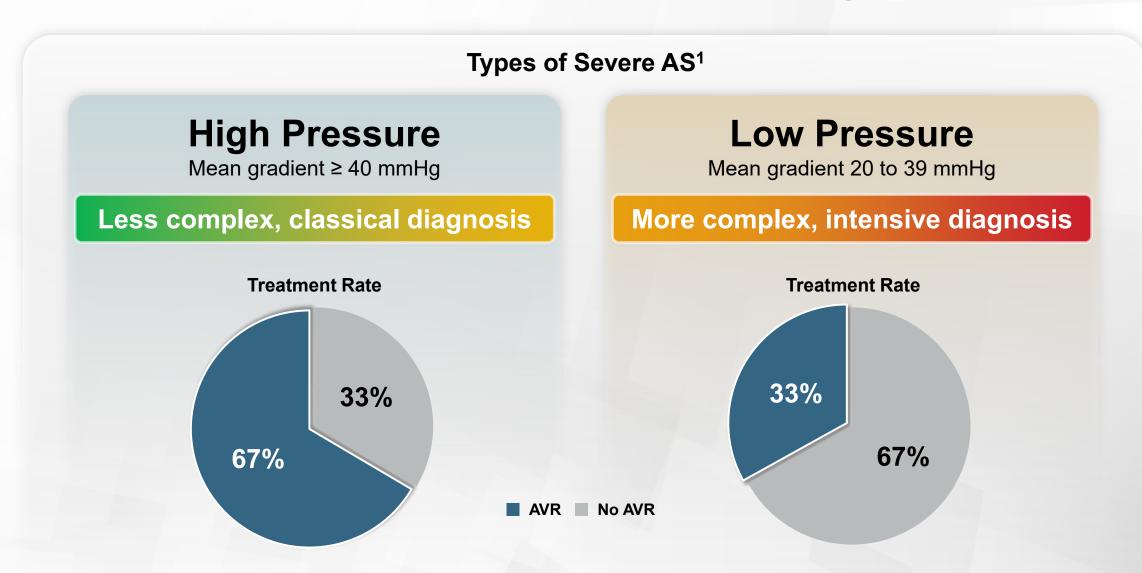


So, Referrers typically focus on only pressure

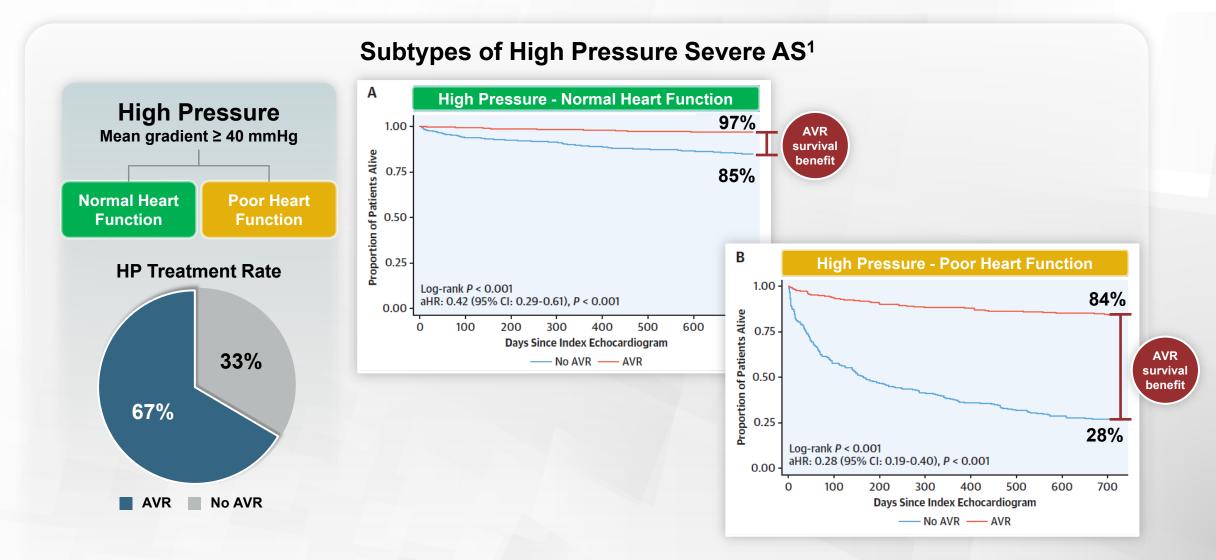


\*Pressure across aortic valve is clinically known as Gradient; High pressure = Mean gradient ( $\Delta P_{mean}$ )  $\geq$ 40 mm Hg

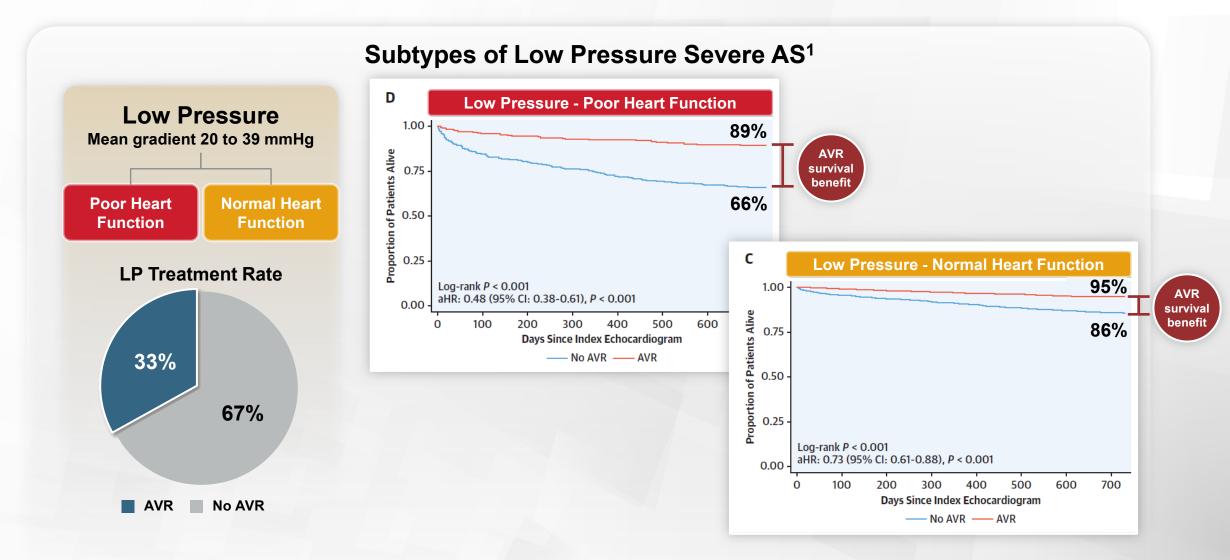
### But, not all Severe AS patients present with high pressure



# High pressure SAS patients benefit significantly from the therapy, regardless of heart function



# There is significantly more undertreatment in the low pressure severe AS group, and all patients benefit from treatment

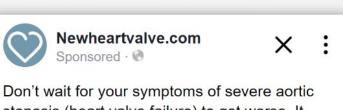


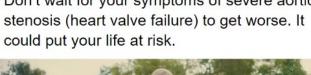
#### In-System

## For patients with high pressure classical diagnosis of severe AS, we believe education is key in improving treatment rates

We are raising urgency to seek care by educating on risks of deadly disease and benefits of therapy

#### **Patients**



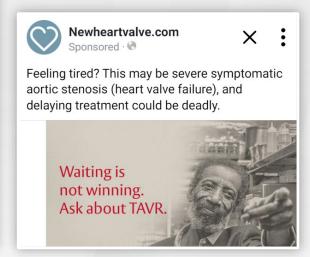




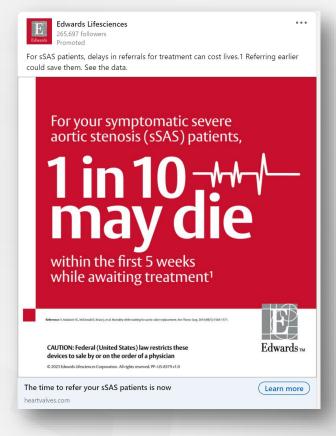
justgettingstarted.com **Ask for TAVR** 

Learn more





#### Referrers

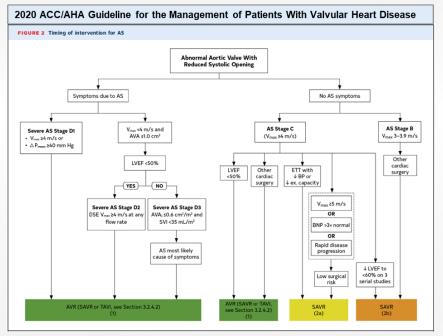


### For severe AS patients with an unclear diagnosis, reducing complexity and streamlining referral is crucial





### Automate guideline-directed diagnosis



We have several workstreams based on Al-driven technology to streamline in-system diagnosis



Solutions to identify SAS patients, leveraging echo and/or EMR data



Seamless workflow integration to facilitate decision making

System

### Beyond echo criteria, symptom assessment is currently a critical step before referral – there is an opportunity to streamline this

Symptom assessment adds further complexity to referral



Delays in referral are often due to referrers<sup>1</sup>:

- Waiting for symptoms to worsen
- Symptoms not attributed to SAS



Understand the impact of TAVR on patients who are

Data expected to be presented at TCT 2024

We believe if EARLY TAVR data is compelling, it will have significant impact on streamlining referral and patient care for all SAS patients

#### In-System

### The AHA Target: Aortic Stenosis will establish quality metrics to drive urgency between diagnosis and referral

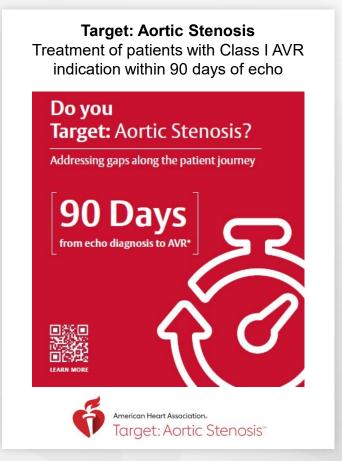
Currently, diagnosis to treatment of SAS patients can take an average of 180 days<sup>1</sup>

