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EDITED TRANSCRIPT

EW.N - Q3 2026 Edwards Lifesciences Corporation Earnings Call

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OVERVIEW:

Company Summary

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PRESENTATION

Operator

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

It is now my pleasure to introduce Gerianne Sarte, Senior Vice President, Investor Relations. Thank you. You may begin.

Gerianne Sarte - *Edwards Lifesciences Corporation - 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 third 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.

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.

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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 the call over to Bernard for his comments.

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

Thank you, Gerianne, and welcome, everyone. We delivered third quarter results that exceeded expectations with both our businesses and regions driving strong broad-based performance.

Even more importantly, we achieved meaningful progress on several of our most important clinical regulatory policy and commercial priorities, strengthening our outlook for durable long-term growth.

The consistency of our top-tier financial performance is a reflection of our focused strategy as well as our commitment to innovation, speed and agility and the strength of execution by our 17,000 dedicated employees across Edwards.

Third quarter sales of [$1.72] billion grew 11.2%. This performance was driven by our structural heart portfolio, including continued strength in TAVR and growing contributions from our portfolio of TMTT therapies with PASCAL, EVOQUE, and SAPIEN M3.

Based on our strong performance this quarter. We are raising our full year sales growth guidance to approximately 11.5% and our adjusted EPS guidance to $2.97 to $3.05, growing 18% at the midpoint versus prior year.

As I reflect on 2026 so far. I am proud of what our teams have accomplished and how we are positioning Edwards for the future.

We are clear on our strategy, focusing on structural heart a large and growing space with significant unmet patient needs. We invest early taking a long-term view with conviction to create entirely new categories of treatment that push the boundaries of what is possible for underserved patients.

And at the same time, we are moving with intention sharpening how we are operating, embracing science and technology advancements, accelerating decision-making and executing against an important set of priorities.

Our focus continues to deliver meaningful progress across the company, underpinned by our foundational patient-focused culture.

All of this together set us apart and is why we are confident in our long-term success. We are pleased to see our strategy deliver particularly impressive progress over the last few months with five meaningful therapy approvals that offer new options to physicians.

In addition, we continue to elevate the clinical evidence standard for structural heart care, including the release of two new practice-changing data sets.

In TAVR, the SAPIEN platform continues to set the benchmark for Vale performance and durability, supported by ongoing innovation and world-class clinical evidence.

The PROGRESS trial marks a turning point in our collective understanding and management of moderate AS, taken altogether, the PROGRESS trial results, early TAVR clinical outcomes and long-term cost fitness data and PARTNER three seven-year durability data are advancing the understanding of aortic stenosis as a disease and reinforcing the differentiation of TAVR with the SAPIEN platform as a compelling treatment strategy for CVS. As a result, this changes how the clinical community looks at the disease.

How to evaluate, who to treat, when to treat? And ultimately, this underscores the value of proactive disease management with the SAPIEN platform.

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In addition, the modernization of NCD represents an important step toward expanded access to TAVR through timely, high-quality care for all AS patients.

In TMTT our years of pioneering development and strategic investments have resulted in a portfolio of therapies allowing our teams a unique opportunity to collaborate with physicians to personalize care for the clinically diverse patients suffering from mitral and tricuspid diseases.

With the recent US approval of PASCAL for tricuspid patients and next-generation capture clarity for mitral patients, we are further strengthening the portfolio of treatment options.

In Surgical, we continue to see strong adoption of our RESILIA portfolio of therapies, and we continue to introduce new therapies to address unmet patient needs, including ARTUS, for congenital patient and ECLIPTIS for surgical lateral appendage accretion.

At the same time, we are paying our proven innovation playbook to new areas of significant unmet need within structural heart, including structure and heart failure and aortic regurgitation, creating additional opportunities for long-term growth.

When I reflect on all of this, I am proud of our impact when Edwards leads everyone benefits. Physicians, providers, payers and most importantly, patients who enjoy restored quality of life and live longer. Now let's dive a little deeper into the recent presentation at TCT.

Physicians presented compelling new evidence on SAPIEN, PASCAL, EVOQUE and SAPIEN M3 that deepens the clinical community's understanding of these therapies and underscores their significant potential to transform care for AS, mitral and tricuspid patients.

