

# Edwards Lifesciences

40<sup>th</sup> Annual J.P. Morgan Healthcare Conference

January 10, 2022

**Mike Mussallem**

Chairman and Chief Executive Officer



Edwards

# 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 2021, 2022 and beyond (including 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 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; and continued development of future innovations.

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.

# Use of Non-GAAP Financial Measures

Unless otherwise indicated, all figures are GAAP financial measures.

The Company uses the term "adjusted sales" or "underlying 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](http://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.

# 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

*life is now*

# Helping Patients Around the World



**600K+**

Patients Treated with  
Transcatheter Therapies

**15,000+**

Global Employees



**50%+**

Millennials and Generation Z



**~2,000**

Engineers



Investment in R&D

**17-18%**

of 2021E sales



**80%+**

Charitable employee  
engagement

**50%+**

Millennials and Generation Z



**7**

Manufacturing Facilities  
Around the World



Resilient Supply  
Chain



**95%+**

Sales from Products with  
#1 Global Market Share

# Patient-Focused Innovation Strategy



## Innovation

Pioneer breakthrough technologies with compelling evidence

## Leadership

Lead groundbreaking standards of care through trusted relationships

## Focus

Singular focus on the large unmet needs of structural heart and critically ill patients

**Create Meaningful Value by Transforming Patient Care**

# Edwards' patient-focused innovation strategy has produced sustained underlying sales growth



Focused on opportunities where **patient demand** is very large



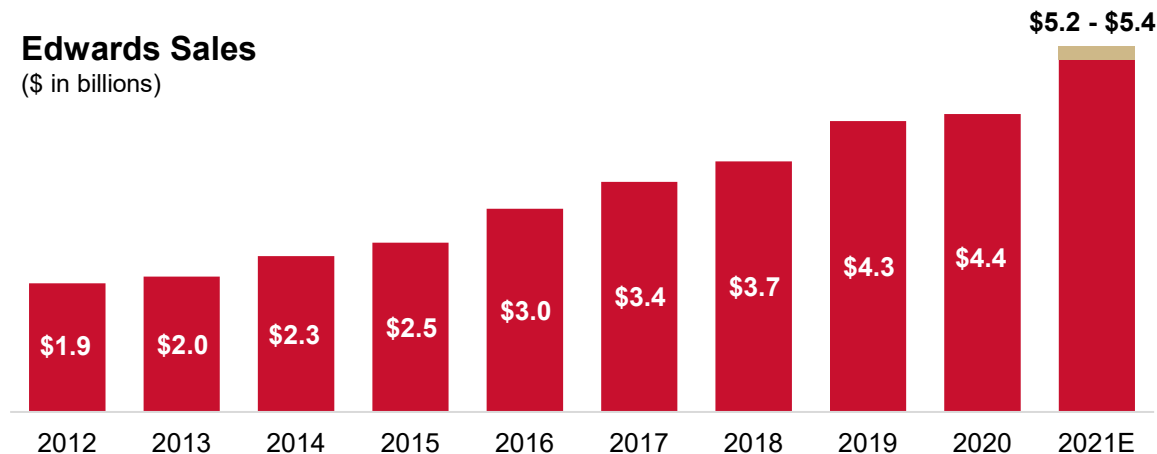
Track record of **triple wins**:

- Improved outcomes
- Enhanced quality of life
- Cost effectiveness



**Long-term investments** have yielded high-value, organic growth

**Edwards Sales**  
(\$ in billions)



# Business Overview

Strong Leadership Positions and  
Significant Growth Opportunities



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# Leader in \$5B Global Transcatheter Aortic Valve Replacement Market

Primary global growth drivers: **greater awareness**, advances in **new technologies**, as well as **indication and geographic expansion**

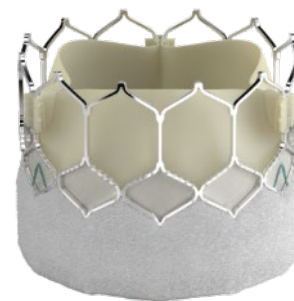
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Globally, **diagnosis and treatment rates of AS remain low** providing opportunity for low-double digit TAVR growth long-term

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Continued **investment in groundbreaking trials** beyond severe symptomatic aortic stenosis and transformational technologies to treat patients

Estimated global  
TAVR opportunity  
**\$10B by 2028**



# Asymptomatic and Moderate Risk Clinical Trials

*Expected to add significant growth beyond 2028*



- **Treating severe AS before symptoms may:<sup>1</sup>**
  - Prevent irreversible myocardial damage
  - Reduce risk of sudden death
  - Early treatment may lead to better outcomes

**Enrollment Completed in Q4 2021**

- Beyond Severe Aortic stenosis, we believe our TAVR therapy may benefit patients with Moderate Aortic Stenosis
- Studies have suggested that Moderate AS disease may have a similarly poor prognosis

**Enrollment Started in Q4 2021**

1. Genereux P. Natural history, diagnostic approaches and therapeutic strategies for patients with asymptomatic severe AS. JACC 2016; 2263-88.

