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EW.N - Q2 2026 Edwards Lifesciences Corp Earnings Call

EVENT DATE/TIME: JULY 23, 2026 / 9:00PM GMT

OVERVIEW:

Company Summary

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PRESENTATION

Operator

Greetings, and welcome to the Edwards Life Sciences second-quarter 2026 earnings conference call. (Operator Instructions) As a reminder, this conference call is being recorded.

It is now my pleasure to introduce Gerianne Sarte, Head of Investor Relations. Thank you. You may begin.

Gerianne Sarte - *Edwards Lifesciences Corp - Investor Relations*

Good afternoon, and thank you for joining us. With me on today's call is our CEO, Bernard Zovighian; and our CFO, Doretta Mistras. Also joining us for the Q&A portion of the call will be Dan Lippis, our global leader of TAVR, and Daveen Chopra, who has global responsibility for TMTT, surgical, and IHFM.

After the close of regular trading, Edwards Lifesciences released second quarter 2026 financial results. During today's call, management will discuss the results included in the press release and accompanying financial schedules, and then use the remaining time for Q&A.

Please note that management will be making forward-looking statements that are based on estimates, assumptions, and projections. These statements speak only as of the date on which they are made, and Edwards does not undertake any obligation to update them after today.

Additionally, the statements involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. Factors that could cause these differences can be found in today's press release and Edwards' other SEC filings, all of which are available on the company's website at [edwards.com](https://www.edwards.com). Unless otherwise noted, our commentary on sales growth refers to underlying sales growth, which is defined in the financial results press release issued earlier today.

Reconciliations between GAAP and non-GAAP numbers mentioned during this call are also included in today's press release. Quarterly and full-year growth rates refer to continuing operations.

With that, I'll turn it over to Bernard for his comments. Bernard?

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Thank you, Gerianne, and welcome everyone. Before we begin, I'd like to welcome Doretta to our first Edwards Lifesciences earnings call. Since joining in June, Doretta has quickly demonstrated her impact and valuable contribution as a member of the team, and we are pleased to have her leadership as we deliver on our patient-centered innovation strategy and our commitments to sustainable, distinguished performance.

Let me begin with a high-level comment on our quarterly performance. We delivered stronger than expected second quarter sales growth of 12.5%. As Edwards continues to invest in new structural heart therapies and expand adoption globally, our results increasingly reflect the strength of our comprehensive portfolio, with growth supported by multiple therapies across TAVR, mitral, tricuspid, and surgical, as well as meaningful contribution from each of our regions.

Today, our company profile has evolved to include multiple strategic platforms across multiple regions that will support durable growth, giving us confidence in our target of 10% total company sales growth on average over the long term. For those most familiar with Edwards, you know that the long-term differentiation of our performance begins with our singular focus on transforming care in structural heart disease. This, combined with our commitment to early innovation and agile execution, enable us to create new categories and expand access for patients.

Equally important is our culture. Our 16,000 employees around the world are aligned with our vision, inspired by their work, and dedicated to delivering exceptional innovation for patients in need. This dedication to developing safe and effective therapies requires unwavering focus, deep expertise, and a commitment to generating world-class evidence both on our therapies and the diseases they address, capabilities that distinguish Edwards as a trusted partner.

Our history of innovation has transformed care for patients around the world, and we know from this experience that establishing new therapeutic categories and changing the practice of medicine requires deep and sustained commitment. We believe this foundation positions Edwards to lead the future of these therapies for many years to come.

As a result of this strategy and focus, Edwards is able to make a differentiated impact and develop best-in-class technologies in TAVR, TMTT, and surgical. Speaking more specifically, in TAVR, years of technology advancement, development of world-class evidence, and partnership with clinicians have positioned SAPIEN as the standard of care for TAVR treatment, setting the benchmark for valve performance and durability. We are committed to continuing to raise the bar for both technology and clinical data while transforming the lives of aortic stenosis patients around the world.

In TMTT, our years of pioneering development and strategic investment have resulted in multiple unique therapies that enable physicians to offer options to the clinically diverse patients suffering from mitral and tricuspid disease. As we continue to build and expand, each of our therapies is advancing along its adoption curve, enabling us to extend these technologies to a broader population of patients.

In surgical, building on 70 years of innovation and leadership. We are continuing to partner with surgeons around the needs of their complex patients by expanding our leadership in valves as well as other therapies to address the many patients best treated surgically. At the same time, we are executing our proven innovation strategy to extend our leadership into structural heart failure and aortic regurgitation, which also represent large unmet patient needs and longer-term growth opportunities.

Generating world-class evidence is a key element of our strategy. We continue to demonstrate the company leadership in advancing high-quality science and innovating for patients through several important clinical presentation at the recent New York Valves Conference. This new data, spanning aortic, mitral, and tricuspid therapies, provide further understanding of the complexity of structural heart disease and the need for innovative treatment options.

Across Edwards, the result of our unique strategy and strong execution is reflected in the significant advancements that are building the foundation for continued long-term growth. In TAVR, this includes long-term SAPIEN valve performance and the asymptomatic indication, both supported by differentiated evidence. In TMTT, PASCAL, EVOQUE, and SAPIEN M3 continue to scale globally. In surgical, this include continued expansion of our portfolio.