The breadth and quality of the dividends reflects the strength of our innovation strategy and our commitment to setting the benchmark for clinical evidence in structural heart disease.

Putting all of this in perspective, these advancements represent meaningful multiyear opportunities that we expect to build over time and which underpin our long-term growth target of approximately 10% average annual sales growth alongside leveraged EPS growth.

Now I will provide more detail about the performance of our product groups. TAVR third quarter global sales of $1.2 billion were stronger than expected and increased 8.8% over the prior year. Edwards growth rates were similar in the US and outside of the US.

Globally, positl've growth benefited from a heightened focus on TAVR and data supporting proactive disease management of severe AS.

Exiting Q3, we saw encouraging signs of procedure growth. after several quarters of modest share gains, we are pleased with how our competitive position, supported by our differentiated SAPIEN platform has contributed to year-to-date TAVR performance. Average selling prices were stable globally.

At TCT results from the PROGRESS trial were presented and published in the New England General Medicine marking a turning point in the management of moderate AS, the remarkable performance and unparalleled safety of the SAPIEN platform, coupled with the superior trial results, validate TAVR as a treatment strategy for moderate AS patients with at risk features.

These findings challenge our long-standing assumption that moderate AS patients can be managed by the current practice of passive surveillance and encourages the clinical community to embrace earlier referral to a valve clinic for comprehensive testing and advanced management for optimal outcomes.

Progress builds on Edwards decade long commitment to generating rigorous clinical evidence that advances their understanding of a serious impact and unpredictable progression of aortic stenosis and continues to validate the patient benefit of proactive disease management.

Also presented at TCT was ACTIVATE, a large real-world investigator initiative study of more than 53,000 patients with AS who were identified with an advanced health care system using EHR.

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The study demonstrated that patients with moderate AS out number was with severe AS nearly 2:1. Additionally, among the patients with moderate AS approximately 80% at least one at list feature, which was associated with an increased risk of death and hospitalization.

The evidence from progress and activate suggest that the in-system and out of system moderate opportunity is at least as large as the severe AS opportunity.

We will continue to share our perspectives on the moderate patient opportunity as the evidence continues to grow and the clinical community gains experienced managing this patient over time.

Additionally, new long-term economic data from the EARLY TAVR trial reinforced the value of proactive disease management in patients with symptomatic severe aortic stenosis, Edward Staver delivered exceptional economic value compared with clinical surveillance and remain highly cost-effective even after accounting for potential future valve reintervention.

Notably, these results were achieved in a highly controlled trial setting, where patients benefited from optimal care and treatment with a median time to intervention of just 32 days compared with approximately 157 days observed in real-world practice.

Taken together, for practice-changing EARLY TAVR and progress studies, deepen our understanding of aortic stenosis and continue to validate the patient benefit of proactive disease management.

This evidence is now clear that intervening before the disease progresses, avoids significant health decline and serious cardiovascular events such as heart failure-related hospitalization and death.

Let me now turn to some commentary on US TAVR. In Q3, procedure growth continued to benefit from a heightened focus on TAVR therapy as the clinical community further incorporates into practice the meaningful evidence supporting productive disease management.

Edward's competitive position in the US was stable sequentially and increased modestly year-over-year, enabled by strong adoption or differentiated SAPIEN M3 ULTRA RESILIA.

During the quarter, CMS released the final updated NCD for TAVR. We are pleased that the updated policy represents an important step towards improving and expanding timely, high-quality access to care, while reinforcing the value of a multidisciplinary heart team. We believe there are 4 important elements within the NCD.

First, the policy will enable greater flexibility for that team at every step of a patient journey from evaluation to treatment.

Second, it will support appropriate site expansion over time for updated hospital procedure volume requirements. Third, the NCD will expand coverage to asymptomatic patients.

And finally, the policy provides a pathway to coverage for Medicare administrative contractors or [MACs], to address reasonable and necessary coverage when future TAVR indication are approved.

Taken together, these changes establish a strong foundation that will expand timely, high-quality access to care, supports the continued evolution of TAVR and ensure that more patients with aortic stenosis will benefit from treatment for many years to come.

Outside of the US, we continue to see strong adoption of our SAPIEN technology. In Europe, updated ESC and EX guidelines are helping shape clinical discussion around earlier intervention and proactive disease management, further reinforcing the role of TAVR across a broader patient population.