2. Including low-risk indication.

# Our portfolio is innovative and durable

## SAPIEN 3 Ultra System

*Further elevates the performance benchmark of SAPIEN 3*



**45**  
minutes

Median  
procedure  
time<sup>7</sup>

**80%**

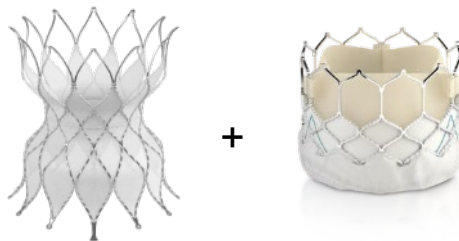
Next day  
discharge  
rate<sup>7</sup>

**0.5%**

PVL  
at  
30 days<sup>7</sup>

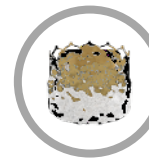
## SAPIEN 3 Pulmonic + Alterra

*Pulmonic platform expands therapy for Congenital Heart Disease patients*



- Alterra Adaptive Presept and SAPIEN 3 Pulmonic System expands therapy

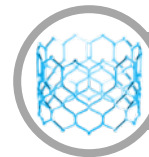
## Next Generation TAVR



### SAPIEN X4

ALLIANCE U.S. IDE  
Approved in Q4 2021

- Enhanced control and precision
- Enables best-in-class safety and efficacy outcomes



### Revolutionary Platform

# TMTT focused on leading and transforming treatment for patients with mitral and tricuspid valve disease

Three key value drivers: a portfolio of **differentiated therapies**, positive results from **pivotal clinical trials** and excellent **real-world clinical outcomes**

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Patients with Mitral and Tricuspid regurgitation remain **undertreated** and suffer from poor quality of life

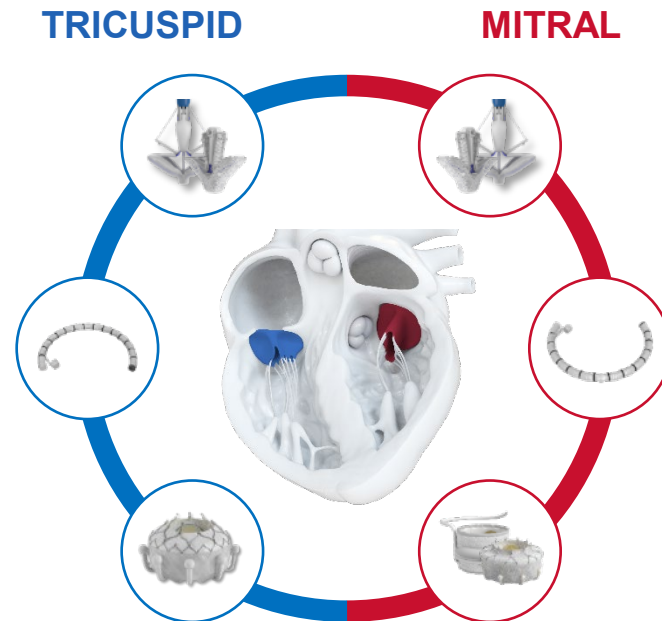
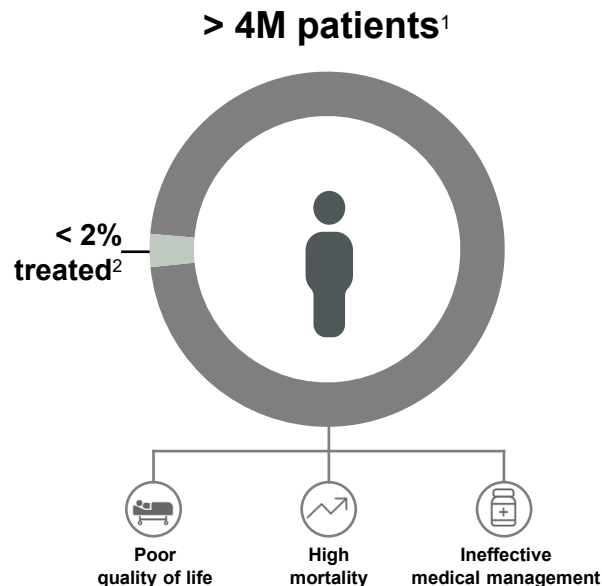
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TMTT is delivering a **portfolio of therapies**, backed by clinical evidence, to address the diversity and complexity of Mitral and Tricuspid disease