Ahead of us, in the remainder of the year, we anticipate the finalization of an updated US. TAVR NCD and the presentation of PROGRESS trial results. A new TR indication for PASCAL in the US, the launch of next-generation PASCAL technology in the US and Europe, and the introduction of surgical left atrial appendage with ECLIPTIS in the US.

All together, we believe these important advancements represent multi-year opportunities that will materialize gradually over time. This underpins our annual sales growth targeting 10% on average alongside operating margin expansion for the company, with TAVR growing mid- to high single digits. As we create and shape new therapeutic categories and achieve important clinical, regulatory, and commercial milestones, there may be some minor variability in growth rate within therapeutic areas.

The more meaningful takeaway is the long-term durability of our growth and distinguished performance. Combined with our financial strength, this give us confidence. Confidence in both the short term and confidence in the long term.

Let me now turn to our financial expectation for the rest of the year. Given our second quarter performance, we are increasing our full year 2026 sales growth guidance for TAVR, TMTT, and total company, and reaffirming our earnings guidance. Our updated 2026 sales guidance is 10% to 11% for the company, with strong earnings leverage and operating margin expansion. As a reminder, our second half performance in 2025 set a higher bar for the second half of 2026.

In summary, let me put our durable performance in perspective. After delivering a strong 2025, we are on track to deliver on our increased company guidance of 10% to 11% this year and remain confident in our longer-term outlook.

Now I will provide more detail about the performance of our product groups. TAVR second quarter global sales of \$1.3 billion were stronger than expected and increased 10.5% over the prior year. Globally, procedural growth benefited from sustained clinical momentum and data supporting proactive disease management of severe AS.

At the same time, treatment decisions continue to be shaped by the long-term differentiation of our SAPIEN platform. Edwards growth rates were similar in the US and outside of the US. Growth also benefited from the exit of a competitor in Q2 2025 and compelling long-term SAPIEN durability data. Average selling prices were stable globally.

At the recent New York Valve Conference, a new partner-free subanalysis of a SAPIEN platform at seven years reinforced the best-in-class valve performance and long-term durability of Edwards TAVR. Further, a five-year analysis from the EARLY TAVR trial adds to the growing evidence supporting a shift toward treating aortic stenosis patient earlier in the disease pathway.

Also, at New York Valves, the PROGRESS trial presentation on baseline characteristics provided new insight into the heterogeneous nature of moderate AS patients. Research has shown that approximately half of these patients present with at least one at-risk feature. The PROGRESS trial is designed to evaluate whether these patients may benefit from TAVR earlier than current guidelines of surveillance suggest. We will learn more about the clinical relevance of treating these patient with TAVR when the PROGRESS trial results are presented at TCT later this year.

We were also pleased to share an update on our next-generation SAPIEN platform. Through our unwavering focus on innovation, we continue to elevate our best-in-class TAVR technology, and the first patients have now been treated with the updated SAPIEN X4-S. We are excited about this innovative platform and look forward to sharing more when the ALLIANCE trial is complete.

Let me now turn to some commentary on US TAVR. In Q2, procedure growth continued to benefit from the heightened focus on the therapy as the clinical community further incorporates into practice the meaningful evidence supporting proactive disease management. Edwards' competitive position in the US increased modestly year-over-year, enabled by continued adoption of SAPIEN 3 Ultra RESILIA.

We are also pleased that CMS continues to prioritize and progress the reconsideration of a NCD for TAVR, and we look forward to the final policy in September. Based on the draft coverage policy, we are encouraged that this update has the potential to advance TAVR therapy for Medicare beneficiary with aortic stenosis.

Outside of the US, we continue to see strong adoption of SAPIEN. In Europe, updated ESC and EACTS guidelines are helping shape clinical discussion around earlier intervention and proactive disease management, further reinforcing the role of TAVR across a broader patient population. Edwards' competitive position increased modestly year-over-year in Europe, which included what we believe to be the final quarter of benefit from a competitor exiting the market.

In Japan, we are encouraged by the growth and continued adoption of SAPIEN 3 Ultra RESILIA. We also received the asymptomatic indication approval in Japan. In summary, we are pleased with our TAVR performance, and given our Q2 result, we are increasing our full-year sales growth guidance to 8% to 9% from 7% to 9%.

Edwards' leadership in TAVR build on differentiated innovation, world-class clinical evidence, and continued indication expansion is increasing patient access and supporting sustained adoption of a SAPIEN platform, creating a durable mid to high single-digit long-term growth opportunity.

With that, let me turn to two of our important growth drivers in mitral and tricuspid. Our differentiated TMTT repair and replacement therapies drove second quarter sales of \$195.9 million, an increase of 44.8% year-over-year. Globally, mitral and tricuspid procedural growth remain in the double digits. Growth from our differentiated TMTT platforms, PASCAL, EVOQUE, and SAPIEN M3 exceeded our expectation in the quarter.

