



Edwards

NEWS RELEASE

Edwards Lifesciences Outlines Growth Strategy at Annual Investor Conference

12/8/2021

IRVINE, Calif., Dec. 8, 2021 /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:

- Reaffirming October 2021 financial guidance
- Projecting 2022 global sales of \$5.5 - \$6.0 billion; underlying growth in the low double-digits
- Projecting 2022 TAVR sales of \$3.7 - \$4.0 billion; underlying growth 12-15%
- Projecting 2022 TMTT sales of \$140 - \$170 million
- Estimating 2022 adjusted earnings per share \$2.50 - \$2.65
- Focused long-term growth investments with 2022 R&D planned at 17-18% of sales
- Meaningful progress on 7 pivotal trials across TAVR and TMTT

- Global market opportunity across 4 product groups projected to double to nearly \$20 billion by 2028

"In 2021, our therapies are benefitting more patients than ever before. We are delivering results and making significant progress on our milestones to drive future success," said Michael A. Mussallem, chairman and CEO. "In 2022, we are projecting another year of double-digit top-line and bottom-line 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 significant clinical trials. We remain confident that our innovative therapies will continue to drive strong organic growth in the years to come, and we're just getting started."

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

Transcatheter Aortic Valve Replacement (TAVR) – Edwards believes the global TAVR market opportunity will reach \$10 billion by 2028, driven by greater awareness, advances in new technologies, as well as indication and geographic expansions. 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 2022 include:

- Continued adoption of the SAPIEN 3 Ultra system, anticipating stable selling prices and share
- EARLY TAVR, a pivotal trial studying the treatment of severe aortic stenosis patients before symptoms develop, will transition to follow-up
- Continued enrollment in PROGRESS, a pivotal trial studying the treatment of moderate aortic stenosis patients
- ALLIANCE pivotal trial to begin for 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 aimed at advancing care for the many 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 pivotal trial results to support approvals and adoption, and excellent real-world clinical outcomes. Continued progress across these areas will result in more patients diagnosed and treated with Edwards' comprehensive portfolio of TMTT products. 2022 highlights and expected milestones include:

- U.S. approval of PASCAL for patients with degenerative mitral regurgitation expected in late 2022
- European approval of the EVOQUE tricuspid valve expected in late 2022
- Continued enrollment in the TRISCEND II pivotal trial for the EVOQUE tricuspid valve
- Continued enrollment in the ENCIRCLE pivotal trial for the SAPIEN M3 mitral valve

- Expanded clinical experience in the MISCEND study with the EVOQUE Eos mitral valve

Surgical Structural Heart – Edwards believes the global surgical structural heart market opportunity will reach \$2 billion by 2028 driven by global cardiac procedure growth. The company remains committed to advancing its leadership as the partner of choice for surgeons. Edwards is focused on helping patients live longer, healthier and more active lives by developing durable therapies like RESILIA, which is changing the standards of tissue durability in cardiac surgery. Edwards looks forward to broadening the adoption of its flagship aortic surgical heart valve, INSPIRIS RESILIA, in 2022, along with the KONECT RESILIA valved conduit. Also in 2022, Edwards expects to launch a new surgical mitral valve, MITRIS RESILIA, in the U.S.

Critical Care – Edwards plans to drive growth and leadership with innovations in critical care technologies, with the goal of improving care for 20 million 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. Furthermore, in 2022, Edwards anticipates the U.S. launch of its Viewfinder network connectivity solution and the initiation of the SMART BP study. Edwards believes the global hemodynamic monitoring market opportunity will reach approximately \$2 billion by 2028.

During the conference, Edwards' management will reaffirm the company's 2021 financial guidance and provide guidance for 2022. Looking ahead to 2022, the company is planning for a gradual COVID recovery with growth across all major regions and no significant impact from new variants.