Estimated global  
TMTT opportunity  
**\$5B by 2028**



# TMTT has a bold vision to transform care for the many patients with Mitral and Tricuspid valve disease...



**...a comprehensive portfolio positions TMTT to realize this vision,  
and lead this rapidly growing opportunity**

# Building clinical evidence to transform standard of care

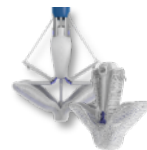
**5** Pivotal  
Studies

THE  
CLASP IID  
TRIAL



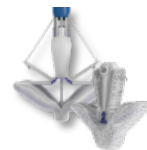
**PASCAL**  
*Degenerative MR*

THE  
CLASP IIF  
TRIAL



**PASCAL**  
*Functional MR*

THE  
CLASP II TR  
TRIAL



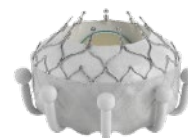
**PASCAL**  
*Tricuspid*

THE  
ENCIRCLE  
TRIAL



**SAPIEN M3**  
*Mitral*

THE  
TRISCEND II  
PIVOTAL TRIAL



**EVOQUE**  
*Tricuspid*

**Strong evidence is central to expanding patient treatment**

# Surgical Structural Heart is transforming patients' lives by solving critical unmet needs in cardiac surgery

The surgical structural heart market will **continue to grow mid-single digits** to \$2B by 2028

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We closely partner with surgeons to **understand and address unsolved challenges** in surgery

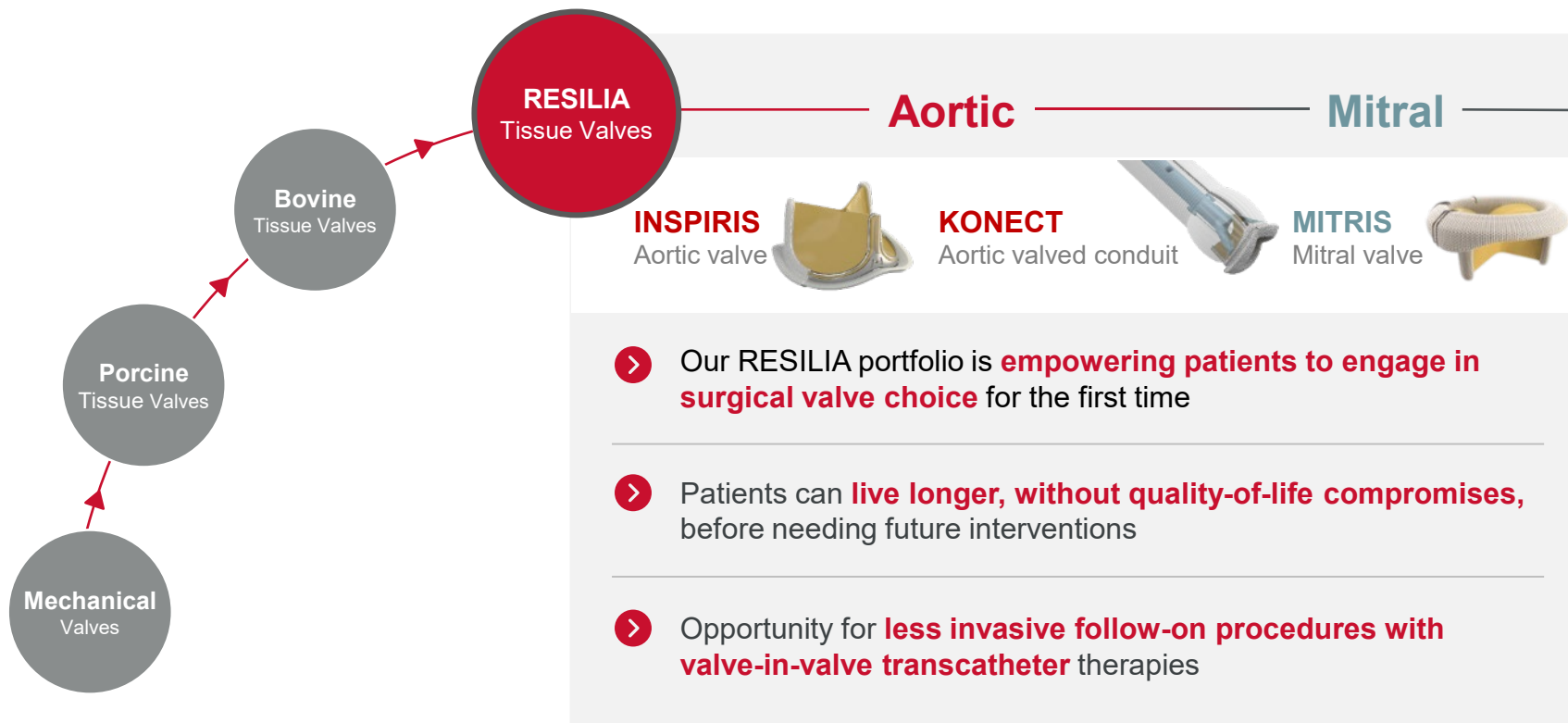
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We are **pioneering life-saving technologies** for patients best treated surgically