Individually, each therapy delivers meaningful benefits for patients and healthcare systems. Collectively, they provide physicians with a comprehensive set of options to tailor treatment to a broader range of patients with the goal of eliminating hesitation, which indicates better outcome for patients.

Adoption of PASCAL continues to increase, reflecting strong physician interest for its differentiated design and clinical outcomes, as well as the significant unmet needs of mitral and tricuspid patients. At last month's New York Valve Conference, real-world outcome demonstrated sustained safety and effectiveness of a PASCAL Precision system for one year in a broad population of more than 4,600 US DMR patients. We continue to expect that our next-generation PASCAL with Capture Clarity technology for both mitral and tricuspid patient in the US and Europe will be approved in the fourth quarter.

Also, in the fourth quarter, we continue to expect Class II TR result to be presented at TCT, and the launch of PASCAL in the US for tricuspid patients. This launch expands the population of patients that can benefit from this impactful therapy and adds another layer of growth for TMTT.

EVOQUE is a significant growth platform from TMTT and continues to scale in the US and Europe. We are increasing patient access to EVOQUE and driving further adoption by expanding into new centers, deepening utilization in existing centers, and streamlining patient screening processes. We believe the value of our growing body of clinical evidence will further increase with time, as

demonstrated by recent reduction in all-cause mortality and heart failure hospitalization, and will support continued physician adoption and expansion of access for patients with TR.

Turning to SAPIEN M3, our early experience validates the significant need for mitral replacement solution for patients who are not well suited for mitral repair or surgery and demonstrate excellent clinical outcomes for patients. We continue to execute a measured launch of SAPIEN M3 in the US and in Europe, steadily opening new centers and supporting sites as they build procedural experience.

During the quarter, results from the ENCIRCLE Mitral Annular Calcification of MAC registry were presented at New York Valves: The Structural Heart Summit demonstrating low 30-day mortality, virtual elimination of regurgitation, and impactful quality-of-life improvements. In Q2, we also received CE Mark for SAPIEN M3 RESILIA and broadened our indication for SAPIEN M3 and SAPIEN M3 RESILIA to include patients with MAC, increasing access to therapy for a patient population with a significant unmet need.

In summary, we enter the second half of 2026 with both a strong foundation and multiple opportunities to further strengthen our position in TMTT. As a result of our continued sustainable performance, we are increasing TMTT sales guidance to \$760 million to \$780 million from \$740 million to \$780 million. Together, PASCAL for mitral, EVOQUE, SAPIEN M3, and PASCAL for tricuspid represent layers of durable growth that support our path to \$2 billion in TMTT revenue in 2030 and position us for additional growth beyond.

In surgical, second quarter global sales of \$284 million increased 5% over the prior year, driven by continued adoption of our portfolio of RESILIA therapies, including INSPIRIS, MITRIS, and KONECT, which provided extended durability for patients. At the recent AATS conference, 10-year data from our COMMENCE trial studying the long-term durability of our best-in-class RESILIA tissue were presented.

The results showed favorable 10-year freedom from structural valve deterioration, or SVD, and a very low rate of SVD-related reoperation regardless of age, even in a relatively young cohort. These defining 10-year clinical milestones add to the growing body of clinical evidence supporting the long-term performance of RESILIA as a differentiated tissue technology.

We also received US approval for ECLIPTIS, our surgical left atrial appendage technology, and are planning for a measured rollout later this year, supported by a continued focus on procedural excellence and patient outcomes.

In summary, our progress in the quarter reflects our long-term commitment to meaningful innovation, lifetime care, and expanded options for underserved surgical patients, and we continue to expect mid-single-digit sales growth in surgical in 2026.

With that, I'll pass it over to Doretta to cover the details of our financial results.

Theodora Mistras - *Edwards Lifesciences Corp - Corporate Vice President, Chief Financial Officer*

Thank you, Bernard. I'm pleased to join you all today to cover our second quarter results. Before I begin, I want to say how excited I am to be part of Edwards and supporting the important work we are doing to meaningfully impact patient lives.

Over the past several weeks, I've had the opportunity to spend time across the organization, meeting many of our employees and getting to know many of our analysts and investors. I look forward to continuing to build upon these relationships going forward.

Now turning to our financial results. We are pleased with our financial performance in the quarter, including strong top-line growth and earnings leverage. Total sales of \$1.74 billion grew 12.5% year-over-year, reflecting strength across all product groups and regions. Adjusted EPS in the quarter was \$0.78.

Based on our second quarter performance, we are increasing our full-year sales guidance for total company to 10% to 11% from 9% to 11%, TAVR sales guidance to 8% to 9% from 7% to 9%, and TMTT guidance to \$760 million to \$780 million from \$740 million to \$780 million. Edwards now expects total company sales of \$6.6 billion to \$6.9 billion and TAVR sales of \$4.75 billion to \$5 billion

at current exchange rates. As a reminder, our second half performance in 2025 set a higher bar for the second half of 2026, particularly in the third quarter when we experienced unusually low impact from seasonality last year.