Fiscal Year 2021 Outlook	December 2020 Guidance	October Guidance (unchanged)
Sales	\$4.9 - \$5.3 billion	\$5.2 - \$5.4 billion
TAVR	\$3.2 - \$3.6 billion	\$3.4 - \$3.6 billion
Surgical Structural Heart	\$800 - \$900 million	\$875 - \$925 million
Critical Care	\$725 - \$800 million	\$800 - \$850 million
TMTT	~\$80 million	\$80 - \$100 million
Adjusted EPS	\$2.00 - \$2.20	High end of the range \$2.07 - \$2.27

Fiscal Year 2022 Guidance	Amount	Underlying Growth Rate
Sales	\$5.5 - \$6.0 billion	Low double-digits
TAVR	\$3.7 - \$4.0 billion	12 - 15%
Surgical Structural Heart	\$870 - \$950 million	Mid single-digits
Critical Care	\$820 - \$900 million	Mid single-digits
TMTT	\$140 - \$170 million	--
FX Impact on Sales (at current rates)	~\$120 million unfavorable	2% downside to reported sales
Adjusted Gross Profit Margin	78% - 79%	--
SG&A as a % of Sales	28% - 30%	--
R&D as a % of Sales	17% - 18%	--
Adjusted Operating Margin	31% - 34%	--
Tax Rate	11% - 15%	--
Adjusted EPS	\$2.50 - \$2.65	--
Free Cash Flow	\$1.2 - \$1.5 billion	--
Shares Outstanding	630 - 635 million	--

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

Daveen Chopra, Corporate Vice President, Surgical Structural Heart;

Katie Szyman, Corporate Vice President, Critical Care;

Scott Ullem, Corporate Vice President, Chief Financial Officer;

Larry Wood, Corporate Vice President, Transcatheter Aortic Valve Replacement; and

Bernard Zovighian, Corporate Vice President, Transcatheter Mitral and Tricuspid Therapies.

Clinical perspectives will also be provided by the following physicians:

TAVR

Rahul Sharma, MD, MBBS, FRACP, Interventional Cardiology, Stanford Healthcare – Palo Alto, Calif.

Tamim Nazif, MD, Interventional Cardiology, Columbia University Medical Center – New York, N.Y.

Philippe Genereux, MD, Interventional Cardiology, Atlantic Health System – Morristown, N.J.

Surgical Structural Heart

Christopher Young, MD, Cardiac Surgery, London Bridge Hospital – London, England

Kevin Accola, MD, Cardiac Surgery, AdventHealth – Orlando, Fla.

TMTT

Firas Zahr, MD, Interventional Cardiology, Oregon Health & Science University – Portland, Ore.

Charles Davidson, MD, Interventional Cardiology, Northwestern School of Medicine – Chicago, Ill.

Volker Rudolph, MD, Interventional Cardiology, Ruhr University Bochum – Oeynhausen, Germany

Philipp Lurz, MD, PhD, Interventional Cardiology, University of Leipzig – Leipzig, Germany

Critical Care

Michael Scott, MBChB, FRCP, FRCA, FFICM, Anesthesiologist, Penn Medicine – Philadelphia, Pa.

Kamal Maheshwari, MD, MPH, Anesthesiologist, Cleveland Clinic Foundation – Cleveland, Ohio

Conference Call and Webcast Information

The Edwards Lifesciences 2021 investor conference can be accessed via live webcast at ir.edwards.com beginning at 8:30 a.m. Pacific Time today. The presentations will be available on the Edwards website following the conference. To ask a question during the Q&A session of the presentation please dial (877) 704-2848 or (201) 389-0893. 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," "expect," "intend," "guidance," "outlook," "optimistic," "aspire," "unstoppable," "confident" or other forms of these words or similar expressions and include, but are not limited to, statements made by Mr. Mussallem, the potential opportunity sizes by 2028 for the products in each of the four business units, 2021 and 2022 financial guidance, expected impact of COVID-19 and recovery therefrom, expected benefits of technological developments, expected growth of opportunities in the long-term, expected investment, expected expansion in geographies, investments in R&D, timing and results of milestones in R&D and expected progress in the timing and enrollment in clinical trials, and expected regulatory approvals, clinical milestones, clinical experience, product introductions and product launches. 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 and difficult to predict. 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 risks and uncertainties associated with the COVID-19 pandemic, the timing and pace of therapy adoption, particularly in TAVR and transcatheter mitral and tricuspid therapies; unpredictability of the effectiveness and timing of new product launches; competitive dynamics; the timing and extent of regulatory approvals and reimbursement levels 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, particularly in our TAVR patent litigation; unpredictability of changes in accounting standards and tax laws; and other risks detailed in the company's periodic reports filed with the Securities and Exchange Commission. These filings, along with important safety information about our products, may be found at **[edwards.com](https://www.edwards.com)**.

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respective owners. PASCAL and MITRIS are not available for commercial sale in the United States. EVOQUE, SAPIEN M3, SAPIEN X4, and Viewfinder are not available for commercial sale in any country.

[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 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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