

Edwards Lifesciences - Where to Place the Next Structural Heart Investment?

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Decision scope: Setting priorities for the next increment of Edwards' clinical, commercial and evidence-generation capacity

Case convention: This is a constructed strategy exercise. The adviser role and decision are hypothetical; company disclosures and clinical evidence are historical. No private meeting or management deliberation is represented.

The decision

On July 23, 2026, Edwards Lifesciences reported second-quarter sales of \$1.741 billion, up 13.6% on a reported basis and 12.5% in constant currency. TAVR, the company's largest platform, generated \$1.26 billion, up 11.3% reported and 10.5% in constant currency. TMTT, its transcatheter mitral and tricuspid portfolio, generated \$195.9 million. Surgical structural heart contributed \$284.9 million. The company raised its full-year sales outlook after the quarter. [S1], highlights and product-group sales table.

Growth was broad, but the portfolio was changing. Edwards had spent decades building its transcatheter aortic valve replacement (TAVR) business. It was also developing transcatheter mitral and tricuspid therapies (TMTT), which now included repair and replacement products. Recent approvals and clinical milestones gave the newer platform room to expand, while TAVR still represented most product-group sales. The next planning cycle would require choices about clinical studies, physician training, field support and launch capacity.

The company's release was accepted by the SEC at 16:29 ET. Edwards had scheduled its earnings call for 17:00 ET. This case stops at the filing time; it excludes call remarks and the Form 10-Q filed in August. [S1].

Assignment: You are a hypothetical adviser preparing a recommendation for a strategy committee. How should Edwards prioritize the next increment of discretionary capacity across TAVR, TMTT, Surgical and earlier-stage structural-heart opportunities? Propose a rule for committing resources over time, the evidence or milestones that would release further investment, and the signals that would lead you to pause or redirect it. Do not assume that a specific committee discussion took place.

A portfolio at different stages

Edwards described its focus as structural heart disease, organized into TAVR, TMTT and Surgical. Its 2025 annual report said TMTT made up 9% of net sales in 2025, compared with 7% in 2024 and 4% in 2023. The increase in TMTT sales during 2025 came primarily from PASCAL repair and EVOQUE replacement products in the United States and Europe. The company also described opportunities in structural heart failure and transcatheter treatment of aortic regurgitation. These are different development and adoption stages; the available disclosures do not show a comparative return by platform. [S2], Item 1 and Item 7.

TAVR had a much larger installed business and continued to grow. Edwards linked its second-quarter procedural growth to clinical evidence and proactive management of severe aortic stenosis. It also said growth benefited from a competitor's exit in Q2 2025 and long-term SAPIEN durability evidence. These are management attributions. The release did not disclose Edwards' market share or estimate how much growth came from each driver. [S1], TAVR discussion.

TMTT's commercial base was smaller, but products spanned both repair and replacement. In December 2025, management had projected TMTT sales of \$740 million to \$780 million in 2026 and 35%-45% growth. In July 2026, the company raised the dollar range to \$760 million to \$780 million. It did not provide a new percentage growth range in the Q2 release. The same release listed an expected U.S. PASCAL tricuspid indication and next-generation PASCAL approvals in the fourth quarter. These figures and milestones were forecasts, not completed outcomes. [S1], Outlook; [S3].

One recent regulatory milestone was SAPIEN M3, a transcatheter mitral valve replacement system approved by the FDA in December 2025. Its U.S. indication covered specified symptomatic mitral regurgitation and mitral dysfunction populations whose multidisciplinary heart teams judged them unsuitable for surgery or transcatheter edge-to-edge repair (TEER). Approval did not mean it was cleared for all mitral patients or that commercial adoption was established. [S4], Indications for Use.

The history of JenaValve also illustrated that external innovation carried regulatory and transaction risk. Edwards' proposed acquisition was blocked by an FTC injunction in January 2026; the merger agreement was terminated days later. Edwards' 2025 Form 10-K described impairment and note investments associated with the transaction. It did not establish that internal development was necessarily superior; it did show that an acquisition route could fail to deliver the planned asset. [S2], Note 20.