Moving to EPS, we have confidence in delivering our previously increased full-year adjusted EPS guidance of \$2.95 to \$3.05, despite now assuming our effective tax rate will be at the high end of our original 16% to 19% range, driven by Pillar Two impact and changes to California law restricting the usage of R&D credits.

I'll now cover additional details of our Q2 results, starting with EPS. Adjusted EPS of \$0.78 in the quarter benefited from our better-than-expected top-line performance, as well as our planned phasing of strategic investments in R&D and SG&A throughout the year. Our GAAP EPS for the quarter was \$0.42, primarily driven by the California R&D tax credit impact. A full reconciliation between our GAAP and non-GAAP measures, including adjusted EPS and other items, is included with today's release.

Moving on to other elements of the P&L. For the second quarter, our adjusted gross profit margin was 77.6%, flat compared to the same period last year, driven by foreign exchange headwinds offset by lower manufacturing expenses. Foreign exchange reduced our second quarter gross profit margin by 70 basis points compared to the prior year.

We now expect gross profit margin to be at the lower end of our full year 78% to 79% gross margin guidance, driven by the impacts of foreign exchange through our hedging program. SG&A expense in the quarter was \$561 million, or 32% of sales, compared to \$502 million in the prior year. This was in line with our expectations and reflects continued investment in resources to support patient care, as well as a higher translation of our OUS expense base from the weakening dollar.

R&D expense was \$279 million in the second quarter, or 16% of sales, compared to \$276 million or 18% of sales in the same period last year. This decrease in R&D as a percentage of sales and increase in total expense reflects our growing revenue and strategic prioritization of investments in our expanding structural heart portfolio. We continue to expect R&D expense as a percentage of sales to be approximately 17% in 2026.

Second quarter adjusted operating profit margin was 30%. Our first half operating margin benefited from the planned phasing of strategic investments in SG&A and R&D during the course of the year. We continue to expect full-year operating margin to be at the high end of the original 28% to 29% guidance, resulting in approximately 150 basis points of constant currency operating margin expansion for the full year. Going forward, we continue to plan for 50 to 100 basis points of underlying operating margin expansion while continuing to invest in the business.

Turning to our tax rate, we now expect our 2026 effective tax rate, excluding special items, to be at the high end of our previous range of 16% to 19%. This reflects an expectation that side-by-side Safe Harbor taxation legislation alongside Pillar Two does not come into effect before the end of the year. Our tax rate is also impacted by changes to California law permanently limiting the usage of R&D credits.

Despite these incremental tax headwinds, we remain on track to deliver operating margin expansion and leveraged EPS growth. If legislation is passed before year-end related to Pillar Two, we would expect to see a benefit to this rate.

Foreign exchange rate changes in the second quarter increased reported sales by approximately \$15 million, or 110 basis points versus the prior year, which was \$6 million higher than our expectation. On a constant currency basis, sales in the second quarter were near the top end of our guidance range. If foreign exchange rates were to hold at current levels, we estimate foreign exchange to be a second half headwind of approximately \$35 million compared to the prior year.

Turning to the balance sheet, we continue to maintain a strong and flexible balance sheet with approximately \$2.9 billion in cash and cash equivalents as of June 30, 2026. Edwards' disciplined approach to capital allocation remains unchanged as we continue to support growth and create long-term value for patients and shareholders. Our highest priority remains investing in organic growth opportunities and strengthening our manufacturing network.

Next, we look for external opportunities within structural heart, where we can create value by applying our unique innovation strategy to address large unmet patient needs. Finally, we will continue to be active in returning capital to shareholders through opportunistic share repurchases. Edwards has approximately \$1.5 billion remaining under our share repurchase authorization. Average diluted shares outstanding during the quarter were 578 million. We continue to expect average diluted shares outstanding for 2026 to be between 575 million and 580 million.

Now let's turn to our Q3 guidance. For the third quarter, we're projecting sales of \$1.63 billion to \$1.71 billion. From a modeling standpoint, as expected, Q3 underlying sales growth will be artificially lower than our first half performance, given the high bar that our 2025 performance set for the second half. On a sequential basis, we expect normalized seasonality in Q3 this year.

We are expecting adjusted EPS in Q3 of \$0.71 to \$0.77. The strength of our first half performance and the strong fundamentals across TAVR, mitral, tricuspid, surgical, and our regions gives us confidence in delivering on our increased outlook for the rest of the year and targeting 10% sales growth on average longer term.

With that, I'll hand it back to Bernard.

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Thanks, Doretta. In summary, our second quarter performance underscores the strength of our focused strategy and reinforces our confidence that the investments we are making today will drive sustainable growth and meaningful value creation over the long term.

Before we move to Q&A, I also like to highlight two upcoming opportunities to engage with our team. We will host an event at the TCT conference in San Diego this fall. We will also host an annual investor conference on December 4 at the New York Stock Exchange. Additional details for both events will be provided. We hope you can join us.

With that, I will turn it back over to Gerianne to facilitate Q&A.