Circulation: Cardiovascular Quality and Outcomes

#### **CARE INNOVATIONS**

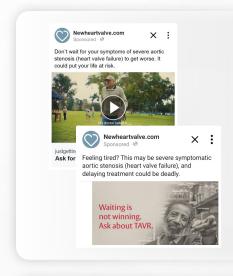
Target Aortic Stenosis: A National Initiative to Improve Quality of Care and Outcomes for Patients With Aortic Stenosis

Brian R. Lindman<sup>®</sup>, MD, MSc; Gregg C. Fonarow<sup>®</sup>, MD; Gary Myers, MS; Heather M. Alger<sup>®</sup>, PhD, MPH; Christine Rutan<sup>®</sup>, CPHQ; Katie Troll, CPHQ; Angeline Aringo<sup>®</sup>, MS; Melanie Shahriary, RN, BSN; Mariell Jessup<sup>®</sup>, MD; Suzanne V. Arnold<sup>®</sup>, MD, MHA; Pinak B. Shah<sup>®</sup>, MD; Wilson Y. Szeto, MD; Clyde W. Yancy<sup>®</sup>, MD, MSc; Catherine M. Otto<sup>®</sup>, MD



### In summary, we have a multifaceted strategy to unlock the insystem opportunity in the near-to-mid term

In-System



Patient / Referrer education



Al-based technologies to help identify patients who warrant evaluation for AVR

Near-tomid term focus

> In-System

**SEVERE AS** 



Evidence on asymptomatic SAS patients



Quality metrics on time from diagnosis to treatment



### We are also focusing on the out-of-system opportunity

Patients who are unaware they have the disease

Multiple efforts ongoing to bring patients into the system

Out-of-System

Mid-tolong term focus

Alternative detection technology

-Multiple companies also innovating to detect patients

























- Goal: Recommended cardiac echo based on age threshold
  - Similar to colonoscopy or breast cancer screening protocols

**SEVERE AS** 

# Strategies and initiatives just discussed address only the SAS patient opportunity



### The treatment of Moderate AS patients has the potential to enhance the patient continuum of care





Understand the true impact of Moderate AS and the optimal time of intervention before damage to the heart occurs

Pace of enrollment has

### exceeded expectations

We now anticipate enrollment to complete

2 years ahead of schedule

Expect to complete enrollment

**Early 2024** 



SEVERE AS



Life

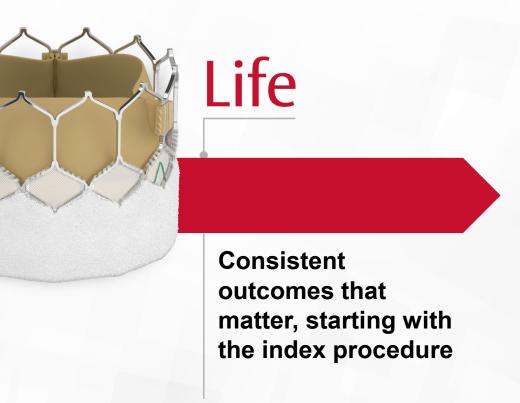
Time

Management

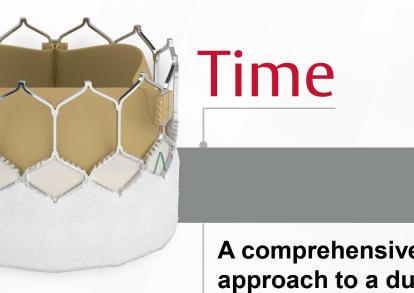
Consistent outcomes that matter, starting with the index procedure

A comprehensive approach to a durable therapy that offers proven long-term patient outcomes

Making future options possible



10/o
death or disabling stroke at 1 year<sup>1</sup>



A comprehensive approach to a durable therapy that offers proven long-term patient outcomes

90% survival at 5 years<sup>1</sup>



# THV-in-THV indication

and design to facilitate future interventions<sup>1</sup>

**SAPIEN 3 Ultra RESILIA further elevates** the TAVR therapy performance benchmark

S3UR adoption is accelerating



**Majority** 

of EW volume today



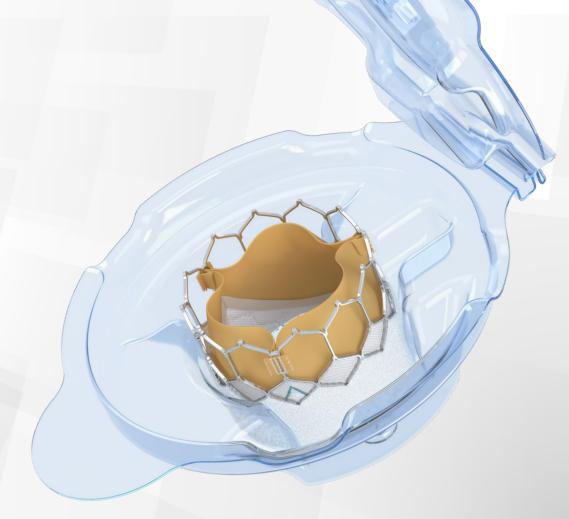
>95%

of EW volume



**Early 2024** 

Approval expected



### Beyond SAPIEN 3 Ultra RESILIA, we are making meaningful progress on SAPIEN X4

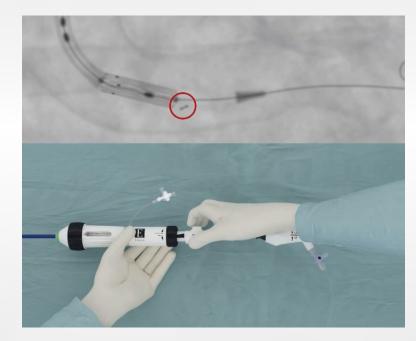


Novel frame and leaflet design to enable adjustable sizing

**RESILIA** tissue

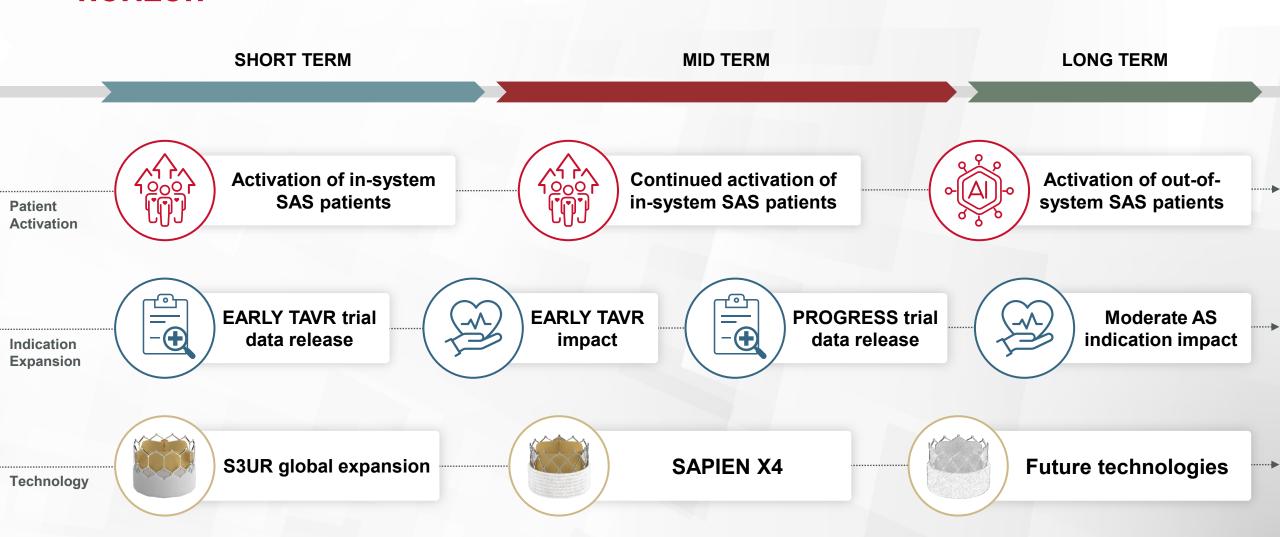
Advanced PET outer skirt technology

Advanced delivery system technology offers commissural alignment



The ALLIANCE Trial is actively enrolling

### We have multiple drivers to support sustainable growth across the horizon



#### 2024 Sales Outlook

8% - 10% Constant Currency Growth

#### **Headwinds**



Overall pressure on healthcare spending



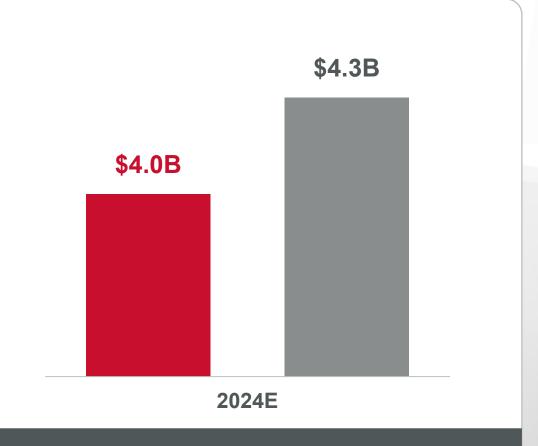
Competitive product launches

#### **Tailwinds**

Improving healthcare system capacity



Technology and new evidence



The fundamentals of TAVR remain strong and the opportunity ahead is significant

### **Transcatheter Mitral and Tricuspid Therapies**

#### **Daveen Chopra**

Corporate Vice President
Transcatheter Mitral and Tricuspid Therapies

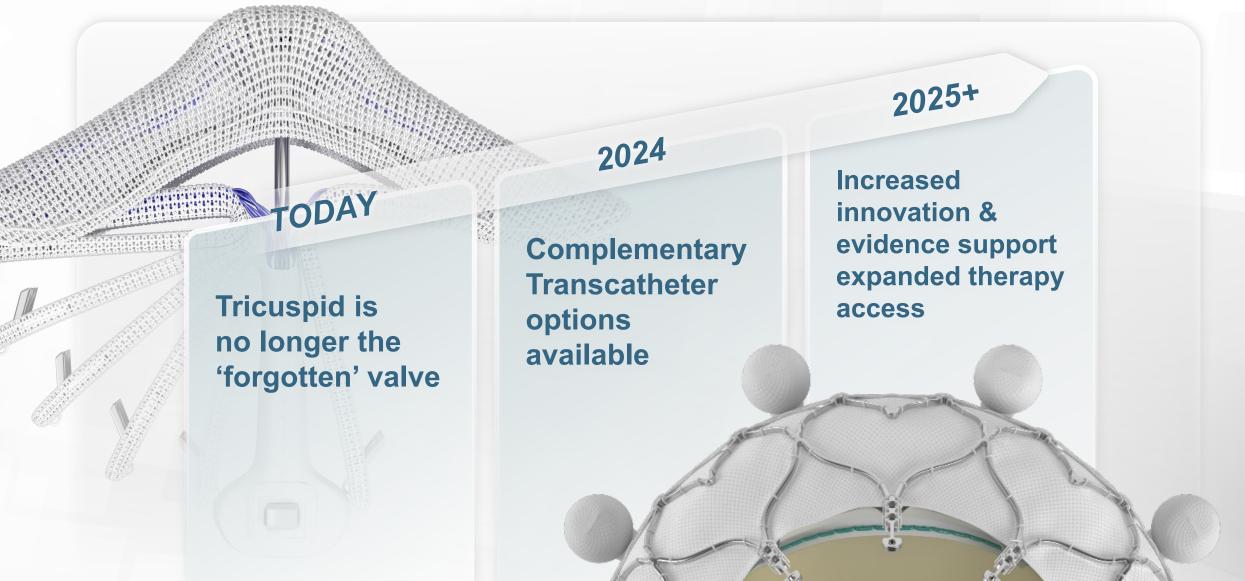


# Millions of patients globally are suffering from Tricuspid and Mitral Regurgitation with limited treatment options



Edwards' Transcatheter Repair and Replacement therapies are transforming patient care