Estimated global  
surgical structural heart  
market opportunity  
**\$2B by 2028**



# Increasing global adoption of RESILIA accelerates long-term growth





# Our surgical portfolio strategy enables sustained growth through innovation

## INSPIRIS RESILIA

Surgical Aortic Valve



- Designed with expandable VFit technology
- More than 5 years of promising clinical data on RESILIA
- Driving global access to accelerate conversion to premium tissue valves

## KONECT RESILIA

Aortic Valved Conduit



- First pre-assembled, ready-to-implant tissue conduit
- For complex aortic valve patients with combined aortic root disease
- Rapidly increasing adoption of this specialized, high premium innovation

## MITRIS RESILIA

Surgical Mitral Valve



- Differentiating RESILIA tissue, ease-of-use enhancements, and valve-in-valve compatibility
- 60% of global mitral valve replacement patients currently receive a mechanical valve
- Leading mitral valve in Japan; US launch planned for 2022

# Critical Care improving the quality of care for patients

Continuing to **shift product mix** towards Smart Recovery, which has highest growth potential of our product groups

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Focusing on **three key building blocks** to advance Smart Recovery patient penetration

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Deploying **right technologies**, generating **clinical evidence** and creating **product awareness** to drive us towards our goal

Estimated global  
hemodynamic monitoring  
market opportunity  
**~\$2B by 2028**



# Three Key Building Blocks for Smart Recovery

## TECHNOLOGY

### Smart Monitoring Platform

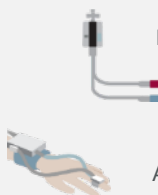


HemoSphere



### Sensors

Acumen IQ Sensor



Acumen IQ Cuff



ForeSight



### Algorithms

Hypotension Prediction Index (HPI)

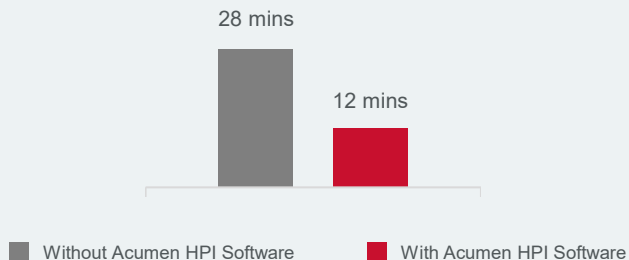
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Viewfinder Remote View



## EVIDENCE

### Hypotension Prediction Index (HPI) Data On Label



## ADOPTION



*"Intraoperative hypotension seems to be a threat to patient safety that is hiding in plain sight."*

– Daniel Cole, MD  
Anesthesiology, UCLA

# Growth Outlook



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# 2021 Driving Value

## Strengthening Positions Despite COVID

- TAVR therapy and geographic expansion
- Critical Care exceeding growth expectations
- Surgical driving adoption of premium technologies
- TMTT implementing bold agenda

## Achieving Clinical and R&D Milestones

- Gaining patient experience in multiple breakthrough therapies
- Advancing portfolio of catheter-based solutions
- R&D 17-18% of 2021E sales