QUESTIONS AND ANSWERS

Gerianne Sarte - *Edwards Lifesciences Corp - Investor Relations*

Thank you, Bernard. We're ready to take your questions. As a reminder, please limit the number of questions to one, plus one follow-up to allow for broad participation. If you have additional questions, please reenter the queue and management will answer as many participants as possible during the remainder of the call. Diego?

Operator

(Operator Instructions)

Robbie Marcus, JP Morgan.

Robbie Marcus - *JPMorgan Chase & Co - Analyst*

Congrats on a great quarter. Bernard, two from me, I'll just ask them both upfront, both revenue-driven, TAVR and TMTT focused. First on TAVR, clearly a very strong quarter. It appears you're getting the benefits of market expansion from asymptomatic and some competitive wins from your main competitor. The share seems to be shifting over.

I'd love if you could dive into those two and talk to the trends you're seeing on competitive share shift, market expansion, and, if you want to throw in how different US and outside US growth was, considering the focus there. And then on TMTT, my guess is it's all the products, PASCAL and EVOQUE, that's driving the upside. If there's any one that contributed more aggressively to the 7% sales beat versus consensus. Appreciate any color.

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Thanks, Robbie, and great to be with all of you. Allow me to start with a very brief comment about the company performance. We are very excited about it, very pleased, better than expected. This is reflecting in our strategy. Our strategy in structural heart is working very well. I want also to recognize our team who is having flawless execution globally. We have seen in Q2 and even in Q1 this year, great performance by therapy and in each of our regions. Again, all of this give us confidence.

Back to your question about TAVR. I would say on TAVR, a little bit of the same. Better than expected. These results are not happening by chance. They are the result of years of technology advancement, about 20 years, building world-class evidence. All of this together has positioned SAPIEN as the benchmark TAVR platform globally with regards to valve performance and valve durability.

It is why it is important for us to always step back and look at why the results, and we believe that because of this, our results are durable. Now if you want to compare US or OUS, our growth rate in TAVR were very similar between US and OUS. They were the result of this renewed focus on TAVR, given all of the clinical data we have produced in the last 12 months and many years. That's probably what I want to say about TAVR. I'm sure Dan later will be able to provide more details.

On TMTT, yes, I think the value of a portfolio is now clearly in action. We have seen PASCAL doing very well with an increased adoption also in US and in Europe because of its differentiated feature. EVOQUE also I've seen an acceleration, and it's doing very well. M3 is also having some -- even though it is early, is going very well. We got very good feedback from European physicians and US physicians. The beauty of this quarter is it is all together. Again, here I'm sure Daveen later today will provide more detail about TMTT. Thanks very much for the question, Robbie.

Operator

Larry Biegelsen, Wells Fargo.

Larry Biegelsen - *Wells Fargo - Analyst*

I'll echo my congratulations on the really strong quarter here. Bernard, just one on PROGRESS and one high-level question from me. Bernard, on PROGRESS, can you talk about why you highlighted the heterogeneity of the PROGRESS population in the press release, and in your prepared remarks. If PROGRESS is positive, how would you frame the impact to your TAVR business, relative to earlier new indications like asymptomatic?

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Let me start about first, why we decided this time to split the PROGRESS presentation in two. The baseline characteristic at New York Valves and the full presentation of the result at TCT. We did that because a little bit of a learning from EARLY TAVR. When you study a disease in eight minutes of a presentation, it is very difficult for a physician to provide everything, what the study design is, why we did it, the baseline characteristic, and then the results.

And so here, given the importance and given the learning from EARLY TAVR, we said it was probably important to split it in two. We went a little bit deeper into, A, one is potentially the size and what we have presented at New York Valves is that moderate is at least as big as severe. Some analysis is showing even bigger. This population is very diverse, very complex.

And so we thought it was important in advance so people understood this disease. We also talk about the fact that there is no difference in age between the severe and moderate AS. But that's a little bit about what we wanted to achieve here. Maybe Dan, you want to add a couple of things on that?

Daniel Lippis - *Edwards Lifesciences Corp - Corporate Vice President - JAPAC (Japan, Greater China and Asia Pacific)*

Yeah, I think you covered it largely. It's the first randomized trial looking at the treatment of moderate AS patients and the heterogeneous nature of this population is not well understood. And I think understanding the baseline characteristics a little bit better give us a greater insight into that and just help us understand when we get to digest the results at TCT later this year, just help us focus on what those results really mean.

As you well know, Larry, this is a trial studying moderate AS patients with at least one at-risk feature, and I think it was important to describe what they are. That population is, at least in the literature anyway, suggests that it's representative of about 50% of the total moderate population. So it's still a large population here.

And so we shouldn't be surprised by it, but maybe some people were. Maybe some people don't understand that the severe AS patient population and the moderate AS population are very similar in terms of their age. In fact, again, the literature on prevalence suggests there's only one year gap between severe and moderate. So all those sort of details come out in the baseline characteristics. And then, again, it allows us to sort of answer those questions and then focus on the results when they drop at TCT.

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Yeah. With regards to impact, Larry, think about it. You know that the practice of medicine is moving slowly. We expect minimal impact in 2026. Our long-term guidance for TAVR, mid to high single digit, is here to accommodate all of these kind of scenarios. What we will do at investor conference is provide a more detailed guidance, obviously, for 2027. Thanks for your question.