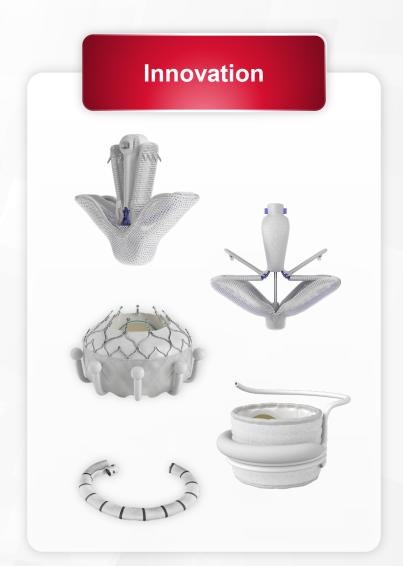
# Transcatheter <u>Tricuspid</u> Repair and Replacement solutions are at the beginning of a revolution of patient care



Transcatheter Mitral adoption increases with expanding Repair evidence and market access, along with the emergence of Replacement















### Real-World Outcomes













The PASCAL Repair System is accurate, versatile, and atraumatic

### PASCAL is demonstrating robust clinical outcomes in those patients suitable for Repair



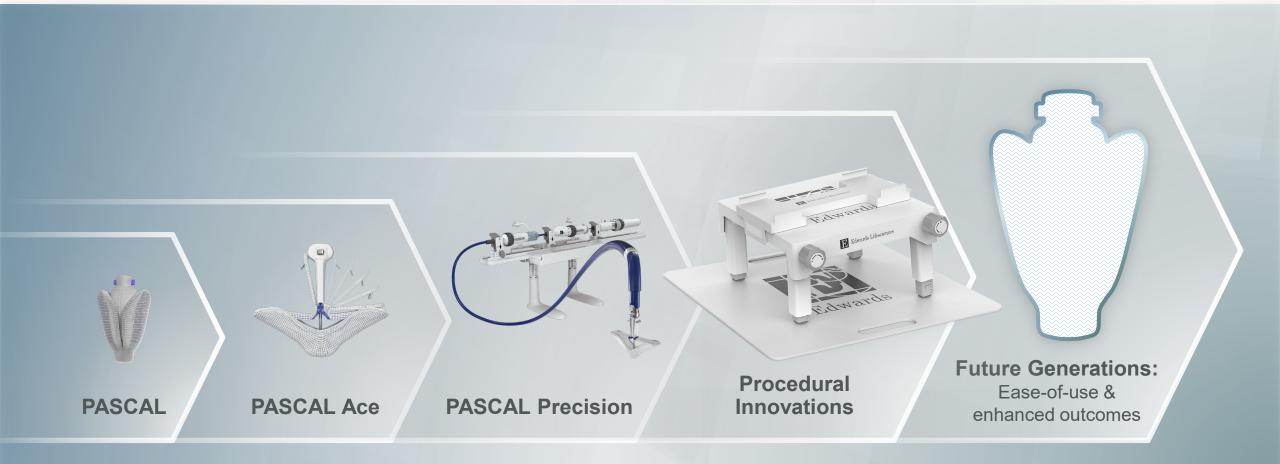
### PASCAL is demonstrating robust clinical outcomes in those patients suitable for Repair





~2000 clinical study patients treated with PASCAL

# Rapid, differentiated PASCAL therapy innovation is driving Repair adoption



### PASCAL Precision continues to expand to more sites in more geographies



**Expanding US field** team and sites



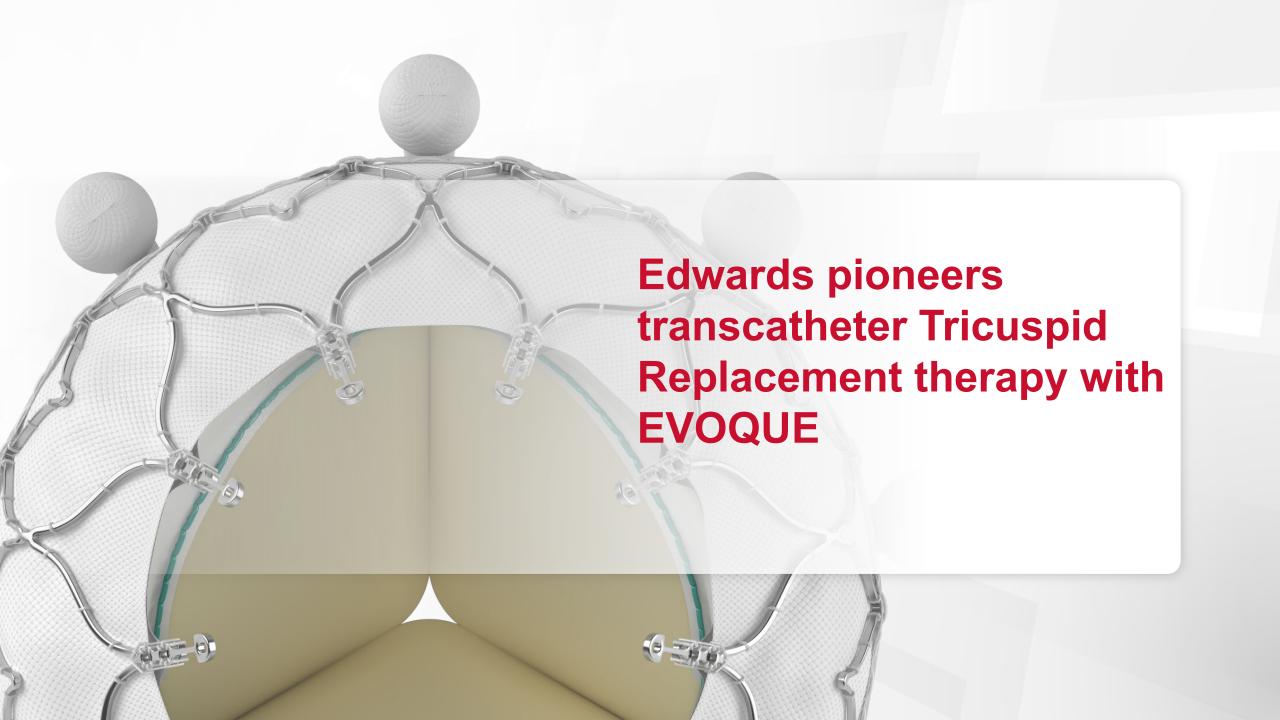
Increasing EU accounts and PASCAL adoption