## Delivering Results while Investing to Create Future Value

- Strong earnings growth while aggressively investing in R&D and infrastructure
- Resilient global supply chain

Estimated 2021  
Sales Growth:  
**High-Teens**

Estimated Adjusted  
EPS growth:  
**21-23%**

**Not Updating  
Guidance**

# 2022 expected to be a year of significant milestone achievements and investment in our future



## TAVR

Moderate AS trial enrollment  
SAPIEN X4 trial enrollment



## TMTT

PASCAL - DMR approval in the U.S.  
EVOQUE TR approval in Europe



## SURGICAL

MITRIS approval in the U.S.  
Continued adoption of RESILIA



## CRITICAL CARE

HemoSphere with Viewfinder  
Smart BP trial enrollment

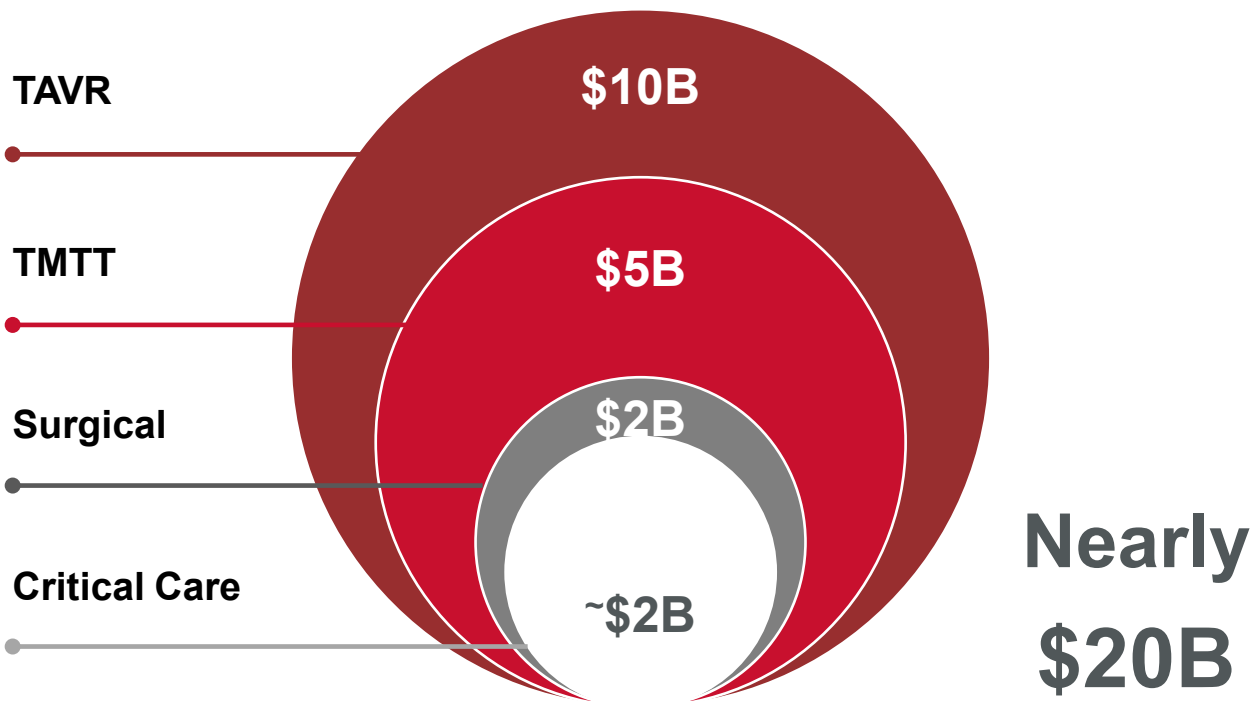
**Low double-digits**  
Underlying sales growth

**2022**  
**EXPECTATIONS**

**\$2.50 - \$2.65**  
Adjusted EPS

# Global Market Opportunity by 2028

Currently around \$10 billion



# Edwards is poised for long-term value creation

## Large Populations

of patients with unmet needs



## Patient-Focused Culture

motivates and guides our global team



## Sustainable

organic long-term sales growth



## Credibility and Trust

with clinicians, regulators,  
payors and patients



## Innovative R&D

produces breakthrough therapies  
and drives shareholder returns



**We are just getting started**





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Helping Patients is Our Life's Work, and

*life is now*