Edward's competitive position increased modestly year-over-year in Europe. In Japan, we continue to be encouraged by the growth and the continued adoption of SAPIEN M3 ULTRA RESILIA.

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Also in Japan, we secured new and dedicated reimbursement for SAPIEN M3 ULTRA RESILIA, which recognizes the value of our innovation and help contribute to Japan's strong performance in the quarter.

In summary, we are pleased with our TAVR performance in the quarter, which was a reflection of procedure growth and competitive position.

Given our better-than-expected third quarter performance, we are raising our full year TAVR guidance to 9% to 9.5%. In the fourth quarter and going forward, we are assuming that growth will be mainly driven by continued increases in procedure volume and less by share gains.

Putting it all together, there is robust evidence, an emerging indication, validating the patient benefits of proactive disease management for AS and with the opportunity that comes from the modernized NCD in the US, we have reinforced confidence in the durable mid- to high single-digit growth of our SAPIEN platform over the long term.

Now let me turn to TMTT. Our differentiated portfolio of mitral and tricuspid repair and replacement therapies drove third quarter sales of $207 million, an increase of 45.6% year-over-year. Globally, mitral and tricuspid procedure volumes continue to grow in the double digits.

The value of our TMTT portfolio is evident as our mitral and tricuspid therapies advanced along their adoption curves, allowing our teams to collaborate with physicians to personalize care for each patient unique needs.

With the recent approval of PASCAL Precision for tricuspid regurgitation, our full portfolio of repair and replacement technologies for the mitral and tricuspid valves is now available in the US as it has been for physicians in Europe. Growth was strong globally.

And as the US scales, it is becoming a more significant driver. New clinical data across the entire portfolio continues to strengthen the growing body at meaningful evidence supporting long-term adoption of our TMTT therapies.

This was evident at TCT, where seven clinical presentations feature compelling new data from across the portfolio.

Turning to an update on each of our TMTT therapy areas, starting with PASCAL. Adoption continues to strengthen, supported by the differentiated design and clinical outcome of a platform and our portfolio approach.

The Class 2 TR pivotal trial presented at TCT met its six-month primary endpoint, demonstrating the superiority of the PASCAL system plus optimal medical therapy compared with OMT alone in patients with severe or greater TR. This was driven by significant improvements in health status for vols receiving PASCAL.

During the quarter, PASCAL [ACE] with Capture Clarity received US approval for use in DMR tier procedures and a major rollout of a technology is underway. PASCAL [ACE] with Capture Clarity is the first FDA-approved tier device to include novel indicators that provide confirmation of a challenging step of leaflet grasping.

In October, PASCAL PRECISION for tricuspid reorigination we see approval in the US expanding the access to this important therapy for patients.

Early clinician feedback is very positive on both PASCAL Capture Clarity and PASCAL tricuspid. Clinicians value the simplification of device placement with the new feature of capture clarity with PASCAL tricuspid, physicians are recognizing that unique feature, including device allegation are particularly beneficial for patients with complex tricuspid anatomy.

Our focus on continued innovation with PASCAL will present a positive step forward for patients in need for mitral and tricuspid repair.

Moving to tricuspid replacement. EVOQUE delivered another strong quarter of growth. as physicians get experience with EVOQUE, they are more consistently achieving mild or less residual TR, a result that is increasingly linked to better outcome for patients.

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We also recently received US approval in C Mark for EVOQUE for transfugular access, enabling patients with complex femoral access to benefit from the EVOQUE procedure.

In addition, a TCT results from EVOQUE patient in the TVT registry with CMS linkage demonstrated that the real-world clinical outcome of patient with more complex disease, replicate those upselled in the [TRISIM2] clinical trial in more than 1,100 patients who were followed for one year, EVOQUE delivered sustained elimination of TR and quality of life improvements, excellent value durability and high rate of procedural success.

Building upon the body of clinical evidence supporting tricuspid intervention, the Edwards supported 3 HF study demonstrated statistically significant reduction and in the combination endpoint of heart failure hospitalization and mobility for tricuspid intervention compared with optimal medical therapy at one year.

Together, the meaningful evidence focused on tricuspid intervention advances clinical practice by highlighting the importance of interventional therapy for TR.

Moving to SAPIEN M3 we continue to see strong demand for patients who are not suitable for mitral tear, and we are encouraged by the excellent early clinical outcomes delivered by the therapy.