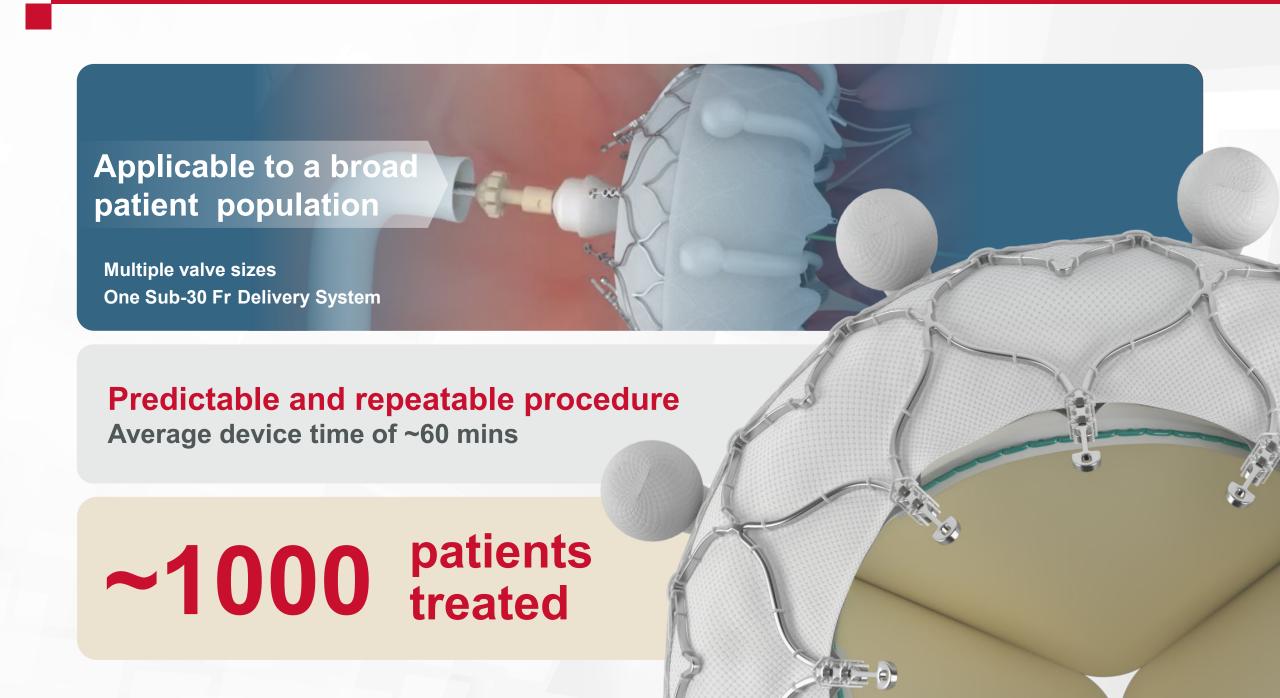


**Initiating Japan Launch** 

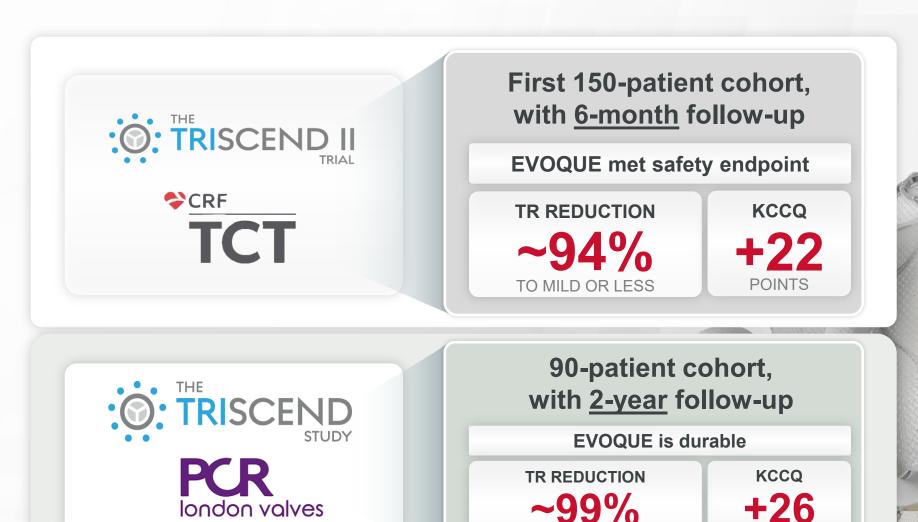








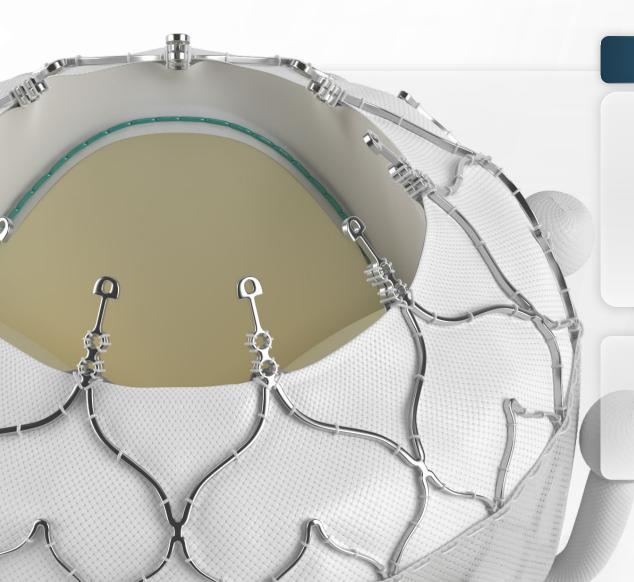
# In robust clinical trials, EVOQUE virtually eliminated TR and substantially improved quality of life for patients



### **EVOQUE** creates Transcatheter Tricuspid Replacement in 2024 in both the EU and US



### **EVOQUE** creates Transcatheter Tricuspid Replacement in 2024 in both the EU and US



#### **Near term EVOQUE milestones**



CE Mark Oct 2023



US approval anticipated in mid-2024



TRISCEND II full cohort presentation expected at TCT '24



56mm valve launch in '25 extends therapy to more patients

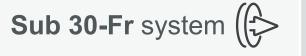
### **EVOQUE** creates Transcatheter Tricuspid Replacement in 2024 in both the EU and US

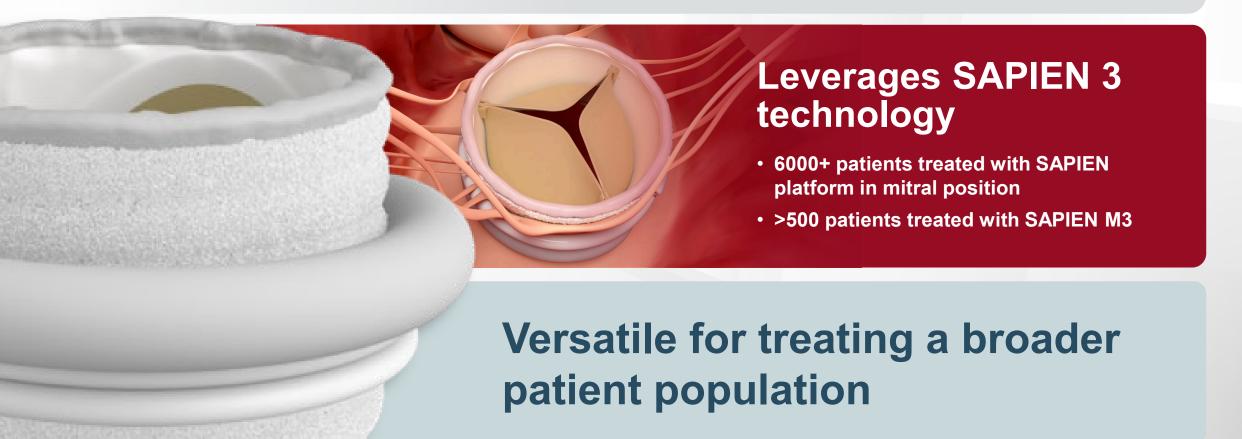






Transfemoral Replacement solution





## Completion of ENCIRCLE enrollment sets the stage for commercial approvals of SAPIEN M3



# **Completed Enrollment**

of 300 patients in the Primary Cohort





## Edwards is primed for growth and leadership with a comprehensive portfolio of Repair and Replacement therapies for Mitral and Tricuspid patients

### **TRICUSPID**

PASCAL and EVOQUE drive leadership



### **MITRAL**

PASCAL accelerates, SAPIEN M3 establishes leadership

PASCAL Continued Growth

**EVOQUE**Launch & Adoption

SAPIEN M3
Launch & Adoption

### 2024 Sales Outlook

#### **Headwinds**



Overall healthcare spending pressure

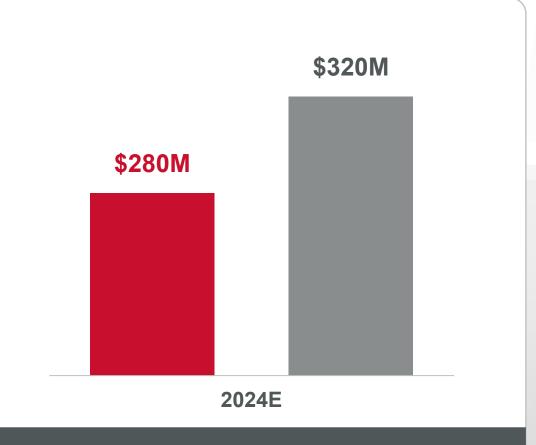


Pace of EVOQUE therapy development

#### **Tailwinds**

- Contemporary Mitral Repair evidence increases therapy confidence

Strong real-world evidence accelerates referral pathways for Tricuspid patients



Edwards' TMTT therapies are at an inflection point in transforming patient care

## **Surgical Structural Heart**

### **Wayne Markowitz**

General Manager and Senior Vice President Surgical Structural Heart



## Edwards Surgical growth outpaced the market in 2023



Our RESILIA innovations are driving growth in established and emerging markets



Our differentiated product portfolio is supported by meaningful clinical evidence

## This will continue with our best-in-class innovation strategy



The global cardiac surgery market is expected to exceed \$2 billion by 2028



We have a rich surgical innovation pipeline to address unmet patient needs

# Our above-market growth in 2023 was balanced across multiple therapies and regions

#### **RESILIA Aortic Gains**

Strong INSPIRIS and KONECT adoption, setting the new standard of care globally



### **Increasing Mitral Sales**

Global MITRIS revenue more than doubled, driven largely by successful US launch



#### **Growth Around the World**

Emerging market revenue grew at **over triple the pace** of developed markets





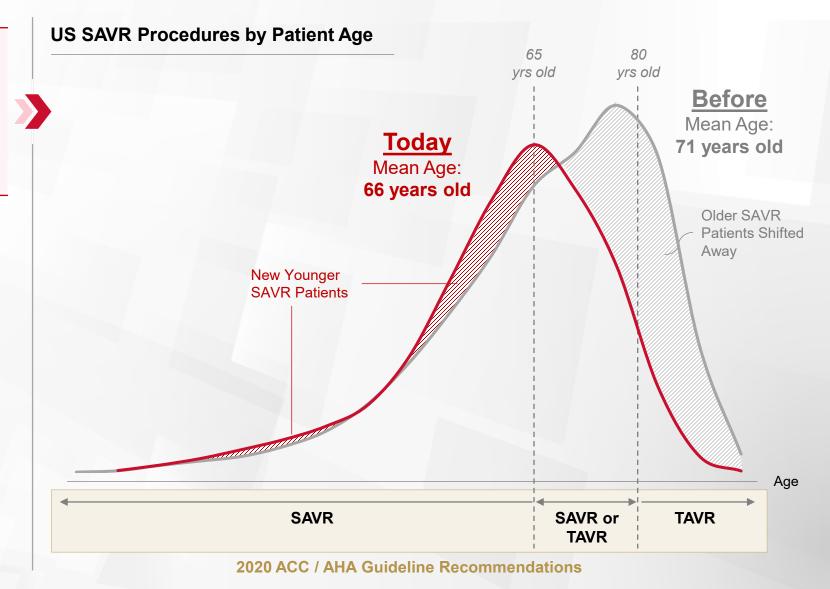
## SAVR has evolved and is growing in patients best treated surgically