Evidence, adoption and competition

A new heart-valve technology depends on more than engineering. Hospitals and clinicians need evidence, training and reimbursement; care teams must coordinate across specialties. A qualitative study of ten physicians at nine German hospitals described the role of reimbursement, procedural skills, local champions and cardiology-cardiac surgery cooperation in the implementation of TAVI. It studied hospitals already performing the procedure, not non-adopters, and its setting predates today's U.S. market. It offers adoption mechanisms, not a forecast for Edwards. [S5], pp. 2-7.

A U.S. Medicare claims study followed 5,116 interventional cardiology practices during 2012-2014. It found that a 1,000-point increase in physician-group market concentration was associated with a 26% higher rate of early TAVR adoption (hazard ratio 1.26; 95% confidence interval 1.16-1.37). The authors discussed the role of early CMS qualification rules and cautioned that the results might not generalize to later TAVR adoption or other technologies.

The finding does not predict Edwards' sales. [S6], pp. 1-6.

Clinical evidence also shaped competition within TAVR. The SMART randomized trial compared self-expanding Evolut valves with balloon-expandable SAPIEN valves in patients with small aortic annuli. A prespecified analysis of 621 women found similar 12-month rates on the composite of death, disabling stroke or heart-failure rehospitalization: 9.4% for self-expanding valves and 11.8% for balloon-expandable valves ($P=.35$). The self-expanding group had lower bioprosthetic valve dysfunction at 12 months: 8.4% versus 41.8% ($P<.001$). These results apply to the studied small-annulus subgroup, not all TAVR patients or the products' overall commercial prospects. [S7], abstract and results.

In May 2026, Medtronic announced three-year SMART results, reporting sustained hemodynamic advantages for Evolut in small-annulus patients and a similar clinical composite. That release came from a competitor and was not independently corroborated here with a peer-reviewed three-year report. Treat it as a provisional competitive signal. [S8].

Resources and guidance

In Q2, Edwards reported \$279 million of R&D expense, equal to 16.0% of sales, compared with 18.0% a year earlier. Management said R&D dollars had increased, while the percentage declined as revenue grew and investment priorities shifted across the structural-heart portfolio. Edwards expected R&D expense to be approximately 17% of sales for 2026. The disclosures did not allocate R&D by product, study, or program. [S1], Additional Financial Results.

Cash and cash equivalents were approximately \$2.9 billion at June 30, 2026, and debt was approximately \$600 million. The company had about \$1.5 billion remaining on its share-repurchase authorization. These figures show financial capacity but do not quantify limits on specialized personnel, clinical sites, manufacturing or field support. [S1], Additional Financial Results.

The July release increased 2026 guidance for total company constant-currency sales growth to 10%-11% and TAVR growth to 8%-9%. It raised the TMTT sales range to \$760 million-\$780 million and reaffirmed adjusted EPS guidance of \$2.95-\$3.05. It expected approximately 150 basis points of constant-currency operating-margin expansion for the year. Each is management guidance, not a realized result. The release also noted expected clinical presentations later in the year; those outcomes were not available at the cutoff. [S1], Outlook and Additional Financial Results.

The public evidence leaves several important questions unanswered. Edwards did not disclose product-level margins, R&D budgets, trial costs, site activation, physician capacity, adoption by indication, or project-level probabilities of regulatory and commercial success. The next allocation cannot be optimized from reported sales alone.

Resource-allocation approaches

The following approaches are constructed alternatives for discussion, not plans announced by Edwards.

1. Defend the established base. Prioritize TAVR evidence, indication expansion and competitive product performance. Maintain baseline support for TMTT and newer opportunities while waiting for more clinical and adoption evidence. This approach concentrates on the platform with the largest current sales base. It also risks letting a newer platform's evidence, launch readiness or clinical relationships fall behind.

2. Accelerate TMTT. Direct the next increment toward mitral and tricuspid clinical evidence, site readiness, training and launch capacity, while sustaining TAVR's current operating base. The smaller platform could gain from early experience and a multi-product portfolio. It also faces narrower indications, evidence and reimbursement requirements, and commercial demand that remains uncertain.