Larry Biegelsen - *Wells Fargo - Analyst*

Okay. Thanks for that comprehensive answer. Bernard, I wanted to ask about your comments about 10% total company growth on average, because you didn't highlight that on the Q1 call. The implied second half underlying growth is about 9%, which is slightly below 10%. I know it's really early, but do you believe you can grow 10% underlying next year? And if so, what are the drivers? Thank you.

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Just to be clear, Larry, my comments on 10% is about the company. It is a guidance comment long-term about the company with TAVR growing between mid to high single digit. I think this was our comment that we did at investor conference. It was the same comment that we did at the end of the Q1 and the same I did today.

Larry Biegelsen - *Wells Fargo - Analyst*

No, I got it. I meant the total company, Bernard. Sorry if there's any confusion. I was asking about total company, not TAVR. But I'll leave it there.

Operator

Travis Steed, Bank of America.

Travis Steed - *BofA Securities - Analyst*

Hey, congrats on a good quarter. Just maybe to follow up somewhat to Larry's question. Given the tough comps in the second half, you mentioned you still expect normalized seasonality in Q3 this year. Just want to make sure I understand what normal Q3 seasonality means. Looking back at the model and worldwide TAVR kind of down anywhere between \$15 million to \$30 million sequentially from Q2 to Q3, which to me, my math puts that at kind of 5% to 6% worldwide TAVR growth. I'm curious if that's kind of the math that we should be doing or if you'd say anything on the seasonality.

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Maybe let me try to put in perspective how we think about the guidance for 2026. First, we had a better than expected first half, Q1 and Q2. We took this sustained performance into consideration in rising our full year guidance.

In addition, what we talk about in Q1 and today is the fact that we expect the second half growth rate to be artificially low because of the high comps from last year. I don't know if you remember, but last year, the summer was very high from growth rate. We have a very high comps to age of 2026.

We took all of that into consideration, to give you the guidance, 10% to 11% for the total company. Is it good enough here, or do you want more detail on this guidance and 1H and 2H dynamic?

Travis Steed - *BofA Securities - Analyst*

Yes, there was a comment in the prepared remarks about normalized seasonality in Q3. Just wanted to make sure we had that down.

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

This year we don't expect like last year, to have a very strong summer. What you are going to see is Q2 to Q3, you are going to have some incremental dollars, Q2 to Q3.

Travis Steed - *BofA Securities - Analyst*

And then the second question is more on the NCD. I don't know how big of a deal you think NCD is on kind of TAVR growth next year, or how to quantify how many centers this opens up, or does it open up capacity for TMTT as well as TAVR, just anywhere on the NCD now that it's kind of more finalized?

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Maybe I'm going to ask Dan to comment on the NCD itself, and then we can discuss about TMTT.

Daniel Lippis - *Edwards Lifesciences Corp - Corporate Vice President - JAPAC (Japan, Greater China and Asia Pacific)*

Yeah, thanks for the question, it's an important one. First of all, we're really pleased, right? That CMS is running this process, the good news is we're getting nearer to the end of it. We've just seen a draft policy position, and the second public comment period is now closed, so final policy memo is expected in September.

This is where we're at in the process. When you look at that draft, there are a couple of opportunities there. We're encouraged by it, number one. I think that's really important to say. I look at it in three different ways, right? The big reasons to sort of open this up and revisit it. Well, first one is, we're encouraged, at least in the draft it says that there's a pathway for asymptomatic indications to be covered. That's really important. That's one opportunity.

The second is that there's a recognition that after all these years, that symptomatic severe aortic stenosis is a reasonable and necessary procedure for Medicare beneficiaries, that it can be covered without evidence development. That's super important.

And then the third is modernization of the policy, around empowering heart teams to give timely access to care for patients in need. These are the big ones that present what we would say tailwind or potential catalyst as far as future opportunity in 2027 and beyond.

Your comment specifically about new centers, if you think about it, the current draft policy states that cardiac surgery programs still need to be in play and exist, for a TAVR program to be covered or TAVR procedure to be covered.

If you think about that, where we are, about 850 odd plus centers and how many surgical centers. There's room for some expansion, but that's not the big add. The big add will be how efficiently patients can be processed, referred, diagnosed, referred, and treated, and what that means from a program efficiency perspective, and that will be very, very important as demand we anticipate to continue increase based on indications and evidence.

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Do you have a follow-up question?

Travis Steed - *BofA Securities - Analyst*

No, that was it for me.

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Okay, thank you.

Operator

Joanne Wuensch, Citibank.

Joanne Wuensch - *Citibank Cameroon SA (Douala Branch) - Analyst*

Good evening, thank you so much for taking my question and for delivering the quarter. We're getting a lot more questions on PROGRESS. I was curious if you could sort of level-set, assuming that the clinical data looks good, how you think the adoption rate might be, and how do you think the steps would be towards having that contribute to revenue?

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Yes, I'm going to let Dan take this one.