Younger Patients Treated
In line with latest ACC/AHA Guidelines

**Growth in non-TAVR Segments** 

Other etiologies and concomitant cases

Greater Use of Tissue Valves
For better patient lifetime management



## SAVR has evolved and is growing in patients best treated surgically

**Younger Patients Treated** 

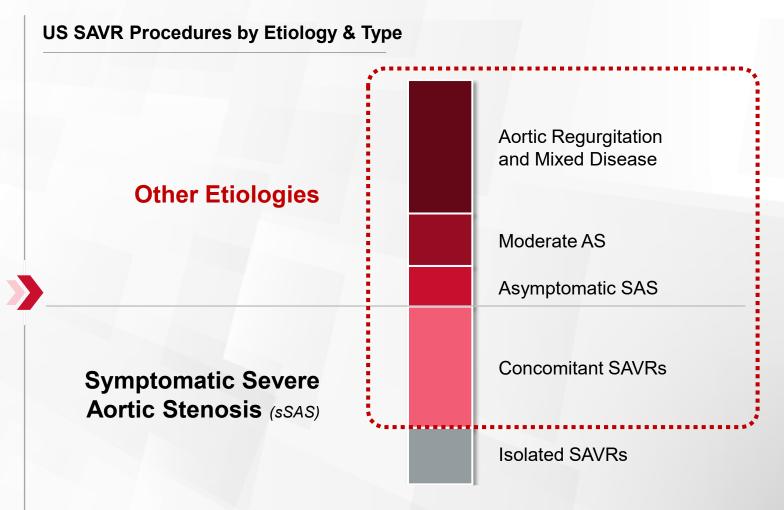
In line with latest ACC/AHA Guidelines

**Growth in non-TAVR Segments** 

Other etiologies and concomitant cases

**Greater Use of Tissue Valves** 

For better patient lifetime management



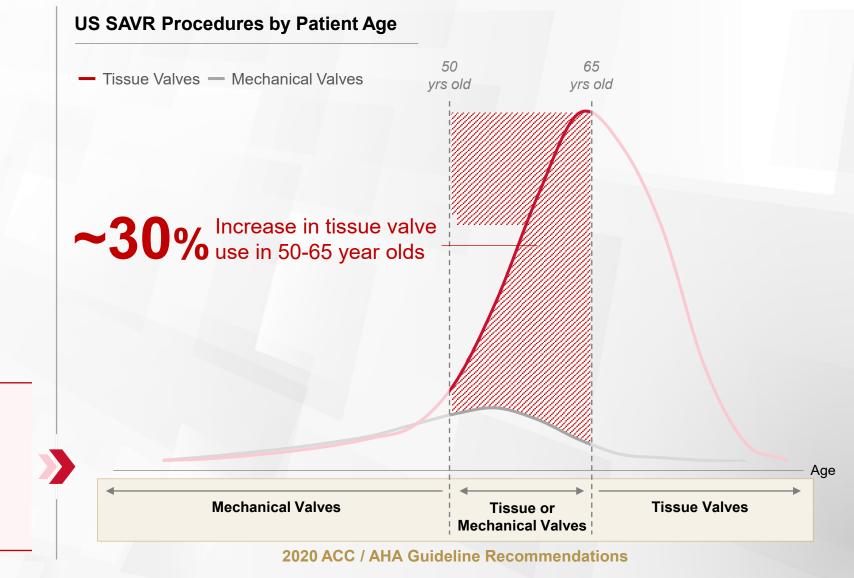
Significant majority of SAVR patient segments untreated by TAVR

# SAVR has evolved and is growing in patients best treated surgically

Younger Patients Treated
In line with latest ACC/AHA Guidelines

Growth in non-TAVR Segments
Other etiologies and concomitant cases

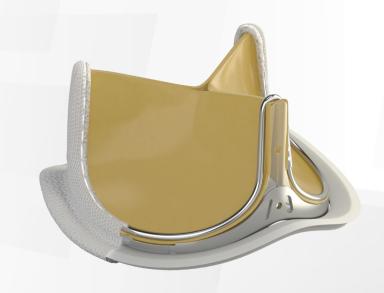
Greater Use of Tissue Valves
For better patient lifetime management



# Our RESILIA Aortic portfolio is ideally suited for the SAVR patients of today and tomorrow

#### **INSPIRIS RESILIA Aortic Valve**

- The leading SAVR valve in the world, featuring RESILIA tissue technology with extended durability
- Unique VFit expandability enables larger TAVR valve-in-valve use for improved patient lifetime management





#### **KONECT RESILIA Aortic Valved Conduit**

■ The only pre-assembled, ready-to-implant, tissue valved conduit for complex Bentall procedures

## Our MITRIS RESILIA Mitral Valve is gaining significant adoption around the world

 Greater ease-of-use features and RESILIA tissue with enhanced durability for mitral patients

 Significant conversion opportunity for MITRIS RESILIA in mitral valves

European CE Mark approval received in October;
 launched in over 50 countries to-date







We are continuing our strong cadence of meaningful clinical evidence to drive RESILIA adoption

2023

2024

Beyond



7-year results published in JTCVS



5-year results published in JTCVS Open



Largest, core lab adjudicated surgical MVR study



**KONECT** 

US post-market study at leading centers



10-year data release from RESILIA pivotal trial



European study of INSPIRIS in younger patients



European study of INSPIRIS in patients with comorbidities



**Beth Allen** 

INSPIRIS RESILIA Valve Patient

28 additional on-going post-market studies in 15 countries following over 13,000 patients

## Latest COMMENCE trial 7-year data demonstrates excellent outcomes of RESILIA tissue in patients

Beaver et al

#### Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis

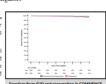
Thomas Beaver, MD, MPH, a Joseph E. Bavaria, MD, MPH, Bartley Griffith, MD, Lars G. Svensson, MD, PhD, Philippe Pibarot, DVM, PhD, Michael A. Borger, MD, PhD, Omar M. Sharaf, BS, a David A. Heimansohn, MD, Vinod H. Thourani, MD, Eugene H. Blackstone, MD, and John D. Puskas, MD, on the behalf of the COMMENCE Trial Investigators

Objective: As bioprosthetic agrtic valve replacement (AVR) extends to younge cohorts, tissue durability is of paramount importance. We report 7-year outcomes from an AVR bioprosthesis utilizing novel tissue.

Methods: This was an international investigational device exemption trial for novel AVR with annual follow-up and a subset re-consented at 5 years for extended 10-year follow-up. Safety end points and echocardiographic measurements were adjudicated by an independent clinical events committee and by a dedicated core laboratory, respectively.

Results: Between January 2013 and March 2016, 689 patients underwent AVR with the study valve. Mean age was 66.9  $\pm$  11.6 years, Society of Thoracic Surgeons risk score was 2.0%  $\pm$  1.8%, and 74.3% of patients were New York Heart Association functional class II and III. Five-year follow-up was completed by 512 patients, and 225 re-consented for extended follow-up. Follow-up duration was 53 ± 2.2 years (3665.6 Resilia tissue valve demonstrated patient-years), and 194 and 195 patients completed 6- and 7-year follow-ups, respec tively. One-, 5-, and 7-year freedom from all-cause mortality was 97.7%, 89.4%, and 854%, respectively. Freedom from structural valve deterioration at 7 years was 7 years in COMMENCE aortic 99.3%. At 7 years, effective orifice area and mean gradients were trial patients. 1.82  $\pm$  0.57 cm $^2$  (n = 153), and 9.4  $\pm$  45 mm Hg (n = 157), respectively. At 7 years predominantly none (96.8% [152 out of 157]) or trivial/trace (2.5% [4 out of 157]) paravalvular regurgitation and none (84.7% [133 out of 157]) or trivial/trace (11.5% [18 out of 157]) transvalvular regurgitation were observed.

Conclusions: We report the longest surgical AVR follow-up with novel tissue in an investigational device exemption trial utilizing an independent clinical events committee and an echocardiography core laboratory. This tissue demonstrates excellent outcomes through 7 years and is the benchmark for future surgical and transcatheter prostheses. (J Thorac Cardiovasc Surg 2023: 1-10)



reedom from SVD and reoperation in COMMENCE aortic patients. (95% CI).

Aortic valve replacement with a 99.3% freedom from SVD at

he COMMENCE trial with Resilia tissue in the durability and clinically stable hemodynamics at mean follow-up of 7.7 years for the re nsented cohort. The extended durability of Re lia tissue is encouraging for patients desiring

From the "Division of Cardiovascular Surgery, University of Florida Health, Gaines-ville, Fla; "Department of Cardiovascular Surgery, Hospital of the University of Pennsylvania, Philadelphia, Pa; "Department of Surgery, University of Maryland Medical Center, Baltimore, Md: "Department of Thoracic and Cardiovascular Surgery, Cleveland Clinic, Cleveland, Ohio; Department of Cardiology, Québec Heart and Lung Institute, Laval University, Ouébec, Ouébec, Canada: University Department of Cardiac Surgery, Heart Center Leipzig, Leipzig, Germany; <sup>8</sup>St Vin-cent The Heart Center of Indiana, Indianapolis, Ind; <sup>9</sup>Department of Cardiovascu-lar Surgery, Marcus Valve Center, Piedmont Heart Institute, Atlanta, Ga; and Department of Cardiovascular Surgery, Mount Sinai Morningside, New York, NY.
The Prospective, Non-randomized, Multicenter Clinical Evaluation of Edwards Pericardial Bioprostheses with a New Tissue Treatment Platform (COMMENCE) Trial

was funded by Edwards Lifesciences. The study sponsor participated in the study design, data collection, analysis, interpretation, and the decision to submit for publication. The authors attest to the accuracy and completeness of data in this manuscript. The authors drafted, reviewed, and revised the manuscript. Lastly, the authors attest to full freedom to explore data and analyze results with authority ClinicalTrials.gov No.: NCT01757665

Informed Consent: All study participants informed written consent for the pub of their study data.

Read at the 103rd Annual Meeting of The American A gery, Los Angeles, California, May 6-9, 2023. Received for publication July 9, 2023; revisions received Sept 7, 2023; accepted for

publication Sept 21, 2023. Department of Surgery, University of Florida Health (E-mail: thomas.beay

Copyright © 2023 The Authors, Published by Elsevier Inc. on behalf of The American Association for Thoracic Surgery. This is an open access article under the CC

The Journal of Thoracic and Cardiovascular Surgery • Volume ■, Number ■ 1



99.3%

freedom from structural valve deterioration (SVD) at 7 years  Outperformed previous-generation surgical tissue valves

 Published in the Journal of Thoracic and Cardiovascular Surgery in September 2023



"The COMMENCE 7-year data were spectacular with regards to structural valve deterioration."