Two-year results from NCIRCL presented recently at TCT reinforced the durability of SAPIEN M3, including sustained reduction of MR, functional improvement and quality of the benefits.

In addition, we introduced SAPIEN M3 with RESILIA in Europe this quarter. RESILIA tissue is a key element of Edward's innovation extending durability for patients who receive our valves, and we plan to incorporate this advanced tissue treatment across all TMTT valve replacement therapies.

In summary, , based on our strong performance. We now expect full year TMTT sales to be between $780 million and $790 million.

Our full portfolio of innovative technologies is now available to patients across the US and Europe, and we are just beginning to realize the opportunity ahead. Together, PASCAL, EVOQUE and SAPIEN M3 provide layers of durable growth that support half to $2 billion in TMTT revenue in 2030.

In surgical, third quarter global sales of $264 million increased 3% over the prior year, driven by continued adoption of RESILIA portfolio of surgical therapies. Our expectation of full year mid-single-digit growth for Surgical remains unchanged.

We are expanding the surgical portfolio with innovative technologies that address additional unmet patient needs in structural heart surgery.

During the quarter, Artis became the first FDA-approved surgical pulmonary valve designed specifically for pediatric anatomy with the ability to expand as a child growth, potentially reducing the need for repeat open-heart surgeries.

We are also advancing a major rollout of ECLIPTIS, our surgical latrial appendage technology in the US, prioritizing exceptional outcomes for patients through physician training and procedural excellence. In summary, we are pleased with the continued strength of our Surgical portfolio and the progress we are making to reach new patients best treated surgically.

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

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

Thanks, Bernard, and good afternoon, everyone. As Bernard mentioned, we are pleased with our financial performance in the quarter. including strong top line growth and earnings leverage.

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Total sales of $1.72 billion grew 11.2% year-over-year, reflecting the strength across product groups and regions. Adjusted EPS in the quarter was $0.80.

As a result of our strong third quarter, we are increasing our full year sales guidance for total company to approximately 11.5% increasing TAVR to 9% to 9.5% and increasing TMTT sales to $780 million to $790 million.

For the fourth quarter, we're projecting total company sales of $1.67 billion to $1.75 billion, with adjusted EPS of $0.61 to $0.69.

This bridges to a full year increased adjusted EPS range of $2.97 to $3.05, which at the midpoint, represents EPS growth of 18% year-over-year. I'll now cover additional details of our Q3 results, starting with EPS.

Adjusted EPS of $0.80 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 $0.53, and primarily driven by the impairment of a certain research and development asset. 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 third quarter, our adjusted gross profit margin was 78.7% compared to 77.9% in the same period last year. Expected impact from the scaling of newer therapies was more than offset by manufacturing efficiencies and foreign exchange.

Foreign exchange benefited our third quarter gross profit margin by 50 basis points compared to the prior year.

As mentioned in Q2, we continue to expect adjusted gross profit margin to be at the lower end of our full year 78% to 79% gross margin guidance driven by the impacts of currency fluctuations through our hedging program.

SG&A expense in the quarter was $561 million or 32.7% of sales compared to $515 million or 33.1% of sales in the prior year.

This was in line with our expectations and reflects continued investment in resources to support patient access and care.

R&D expense was $281 million in the third quarter or 16.4% of sales compared to $281 million or 18.1% of sales in the same period last year. This investment in innovation reflects our focus on our expanding structural heart portfolio, we expect R&D expense as a percentage of sales to be approximately 16.5% in 2026.

Third quarter adjusted operating profit margin was 30.3%. Our year-to-date operating margin benefited from strong underlying business performance as well as 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.

This implies a fourth quarter operating margin in the mid-20s consistent with our own expectations and with prior year phasing. Beyond 2026, we continue to prioritize leveraged EPS growth and 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 continue to expect an effective tax rate at the high end of our 16% to 19% guidance. This reflects an expectation that side-by-side safe harbor taxation legislation alongside Pillar 2 does not come into effect before the end of the year.

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As a reminder, our tax rate is also impacted by changes to California law permanently limiting the usage of R&D credits. If legislation is passed before year-end related to Pillar 2, we may see a benefit to this rate.

