



Edwards

NEWS RELEASE

EDWARDS LIFESCIENCES OUTLINES GROWTH STRATEGY AT ANNUAL INVESTOR CONFERENCE

12/8/2022

IRVINE, Calif., Dec. 8, 2022 /PRNewswire/ -- Edwards Lifesciences Corporation (NYSE: EW) will discuss the company's strategy for longer-term growth, provide an update on its technology pipeline and share its financial guidance¹ today during its annual investor conference.

Highlights of today's conference include:

- Global market opportunity across 4 product groups projected to double to nearly \$20 billion by 2028
- Reaffirming October 2022 financial guidance
- Projecting 2023 global sales of \$5.6 - \$6.0 billion; underlying growth of 9% - 12%
- Projecting 2023 TAVR sales of \$3.6 - \$4.0 billion; underlying growth of 9% - 12%
- Projecting 2023 TMTT sales of \$160 - \$200 million
- Estimating 2023 adjusted earnings per share of \$2.45 - \$2.60
- Focused long-term growth investments with 2023 R&D planned at 17% - 18% of sales

- Meaningful progress on 8 pivotal trials across TAVR and TMTT

"I'm proud of the meaningful progress that the company made in 2022 advancing our strategic milestones to drive future success," said Michael A. Mussallem, chairman and CEO. "In 2023, we are projecting strong underlying sales growth while we continue to aggressively pursue breakthrough therapies for millions of patients suffering from structural heart diseases. During the year, we look forward to significant milestones, including new product launches and progress on multiple important clinical trials. We remain confident that our innovative therapies will continue to drive strong organic growth in the years to come as we embark on a new era of structural heart innovation."

Among the topics being discussed at today's conference are:

Transcatheter Aortic Valve Replacement (TAVR) – Edwards is confident that TAVR fundamentals remain strong and believes that hospital staffing challenges are transient and will gradually improve. To address these challenges, Edwards is focusing on supporting its hospital partners and engaging with the clinical community to address undertreatment. The company continues to believe that the global TAVR market opportunity will reach \$10 billion by 2028, driven by greater awareness and advances in new technologies, as well as indication expansion and increased global adoption. The company will continue investing in groundbreaking trials and research and development to help more patients and further strengthen its long-term leadership position. Highlights and expected milestones in 2023 include:

- Strong adoption of SAPIEN 3 Ultra RESILIA, anticipating stable selling prices and share
- EARLY TAVR, a pivotal trial studying the treatment of severe aortic stenosis patients before symptoms develop, is fully enrolled and advancing through the follow-up process
- Continued enrollment in PROGRESS, a pivotal trial studying the treatment of moderate aortic stenosis patients
- Continued enrollment in ALLIANCE, a pivotal trial studying the next-generation SAPIEN X4

Transcatheter Mitral and Tricuspid Therapies (TMTT) – With the global market opportunity estimated to reach \$5 billion by 2028, Edwards will discuss its strategy to use minimally invasive technology aimed at transforming treatment for the millions of patients suffering from mitral and tricuspid valve diseases. To transform treatment and unlock this significant long-term growth opportunity, the company will remain focused on three key value drivers: a portfolio of differentiated therapies, positive clinical trial results to support approvals and adoption, and favorable real-world clinical outcomes. Continued progress across these areas will result in more patients diagnosed and treated with Edwards' comprehensive portfolio of catheter-based technologies. Highlights and expected milestones in 2023 include:

- Continued U.S. and European launch of PASCAL Precision
- Presentation of CLASP IID full cohort data for PASCAL, with 1-year follow-up
- Completion of enrollment in the main cohort of the ENCIRCLE pivotal trial for SAPIEN M3
- European approval of the EVOQUE tricuspid valve expected by year-end
- Completion of enrollment in the TRISCEND II pivotal trial for the EVOQUE tricuspid valve

Surgical Structural Heart – Edwards remains committed to advancing its leadership in surgical structural heart therapies. The company is focused on identifying and solving critical unmet needs in cardiac surgery to help patients live longer, healthier and more active lives. In 2023, Edwards looks forward to broadening the adoption of its flagship surgical aortic heart valve, INSPIRIS RESILIA, which is changing the standards of tissue durability in cardiac surgery. Also in 2023, Edwards expects to accelerate its surgical mitral valve leadership with the ongoing launch of its MITRIS RESILIA valve.