**Prof. Michael Borger** Department of Cardiac Surgery, Leipzig Heart Center

## Surgical Structural Heart's future is bright with many patients to treat globally







## Significant Surgical Opportunity

In both developed and emerging markets

## Differentiated RESILIA Portfolio

Ideally suited for surgical patients of today and tomorrow

## Rich Innovation Pipeline

Addressing unmet needs across cardiac surgery

### 2024 Sales Outlook

Mid-Single Digit Constant Currency Growth

#### **Headwinds**



Healthcare spending pressures



Competitor pricing tactics

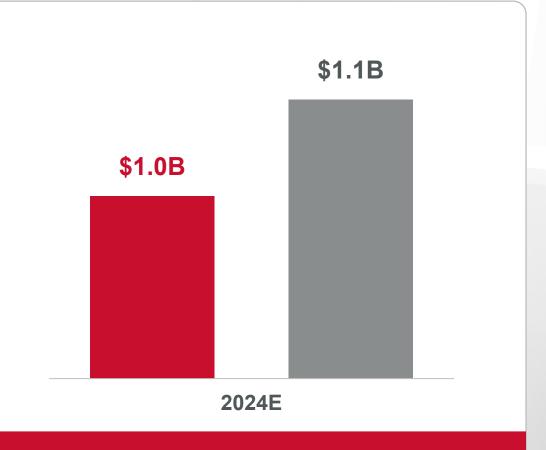
#### **Tailwinds**



Global RESILIA Aortic adoption



Accelerated MITRIS RESILIA penetration



Many patients to be treated with our differentiated RESILIA portfolio backed by clinical evidence

## **Critical Care**

### **Katie Szyman**

Corporate Vice President Critical Care



### Driving growth through Smart Recovery and Smart Expansion



Shifting our patients from classic to smart monitoring **technology** 



Driving **Smart Recovery** drives **adoption** with clinical **evidence** 



Leveraging our **leadership** to drive **Smart Expansion** and growth

**Getting Patients Home to their Families Faster** 



### Large opportunities for Smart Recovery and Smart Expansion

#### **Smart Recovery**

Smart Monitoring

+

Faster **Recovery** 

=

Smart Recovery

#### **Current Patient Settings**





OR

ICU

20M+ Patients

Shifting from classic monitoring solutions to smart monitoring and Acumen IQ technology

### **Smart Expansion**

Continuous
Non-Invasive Monitoring

Clinical Need

Smart Expansion

#### **Potential Expansion Opportunities Starting in 2024**







**Outpatient Surgery** 

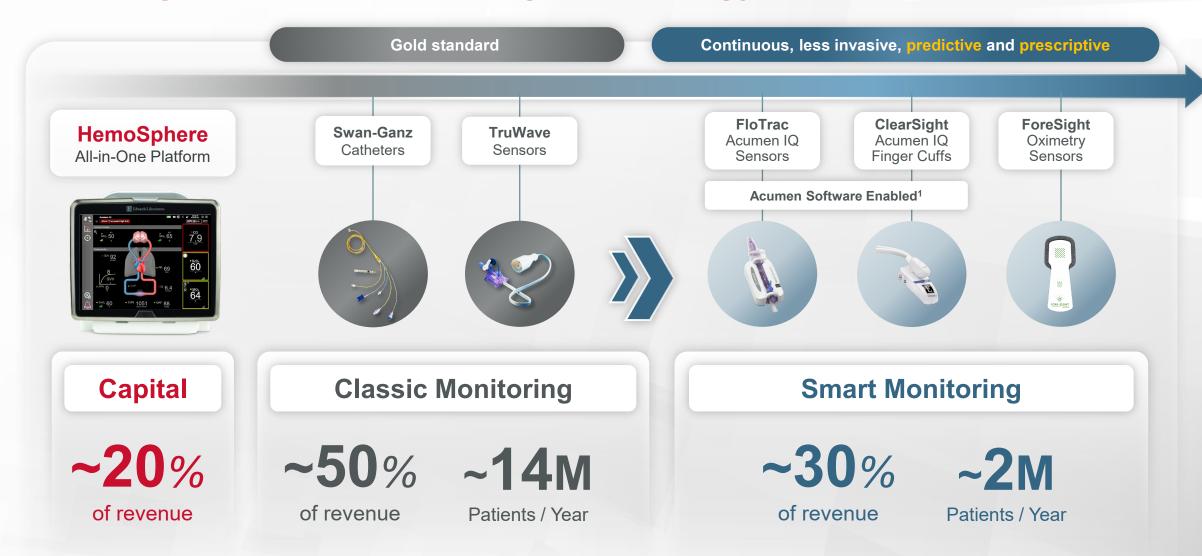
**Pediatrics** 

**Obstetrics** 

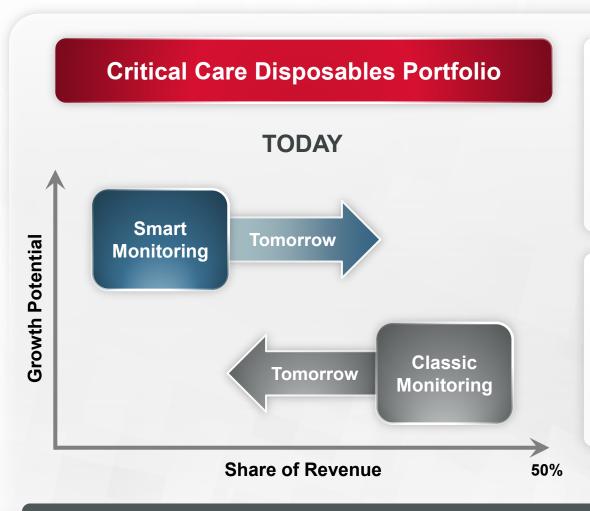
**30M+ Patients** 

**Expanding with Continuous Non-invasive Blood Pressure** 

## **Shifting to Smart Monitoring Technology**



## **Continuing the shift toward Smart Monitoring**



### **Double Digit Growth**

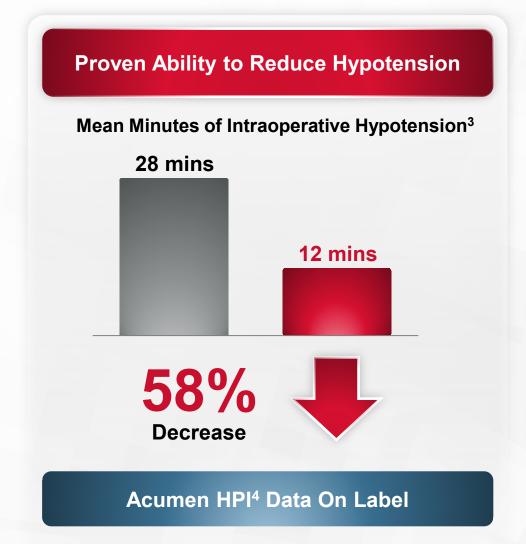
5-Year CAGR Smart Monitoring
Under penetrated opportunity with greater clinical value

## Single Digit Growth

5-Year CAGR Classic Monitoring
Larger, but highly penetrated segment



### **Driving Adoption with Clinical Evidence**



75+ Studies Showing Importance of Smart Recovery<sup>1</sup>



25% of surgical patients experienced complications leading to longer hospital stays, readmission and even death<sup>2</sup>

Mix of Benefits Associated with Smart Recovery



Reduced



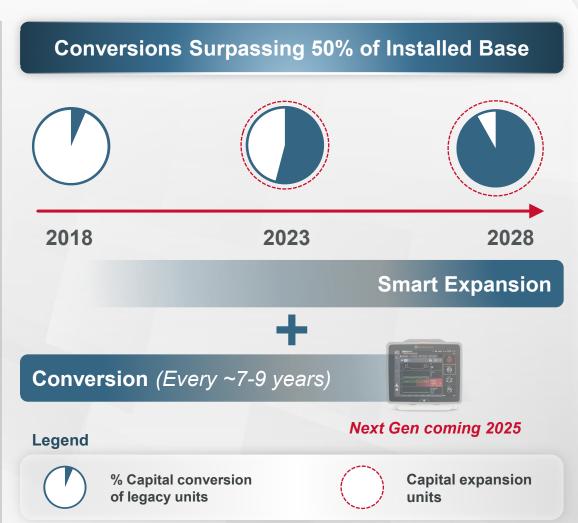


### Successful Capital Conversion and Smart Expansion

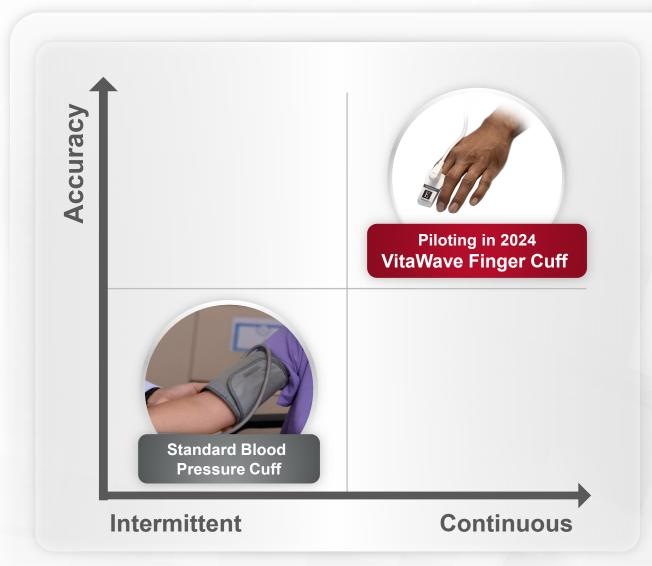
#### 7th Generation HemoSphere Platform



All-in-One, Al-Enabled, Connected Platform Supporting our Portfolio of Products



### **Smart Expansion with Continuous Non-Invasive Blood Pressure**



### **Clinical Studies Results**



Proven accuracy of continuous non-invasive blood pressure technology<sup>2</sup>



Continuous finger-cuff based blood pressure monitoring is superior to intermittent cuff<sup>3,4,5</sup>



Critical inaccuracies with intermittent blood pressure cuff<sup>1</sup>

### **Smart Expansion with HemoSphere Vita**

#### **Piloting in 2024**



## Beat-to-beat insights for elevated care

Actionable blood pressure trends for informed, proactive interventions.