Daniel Lippis - *Edwards Lifesciences Corp - Corporate Vice President - JAPAC (Japan, Greater China and Asia Pacific)*

First, we can make a whole bunch of assumptions. I think the first thing is we have to see the results, and those results will be, as you know, presented, published, at TCT this year. Taking a step back, I think we need to think about this patient population in a very similar way as the asymptomatic patient population. These are new indications that don't have a predicate, right? We spent 15 years doing a lot of evidence generation on TAVR as an alternative to surgery. And whether it be an asymptomatic patient population or a moderate disease patient population, the guidelines, surveillance is the recommendation for these particular indications, not surgical intervention.

There's that element of change management and human behavior change and education, et cetera, that has to go along with any of these new indications or new data sets. And so I think that we can look at that very similarly. I think it's going to be important data. There's going to be a lot of learning. We can think about those two things in a similar way relative to, say, high risk, intermediate risk, low risk, where it's just against an existing predicate. Does that make sense, Joanne?

Joanne Wuensch - *Citibank Cameroon SA (Douala Branch) - Analyst*

It does. Thank you so much.

Operator

Pito Chickering, Deutsche Bank.

Pito Chickering - *Deutsche Bank AG - Research Analyst*

Thanks for taking the questions, and great quarter. I'll put my two questions up front. Looking at PASCAL tricuspid, with the approval expected in the fourth quarter, and we're seeing the data at TCT in the fall, is it safe to say that the trial was successful and has already been submitted to the FDA? Any color there? The follow-up is, with market share gains you've seen in mitral with PASCAL, can you talk about how you think you're positioned to enter the tricuspid market with PASCAL?

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

I can tell you, we are very pleased about the PASCAL performance. I'm going to let Daveen provide more detail. He's very close to it.

Daveen Chopra - *Edwards Lifesciences Corp - Corporate Vice President - Transcatheter Mitral and Tricuspid Therapies*

Yeah, as you said, exactly, right now we're expecting both the data to be released at TCT this year. I think we'll all look at the data together, and our expectation is for a Q4 approval in the US, is our current planning right now.

If you look at PASCAL tricuspid, however, so far, we've obviously had this technology now in Europe for a few years, and we see that some of those differentiated features with the PASCAL device on the mitral side come off even more so in the tricuspid side. Physicians

can see that some of those cool features about independent grasping, et cetera, they really make a difference in treating their tricuspid patient. As a result, we see that physicians want to use PASCAL more and more often in the tricuspid situation in Europe.

I think it's on the back of that as we think about the US tricuspid approval and launch as that next layer of growth, as that next wave of potential growth for the TMTT business, where we think that those differentiated features should be able to come over to the US. We've got a large number of physicians who were in the trial, who are in the continued access for the trial as well, and I think there is that kind of looking forward to this technology coming and helping their patients here in the US.

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

What we like with this PASCAL Tricuspid upcoming approval in the US, this is adding a layer of growth for TMTT. We have today PASCAL mitral. We have EVOQUE still scaling. We have M3 at the beginning, and we are going to add this fourth layer of growth for TMTT. This give us confidence. One is that physician will have all of the tool they need, best-in-class tool they need to treat their patients, but also confidence in TMTT achieving \$2 billion in 2030.

Operator

Vijay Kumar, Evercore ISI.

Vijay Kumar - *Evercore Inc - Equity Analyst*

Congrats on the nice sprint here. Bernard, it looks like in the press release, you called out EVOQUE. I'm curious on this TMTT performance. Have you seen an inflection in EVOQUE, and is that what's driving the strength, or is this more broad-based when you look at the TMTT portfolio?

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Let me make a brief comment about it, and then I will ask Daveen to add additional color here. I would say we have seen an inflection in EVOQUE since the beginning. The demand is very high, and so it's growing very well. What we have seen in the quarter is great adoption. I'm going to let Daveen, who is very close to this action.

Daveen Chopra - *Edwards Lifesciences Corp - Corporate Vice President - Transcatheter Mitral and Tricuspid Therapies*

I think I'll speak first a little bit more broadly. As Bernard mentioned upfront in the call to Robbie's question, we've seen a growth coming across all of the platforms in TMTT and, to be honest, all the regions for TMTT. It's been great to see that all the technologies are adopted.

As you can imagine, PASCAL was our first technology, so it's actually our largest technology by revenue. EVOQUE, though, is second in size, but growing very quickly. There's a lot of excitement for the technology. We see the continued new data coming out, people adding to the overall clinics portfolio that makes people want to use EVOQUE. And then we've got the new kid on the block, obviously, with SAPIEN M3, which is the newest, high growth rate, but the smallest because it's just the newest in terms of its timing.

What we're seeing overall is that it was specifically, if you dive a little bit into EVOQUE, we see a couple different factors. We see a kind of deepening overall adoption coming from, we have new centers opening up every week, every month across the world. New centers are getting exposed to EVOQUE. We see that in existing centers.