3. Stage a balanced portfolio. Protect minimum support for TAVR and Surgical, then release additional TMTT and emerging-therapy capacity in stages against specific clinical, regulatory, site-readiness and utilization milestones. This preserves the option to expand or stop as evidence arrives. It can also spread specialist capacity too thin or delay a platform whose adoption requires early commitment.

Students may develop another portfolio rule if it meets the same constraints: identify the capacity being allocated, set measurable gates, and explain what evidence would change the plan. No precise budget split can be inferred from the public disclosures.

Recommendation memo

Prepare a two-page memo that:

1. Recommends a portfolio priority and explains why it fits Edwards' capabilities and evidence at the cutoff.
2. States what is committed now versus what is conditional on later evidence.
3. Defines two to four milestones, measures or stop/defer triggers.
4. Identifies the strongest argument against the recommendation and what information would resolve it.
5. Separates reported results, management forecasts, clinical endpoints and your own assumptions.

You may use 100 notional investment points to make trade-offs visible, but those points are a classroom device, not company spending guidance. Do not calculate a financial return from undisclosed product margins or transfer market effects from the academic studies to Edwards. Recommendations and assumed allocation gates are hypothetical.

Discussion questions

1. What capabilities and evidence support Edwards' TAVR position, and what competitive vulnerability does the SMART subgroup evidence raise?
2. What would need to be true for TMTT's growth and SAPIEN M3 approval to translate into durable adoption?
3. How should Edwards divide resources between established programs, near-term launches and earlier-stage options when program budgets and returns are not public?
4. Which milestones would justify releasing a second tranche of investment? What result should trigger a pause or a reallocation?
5. What additional evidence would change your recommendation most?

Sources and conventions

S1. Edwards Lifesciences, [Q2 2026 results release](#), furnished with Form 8-K, 23 July 2026, accession 0001099800-26-000038. The SEC filing index records acceptance at 16:29:00 ET. Cited sections: Highlights, TAVR, TMTT, Additional Financial Results, Outlook, product-group reconciliation and forward-looking-statement discussion. The call was scheduled for 17:00 ET; call and webcast are excluded.

S2. Edwards Lifesciences, [2025 Form 10-K](#), filed 25 February 2026. Cited: Item 1, Research and Development, Sales and Marketing, and Competition; Item 7, Financial Highlights and Market Update; Note 20, JenaValve.

S3. Edwards Lifesciences, [2025 annual investor conference strategy release](#), 4 December 2025. Cited: 2026 guidance and portfolio priorities. Targets are forecasts.

S4. U.S. Food and Drug Administration, [SAPIEN M3 Summary of Safety and Effectiveness Data](#), PMA P250019, approved 22 December 2025. Cited: Indications for Use.

S5. Merkel et al., [“The transcatheter aortic valve implementation \(TAVI\)-a qualitative approach to the implementation and diffusion of a minimally invasive surgical procedure”](#), *Implementation Science* 10, 140 (2015). Cited: methods, results and limitations, pp. 2-7.

S6. Groeneveld et al., [“The Effects of Market Competition on Cardiologists' Adoption of Transcatheter Aortic Valve Replacement”](#), *Medical Care* (2020). Cited: cohort, method, results and limitations, pp. 1-6.

S7. Herrmann et al., [“Transcatheter Aortic Valve Implantation by Valve Type in Women With Small Annuli: Results From the SMART Randomized Clinical Trial”](#), *JAMA Cardiology* (2024). Cited: design, abstract, subgroup results and interpretation. The findings concern women in the studied small-annulus subgroup, through 12 months.

S8. Medtronic, [SMART trial three-year results announcement](#), 20 May 2026. Competitor-sponsored release; the three-year claims are provisional in this case because a peer-reviewed report was not independently verified.

All monetary values are nominal. Unless marked as a calculation or hypothetical teaching assumption, the facts are company, FDA or study disclosures. Constant-currency growth, reported growth, adjusted/non-GAAP measures and management guidance are not interchangeable. No information after 23 July 2026, 16:29 ET is included.