VitaWave Finger Cuff

ForeSight Oximetry Sensors



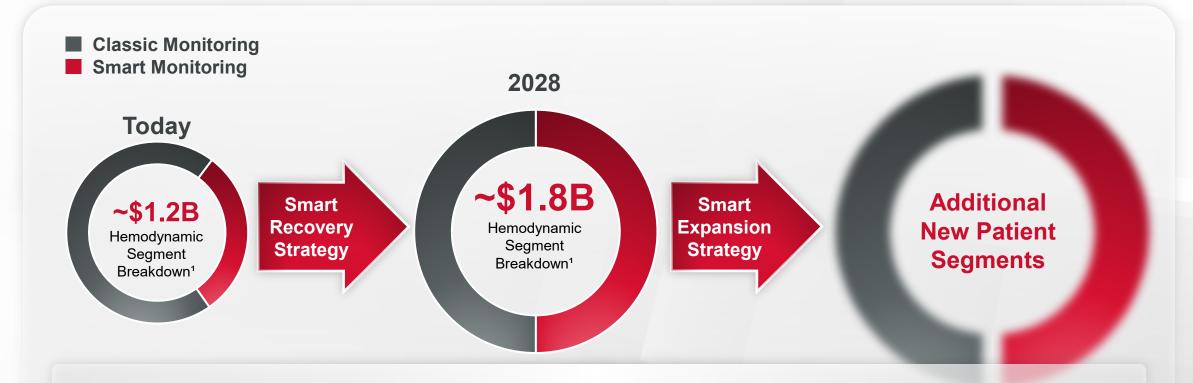


"...there is still a critical need for a continuous non-invasive blood pressure monitor that will, beat-bybeat, give you a blood pressure."

**Dr. Thomas Fogarty** "From the Innovator's Workbench" Jan 2003

**HemoSphere Vita** 

## **Expanding Long-term Market Opportunity**



- ✓ Strong growth above general patient monitoring market rate
- ✓ Unlocking value by shifting from basic sensors to smart sensors with **smart monitoring premium**
- ✓ Potential upside opportunity **expanding into new patient segments**

### 2024 Sales Outlook

Mid-Single Digit Constant Currency Growth

#### **Headwinds**



**Hospital Budget Constraints** 



Supply Chain Risks

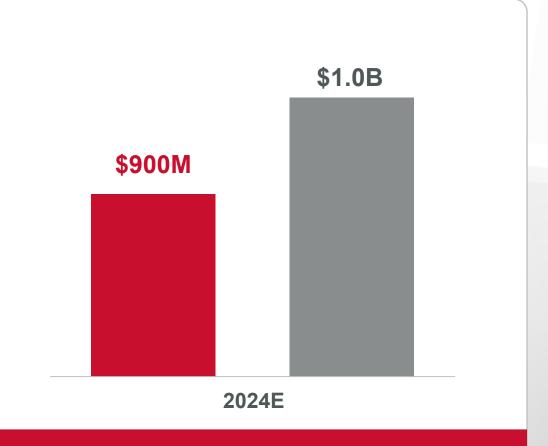
#### **Tailwinds**



Accelerated shift to Smart Recovery



Successful pilots for Smart Expansion



We are ready. The best is yet to come.

## Financial Outlook

Scott Ullem
Chief Financial Officer



## **Approach to Financial Value Creation**



## Strong Organic Sales Growth

Constant currency long-term sales growth goal of 10%+ with contributions from Valvular and additional Structural Heart Disease initiatives



## Healthy Profitability

Exceptional gross profit margin supported by value-added therapies with differentiated technology. Operating margin expansion over time, tempered by new product launches and procedure support strategy



## Strategic Capital Deployment

Conservative balance sheet with flexibility to fund early-stage structural heart acquisitions, as well as repurchase shares to offset dilution from employee performance options

## 2023 expectations in line with prior guidance

	2022 Investor Conference Guidance	October Guidance	Current Outlook
Total Company Sales Growth (Constant Currency)	9 - 12%	10 - 13%	10 - 13%
Gross Profit Margin	76 - 78%	76 - 78%	76 - 78%
Earnings Per Share	\$2.45 - \$2.60	\$2.47 - \$2.53	\$2.47 - \$2.53

## **Future Financial Goals**

	2024 Guidance	2025 and Beyond (Excluding Critical Care)
otal Company and AVR Sales Growth Constant Currency)	8 - 10%	10% +
Operating Margin	29 - 30%	Margin expansion over time
Earnings Per Share	\$2.70 - \$2.80 (9 - 11% growth)	Double-digit growth (subject to tax law changes)

## **Edwards Financial Objectives**

### **Strong Organic Sales Growth**



Addressing large and growing patient populations



Growth fueled by successful longterm R&D investments to drive breakthrough therapies



Sustained leadership position supported by strong evidence-based value to patients, clinicians and healthcare systems

## 2024 Sales Outlook by Product Group

#### **TAVR**

8% - 10% growth



- Continued global launch of SAPIEN 3 Ultra RESILIA
- Focused patient activation initiatives

#### **TMTT**

\$280 - \$320 million



- **Solution** EVOQUE transcatheter tricuspid valve launch in Europe and U.S.
- PASCAL global expansion: Japan launch and France reimbursement

#### **Surgical Structural Heart**

Mid-single digit growth



- Continued global leadership supported by clinical data
- MITRIS RESILIA launch in Europe

#### **Critical Care**

Mid-single digit growth



- Advancing next generation of predictive sensor technology
- Driving Smart Recovery adoption with clinical evidence

## **Edwards Financial Objectives**

### **Healthy Profitability**



Generating strong gross profit



Funding growing field organization and strengthening global supply chain



Investing aggressively in innovation for profitable organic growth



Maintaining efficient tax structure

# Profitability fueled by high value products, efficient supply chain, strategic R&D, and disciplined spending

## Healthy Gross Profit Margin

76 - 78% of 2024 sales

#### Strategic R&D

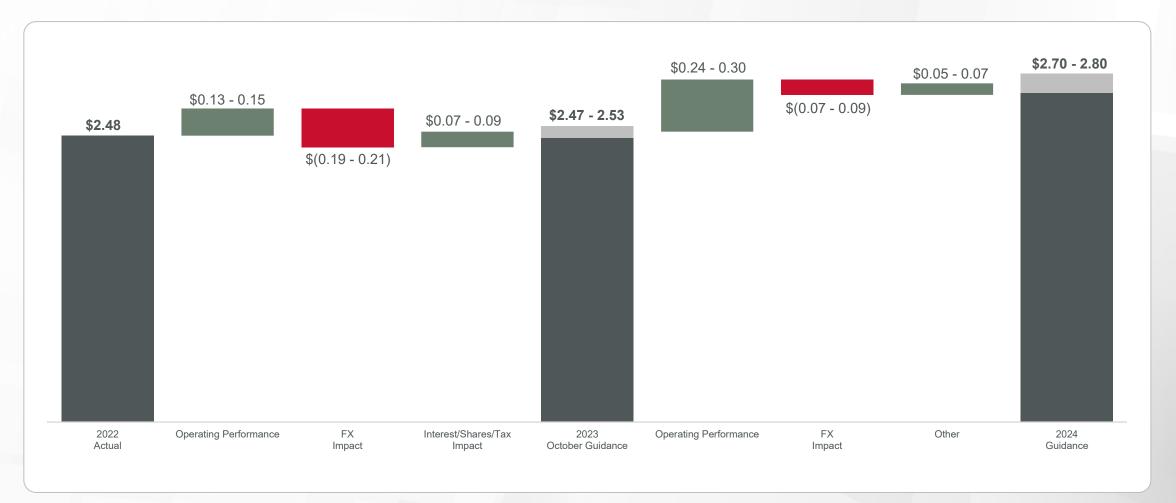
17 - 18% of 2024 sales

#### **Disciplined Spending**

SG&A: 29 - 30% of 2024 sales

- High value technologies yield strong gross profit margins
- Proven model for gaining efficiencies as volumes increase, partially offset by new product introductions
- Durable and redundant manufacturing footprint in the Americas, Europe and Asia, with five Structural Heart facilities
- In-sourcing critical component technology
- Third party supplier rationalization
- Focused investment in clinical trials to expand indications
- Strategic investments in new technology platforms for structural heart disease initiatives
- Continued investment in patient activation initiatives
- Expansion of field-based personnel
- Increased focus on efficient G&A leverage

## 2023 investments set to fuel 2024 earnings



# 2024 Implications of Critical Care Spin-off

No core financial impact in 2024; separation expected at the start of 2025

One-time charges associated with typical spin-off transactions

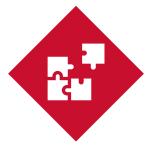
More financial information to be filed with Form 10 in mid-2024

## **Edwards Financial Objectives**

## **Robust Cash Flow and Strategic Capital Deployment**



Supports global capacity expansion



Strategic acquisitions to support and supplement R&D initiatives



Returning capital to shareholders through opportunistic share repurchases

## **Cash Flow and Capital Deployment**

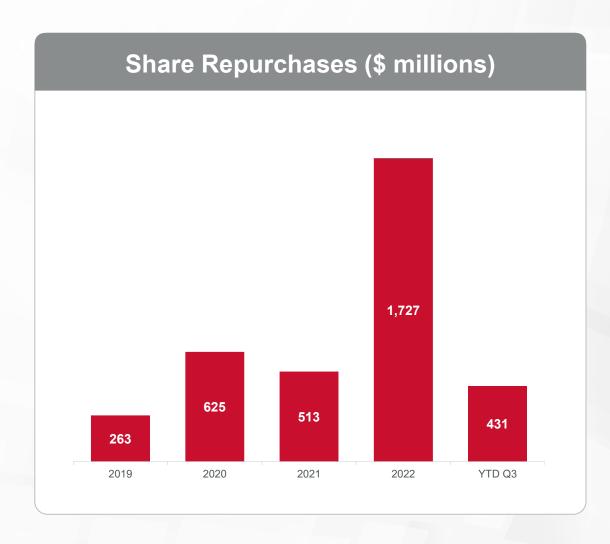
### **2024 Expectations**

- Oontinued growth results in significant cash flows that fund future internal and external opportunities
- Strong free cash flow conversion supporting healthy balance sheet
- Diluted shares outstanding estimated between 600 and 610 million

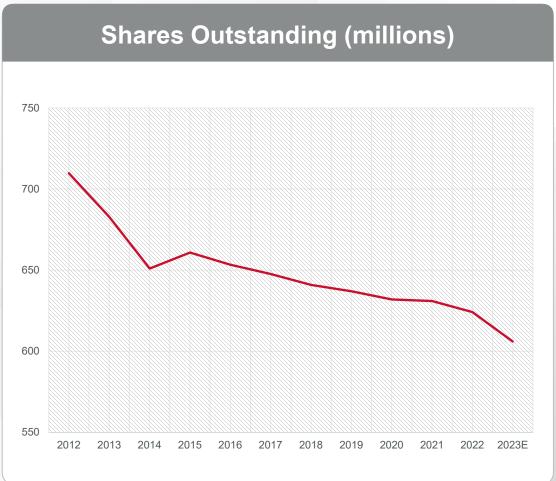
## Adjusted Free Cash Flow (\$ in billions)