Over time, we're continuing to work closely with them to streamline the whole process of an EVOQUE patient, from the pre-case plan to getting ready for that patient to actually executing the case. That then enables those centers to actually do more cases and actually increase the kind of amount of usage in each case. I think those together are helping keep the momentum going in EVOQUE, but I don't want to underscore the momentum we see today, both in PASCAL and the initial momentum we're seeing with M3.

Vijay Kumar - *Evercore Inc - Equity Analyst*

That's helpful, Daveen. Maybe Bernard, one on PROGRESS. I know there were a lot of heterogeneous population, and you guys did a good job trying to balance out the different factors. Most of these patients had heart failure symptoms. What were the baseline drugs in this trial? Was it a consideration when randomizing? I don't know if you can answer that, but if you could talk about how drug arms in both arms, how the drugs in both arms were, whether they were randomized or was that a criteria?

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Thanks, Vijay. I'm going to ask Dan to reply to this one. It is a technical question, Vijay. Dan is best positioned here.

Daniel Lippis - *Edwards Lifesciences Corp - Corporate Vice President - JAPAC (Japan, Greater China and Asia Pacific)*

I think this is one of the reasons why we presented the baseline characteristics and perhaps it's important for everyone to understand, this is not a heart failure trial, right? This is a trial on moderate AS patients with at-risk features.

UNLOAD was a heart failure trial where the patients happened to have moderate AS. These are two very different patient populations. You could see from the baseline characteristics, what's interesting about them is perhaps clinically not benign. We'll see. These patients did have symptoms. They did have at-risk features as the trial design was intended.

But they also had very healthy left ventricular function. This is the type of patient that we're dealing with. They're not a heart failure patient. They're a moderate AS patient with certain characteristics that may predispose them to greater risk clinically than what current guidelines suggest, which is active surveillance.

Again, a lot of learning here, understanding the patients. Drug regimes don't play into a big factor here because these patients don't have heart failure symptoms, although the primary endpoint is going to include hospitalization and heart failure events, obviously, when you're doing a comparator against surveillance like this. A lot to learn and we'll learn more when the results are presented at TCT. Thanks for the question.

Operator

Josh Jennings, TD Cowen.

Joshua Jennings - *Cowen and Company LLC - Analyst*

First, I just wanted to talk about TAVR market growth drivers. I mean, the CMS NCD update and the low-risk indication are two clear ones. TAVR in TAVR has kind of been on the back burner, but low-risk indication was approved in 2019, so next year will be the eighth year post-approval.

Edwards hasn't been very vocal about TAVR in TAVR as a potential driver. The SAPIEN is well-positioned for that procedure. Maybe, could you help provide some insights on Edwards' internal expectations for the TAVR opportunity and when these procedures could potentially contribute at a meaningful level to volume growth?

Daniel Lippis - *Edwards Lifesciences Corp - Corporate Vice President - JAPAC (Japan, Greater China and Asia Pacific)*

Yeah, Josh, maybe I answered that question. You're absolutely right when you talk about some of the more obvious sort of milestones ahead of us with NCD progress, et cetera. Lifetime management, I think we've talked a lot about this. This is something that is becoming absolutely more important and more critical, particularly as the evidence suggests that you get benefit by treating earlier in the disease pathway.

Not just younger. I mean, earlier in the disease pathway, as we learn, can mean different things to different patients at different age groups. But the reality is that we anticipate as the therapy penetrates, is that there are going to be patients who outlive the durability of their valve, and we're seeing that in various trials, et cetera, and various patient populations.

So lifetime management becomes a thing, and the planning of when to treat, with what option, and how to treat the second option, and there's a lot of complexity in there. We have modeled that in to our market model. We look at that. Right now it represents a relatively small part of the market, relatively. We anticipate that to grow, and that's all factored into the TAVR market.

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

If you put all of this in perspective, we are, in my mind, sitting in front of an amazing opportunity. You look at TAVR. It is still under-penetrated. It is still under-adopted. We have the asymptomatic indication to unlock with the NCD. The NCD has the potential, if the draft remain like it is, to streamline timely access for patients. If a study is positive, a PROGRESS study is positive, another indication for this patient population.

So we look at TAVR as a very durable growth engine for the company. You add all of the catalysts we are having on TMTT, PASCAL, M3, EVOQUE, and you look at surgical also. We didn't discuss about surgical today, but we have also many opportunities in surgical. Altogether, for TAVR, and altogether for the company, we feel very confident.

You look at what we did last year, what we are doing this year, the kind of execution we are having also. All of this together, in my mind, it is what give us confidence about achieving long-term, about 10% EPS leverage and operating margin improvement, 50 to 100 points. Again, excited, confident. I like what the team is doing, and it's great to be able to report this kind of quarter.

Operator

Ladies and gentlemen, that's all the time we have for questions today. I'll now hand the floor back to Bernard Zovighian for closing remarks.

Bernard Zovighian - *Edwards Lifesciences Corp - Chief Executive Officer, Director*

Thank you all for your interest in the company. You know that we are available for any call. Doretta, Jared, and Sydney, and myself are available. I know that you are going to have phone call with the team. Thank you so much, and have a great day.

Operator

Thank you. With that, we conclude today's call. All parties may disconnect. Have a good day.

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