Critical Care – Edwards plans to drive growth and leadership with innovations in critical care technologies, with the goal of improving the quality of care for millions of patients annually. The company is currently integrating a full range of Smart Recovery technologies on the HemoSphere monitoring platform that will create a unique offering of enhanced recovery tools to further strengthen the company's leadership in smart monitoring. Edwards is committed to growing adoption of its Critical Care products with the goal of getting patients home to their families faster.

During the conference, Edwards' management will reaffirm the company's 2022 financial guidance and provide guidance for 2023. Looking ahead to 2023, the company is planning for a gradual improvement in hospital staffing with growth across all major regions.

2022 Outlook

	December 2021 Guidance	October Guidance Unchanged
Sales	\$5.5 - \$6.0 billion	Low end \$5.35 - \$5.55 billion
TAVR	\$3.7 - \$4.0 billion	Low end \$3.5 - \$3.7 billion
Surgical Structural Heart	\$870 - \$950 million	\$870 - \$950 million
Critical Care	\$820 - \$900 million	\$820 - \$900 million
TMTT	\$140 - \$170 million	Q4 similar to Q3
FX Impact on Sales	~\$120 million unfavorable	~\$270 million unfavorable
Adjusted EPS	\$2.50 - \$2.65	\$2.40 - \$2.50

2023 Guidance

	Amount (at current rates)	Underlying Growth Rate
Sales	\$5.6 - \$6.0 billion	9 - 12%
TAVR	\$3.6 - \$4.0 billion	9 - 12%
Surgical Structural Heart	\$870 - \$970 million	Mid single-digits
Critical Care	\$840 - \$940 million	Mid single-digits
TMTT	\$160 - \$200 million	--
FX Impact on Sales	~\$100 million unfavorable	1.5pp downside to reported growth
Adjusted Gross Profit Margin	76% - 78%	--
SG&A as a % of Sales	29% - 30%	--
R&D as a % of Sales	17% - 18%	--
Adjusted Operating Margin	~30%	--
Tax Rate	13% - 17%	--
Adjusted EPS	\$2.45 - \$2.60	--
Free Cash Flow	\$1.0 - \$1.4 billion	--
Diluted Shares Outstanding	610 - 615 million	--

In addition to **Mr. Mussallem**, other members of Edwards' management team presenting include:

Larry Wood, Corporate Vice President, Transcatheter Aortic Valve Replacement;
Bernard Zovighian, Corporate Vice President, Transcatheter Mitral and Tricuspid Therapies;
Daveen Chopra, Corporate Vice President, Surgical Structural Heart;
Katie Szyman, Corporate Vice President, Critical Care; and
Scott Ullem, Corporate Vice President, Chief Financial Officer

Clinical perspectives will also be provided by the following physicians:

TAVR

Brian Lindman, MD, Interventional Cardiology, Vanderbilt Medical Center – Nashville, Tenn.
Sammy Elmariah, MD, Interventional Cardiology, UCSF Cardiology – San Francisco, Calif.

TMTT

D. Scott Lim, MD, Interventional Cardiology, University of Virginia – Charlottesville, VA.
Nishtha Sodhi, MD, Interventional Cardiology, University of Virginia – Charlottesville, VA.
Linda Gillam, MD, MPH Cardiology, Atlantic Health System – Morristown, N.J.
Robert Smith, MD, Cardiac Surgery, Baylor Scott & White – Plano, Tex.
Sam Dawkins, MBBS, DPhil, Interventional Cardiology, John Radcliffe Hospital – Oxford, U.K.