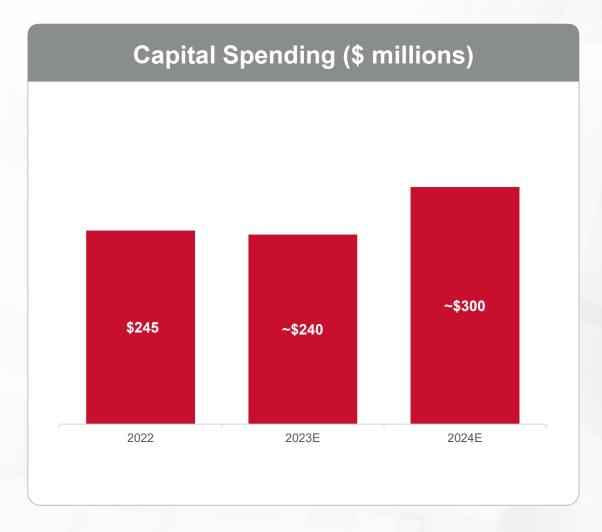
## Track Record of Opportunistic Share Repurchases

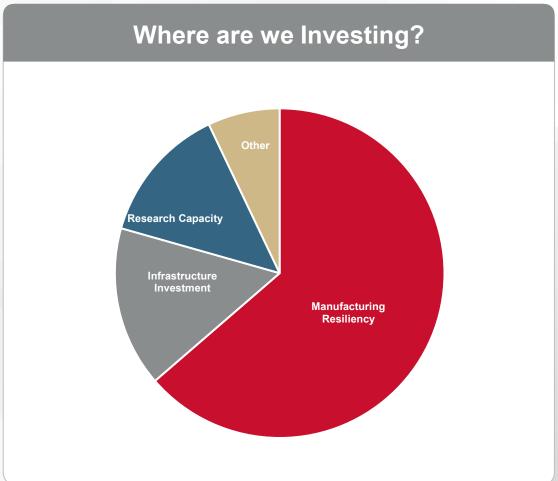


**PROFITABILITY** 



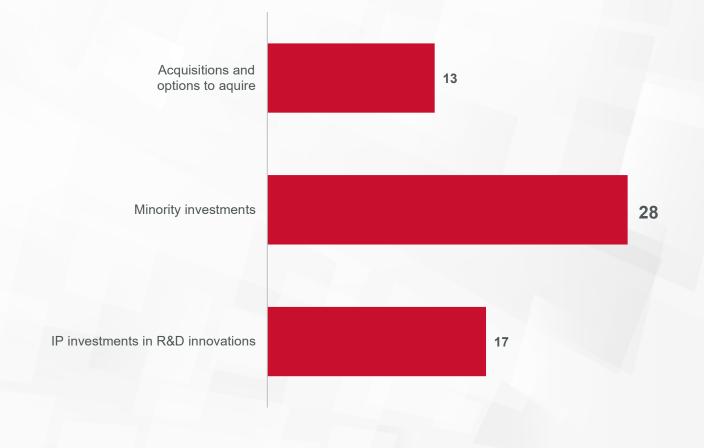
## **Investing Capital for the Future**





# **Active Portfolio Management**

### **Closed Transactions in Last 5 Years**



## **FOCUSED ADDITIONS**

- > TAVR / TMTT / Surgical
- New SHD segments
- Early-stage, pre-revenue start-ups

## **EXITS**

- Non-strategic products
- Low growth potential

# **2024 Guidance Summary**

		_		
Sales	\$6,300 - 6,600	Operating Margin	29% - 30%	
Constant Currency Growth	8 - 10%	Tax Rate	14 - 17%	
FX Impact on Sales At current rates	~(\$50) (1.0pp downside to growth)	Earnings Per Share	\$2.70 - 2.80	
Gross Profit Margin	76 - 78%	Diluted Shares	600 – 610	
SG&A % of Sales	29 - 30%	CAPEX	~\$300	
R&D % of Sales	17 - 18%	Free Cash Flow	\$1,100 - \$1,400	

Note: \$ in millions except earnings per share. Excludes special items.

## **Longer-Term Outlook**



Sales

Constant currency sales growth of 10%+



### **Operating Efficiency**

### **Gross Profit Margin**

Mix and efficiencies expected to benefit margin, partially offset by new product introductions

### SG&A

Leveraging scale and controlling G&A expenses, partially offset by investments to support growth initiatives

#### R&D

Significant investments in clinical trials to expand indications and develop new technologies, likely outpaced by growth in sales



### **Earnings**

### **Tax Rate**

Upward pressure, subject to tax law changes

### **Earnings Per Share**

- Routine share repurchases to offset dilution from employee options
- Opportunistically reduce net shares outstanding
- FX volatility mitigated by consistent hedging strategy

# **Closing Remarks**

## **Bernard Zovighian**

Chief Executive Officer



## **Entering a new era of Structural Heart innovation**



# Sharpened Focus on SHD



# Expanding **Opportunity**



# Sustainable **Growth**

### **Our Credo**

At Edwards Lifesciences, we are dedicated to providing innovative solutions for people fighting cardiovascular disease.

Through our actions, we will become **trusted partners** with customers, colleagues, and patients – creating a community unified in its mission to improve the quality of life around the world. Our results will benefit customers, patients, employees and shareholders.

We will celebrate our successes, thrive on discovery, and continually expand our boundaries. We will act boldly, decisively, and with determination on behalf of people fighting cardiovascular disease.

Helping patients is our life's work, and



### **Patient-Focused Culture**



### **Unique Innovation Strategy**



## Our leadership creates momentum within SHD

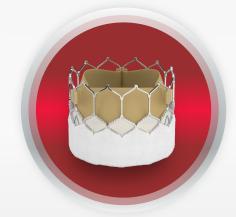
# Leading innovator



## Surgical

Innovating premium technology for patients best treated with surgery

# Revolutionizing AS treatment



## TAVR

Accelerating the transformation of care for millions of AS patients still untreated

# Pioneering breakthroughs



## TMTT

Reaching inflection point with a therapy portfolio to treat millions of MR and TR patients

# Natural progression



### Interventional HF

Investing in early-stage technology solutions

## Clear strategy for sustainable growth

2024

# **Building** momentum

Key milestones and strong financial performance

2025-2026

# Faster growth

Achievement of new indications and launch of new technologies following spin-off

Long-term

# **Expanding** opportunities

Continued healthy momentum driven by new indications, new technologies, and new adjacencies



#### **EDWARDS LIFESCIENCES CORPORATION**

#### **Non-GAAP Financial Information**

To supplement the consolidated financial results prepared in accordance with Generally Accepted Accounting Principles ("GAAP"), the Company uses non-GAAP historical financial measures. Management makes adjustments to the GAAP measures for items (both charges and gains) that (a) do not reflect the core operational activities of the Company, (b) are commonly adjusted within the Company's industry to enhance comparability of the Company's financial results with those of its peer group, or (c) are inconsistent in amount or frequency between periods (albeit such items are monitored and controlled with equal diligence relative to core operations). The Company uses the term "underlying" when referring to non-GAAP sales and sales growth information, which excludes currency exchange rate fluctuations. The Company uses the term "adjusted" to also exclude intellectual property litigation expenses, intellectual property agreements, amortization of intangible assets, and fair value adjustments to contingent consideration liabilities arising from acquisitions.

Management uses non-GAAP financial measures internally for strategic decision making, forecasting future results, and evaluating current performance. These non-GAAP financial measures are used in addition to, and in conjunction with, results presented in accordance with GAAP and reflect an additional way of viewing aspects of the Company's operations by investors that, when viewed with its GAAP results, provide a more complete understanding of factors and trends affecting the Company's business and facilitate comparability to historical periods.

Non-GAAP financial measures are not prepared in accordance with GAAP; therefore, the information is not necessarily comparable to other companies and should be considered as a supplement to, and not as a substitute for, or superior to, the corresponding measures calculated in accordance with GAAP. A reconciliation of non-GAAP historical financial measures to the most comparable GAAP measure is provided in the tables below.

Fluctuations in currency exchange rates impact the comparative results and sales growth rates of the Company's underlying business. Management believes that excluding the impact of currency exchange rate fluctuations from its sales growth provides investors a more useful comparison to historical financial results.

Guidance for sales and sales growth rates is provided on an "underlying basis," and projections for diluted earnings per share, net income and growth, gross profit margin, taxes, and free cash flow are also provided on a non-GAAP basis, as adjusted, for the items identified above due to the inherent difficulty in forecasting such items without unreasonable efforts. The Company is not able to provide a reconciliation of the non-GAAP guidance to comparable GAAP measures due to the unknown effect, timing, and potential significance of special charges or gains, and management's inability to forecast charges associated with future transactions and initiatives.

Management considers free cash flow to be a liquidity measure which provides useful information to management and investors about the amount of cash generated by business operations, after deducting payments for capital expenditures, which can then be used for strategic opportunities or other business purposes including, among others, investing in the Company's business, making strategic acquisitions, strengthening the balance sheet, and repurchasing stock.

#### The items described below are adjustments to the GAAP financial results in the reconciliations that follow:

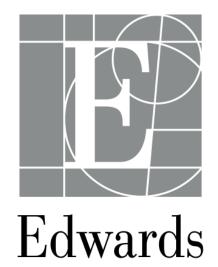
**Adjusted Free Cash Flow** - The Company defines free cash flow as cash flows from operating activities less capital expenditures. During 2023, the Company excluded from its calculation payments related to an Intellectual Property Agreement.

#### EDWARDS LIFESCIENCES CORPORATION Reconciliation of GAAP to Non-GAAP Financial Information Adjusted Free Cash Flow \*

(in millions)	Year Ended December 31, 2022		Nine Months Ended September 30, 2023	
Net cash provided by operating activities		\$1,218.2	\$759.2	
Capital expenditures		(244.6)	(164.7)	
Intellectual property agreement			 300.0	
Adjusted Free Cash Flow	\$	973.6	\$ 894.5	

<sup>\*</sup> See description of "Adjusted Free Cash Flow" on the Non-GAAP Financial Information page.





Helping Patients is Our Life's Work, and Oilo now