Surgical Structural Heart

Michael Chu, MD, FRCSC, Cardiac Surgery, London Health Sciences Center – Ontario, Canada

Michael Mack, MD, Cardiac Surgery, Baylor Scott & White Health – Plano, Tex.

Ralph Damiano Jr., MD, Cardiac Surgery, Washington University School of Medicine – St. Louis, MO

Olaf Wendler, MD, PhD, FRCS, Cardiac Surgery, Cleveland Clinic London – London, UK

Gorav Ailawadi, MD, MBA, Cardiac Surgery, University of Michigan – Ann Arbor, Mich.

Ismail El-Hamamsy, MD, PhD, Cardiac Surgery, Mount Sinai Hospital System – New York, N.Y.

Pavan Atluri, MD, Cardiac Surgery, University of Pennsylvania – Philadelphia, Penn.

Critical Care

Ashish Khanna, MD, MS, FCCP, FCCM, FASA, Wake Forest University – Winston-Salem, N.C.

David Stout, MD, Anesthesiologist, Swedish Hospital – Seattle, Wash.

Conference Call and Webcast Information

The Edwards Lifesciences 2022 investor conference can be accessed via live webcast at **ir.edwards.com** beginning at 10:00 a.m. Pacific Time today. The presentations will be available on the Edwards website. The webcast will be archived on the "Investor Relations" section of the Edwards website at **ir.edwards.com** or **www.edwards.com**.

About Edwards Lifesciences

Edwards Lifesciences is the global leader of patient-focused innovations for structural heart disease and critical care monitoring. We are driven by a passion for patients, dedicated to improving and enhancing lives through partnerships with clinicians and stakeholders across the global healthcare landscape. For more information, visit **Edwards.com** and follow us on Facebook, Instagram, LinkedIn, Twitter and YouTube.

This news release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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," "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, statements made by Mr. Mussallem, statements in the highlights of today's conference section, full year 2022 financial guidance and finance guidance for 2023, statements regarding the TAVR and TMTT opportunity, statements regarding 2023 milestones, statements regarding the RESILIA tissue technology, and the international adoption of

TAVR, the compounded annual growth rate, statements regarding transforming patient treatment, approvals, pivotal trials, clinical outcomes and adoption. No inferences or assumptions should be made from statements of past performance, efforts, or results which may not be 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 or experience to differ materially from that expressed or implied by the forward-looking statements include risk and uncertainties associated with the COVID pandemic, clinical trial or commercial results or new product approvals and therapy adoption; unpredictability of product launches; competitive dynamics; changes to reimbursement for the company's products; the company's success in developing new products and avoiding manufacturing and quality issues; the impact of currency exchange rates; the timing or results of R&D and clinical trials; unanticipated actions by the U.S. Food and Drug Administration and other regulatory agencies; unexpected litigation impacts or expenses; and other risks detailed in the company's filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2021, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, its Quarterly Report on its Form 10-Q for the quarter ended June 30, 2022, its Quarterly Report on its Form 10-Q for the quarter ended September 30, 2022 and its other filings with the SEC. These filings, along with important safety information about our products, may be found at **edwards.com**.

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[1] Guidance for underlying sales growth and adjusted earnings per share are provided on a non-GAAP basis, adjusted for special items described below, due to the inherent difficulty in forecasting such items without unreasonable efforts. The Company is not able to provide a reconciliation of these 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.

To supplement the consolidated financial results prepared in accordance with Generally Accepted Accounting Principles ("GAAP"), the Company uses non-GAAP 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" or "organic" growth rate when referring to non-GAAP sales information as adjusted for items referenced in (a) – (c) above, which in the future may exclude, as applicable, items such as foreign exchange rate fluctuations, sales return reserves associated with product upgrades, and proforma sales results of business acquisitions and divestitures. The Company uses the term "adjusted earnings per share" which may in the future 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, the purchase of intellectual property, realignment expenses, and the impact from implementation of tax law changes and settlements.

"Free cash flow" is defined as cash flows from operating activities less capital expenditures.

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