Foreign exchange rate changes in the third quarter decreased reported sales by approximately $10 million or 70 basis points versus the prior year, which was $9 million better than our expectation.

On a constant currency basis, sales in the third quarter were near the top end of our guidance range. If foreign exchange rates hold at current levels, we estimate FX to be a fourth quarter headwind of approximately $15 million compared to the prior year.

Turning to the balance sheet.

We continue to maintain a strong and flexible balance sheet with approximately $3.1 billion in cash and cash equivalents as of September 30, 2026. Edwards has performed share repurchases of approximately $700 million through the third quarter.

Additionally, we have approximately $1.3 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.

The strength of our year-to-date performance across TAVR, mitral, tricuspid surgical and our regions gives us confidence in delivering on our increased 2026 outlook and targeting 10% longer-term sales growth on average with EPS leverage.

And with that, I'll hand it back to Bernard.

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

Thanks, Doretta. In closing, this was an important quarter for Edwards, marked by category shaping medicines across TAVR, TMTT and surgical as well as compelling clinical evidence presented at TCT that will inform and impact clinical practice.

These accomplishments reflect the strength of our strategy and the breadth of innovation across our businesses. We enter the future, confident in our ability to impact even more patients and deliver strong, sustainable growth.

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

Gerianne Sarte - *Edwards Lifesciences Corporation - Investor Relations*

Thank you, Bernard. Before I move to Q&A, I'd like to remind you about our 2026 Investor Conference on Friday, December 4, at the New York Stock Exchange. We hope you'll join us as we discuss our patient-focused innovation strategy and the opportunities ahead. We're ready to take your questions now. [Operator Instructions] Operator, we're ready to take questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Travis Steed, Bank of America.

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Travis Steed - *Bank of America - Analyst*

Hey, congrats on good quarter. TAVR accelerating once again in Q3. I wanted to ask about the quote that you said exiting Q3 saw encouraging signs of procedure growth. And is this what are you seeing on the ground? And how much is this EARLY TAVR starting to play out in some of the early referrals starting to come through in a better market growth rate?

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

Yes. Thanks for the question, Travis. We have been talking in the last few quarters about the item focus on TAVR, which was driven by the evidence we brought to the clinical community, starting with stable long-term performance, EARLY TAVR and now going to progress, but also the NCD. So we have been seeing that in the last few quarters, it was a leading indicator. And now what we believe what we can say is that we have a strong dynamic in the market.

As a matter of fact, exiting the quarter in the last few weeks of the quarter, we saw early indicator of positive procedure signal which gives us a lot confidence that all of this item focus, all of this evidence, all of this positive evidence is having an impact on the market. We also have seen a modest share gain in the quarter year-over-year, but it was mainly market growth.

Travis Steed - *Bank of America - Analyst*

That's helpful. And then the results of the comment, I think you made more growth is going to be driven by more procedure volumes and less by share gains going forward. I just wanted to understand that comment a bit more the procedure volumes improve and share gains stabilized, so the total is better going forward? Or is it that you've had a benefit of share gains and that goes away?

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

Yeah. No, let me start at a high level, and I'm going to ask Dan to give some more details into this one. We were very pleased a year ago, more than a year ago at our competitive position. In the last few quarters, we gained share and our competitive position improved. But we believe that we have reached a plateau here, but I'm going to explain -- I'm going to ask Dan to explain why.

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

Thanks, Bernard and Hi, Travis. I think if we look back May 2025, that's when we had the Boston Scientific exit in Europe and OUS. And and now we're sort of -- we've annualized that now.

We've had multiple quarters more than four quarters of year-over-year benefit, but that's now fully annualized. And if you think about it relative to our other competitors in and our competitive position there.

We've also observed four quarters of modest share gains. And so -- and if you couple all of that with the most recent quarters, the last two quarters, we're seeing sequential stability there. So this is why we are thinking that going forward, it's more about the underlying fundamentals of the market growth. And it's really important to note that like we feel really good about that. The underlying signals there are really positive. And we're happy with how Q3 went, and we'd expect that to continue into Q4.

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

And if you look at the big picture here, this made us very confident. It is not dependent on share gains. It's truly dependent about growing the number of patients who can get access to the best TAVR having the best performance and best durability. And we have all of the

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evidence to educate, to make sure you're a physician can treat their patient in the best way possible. So we have been working hard to be where we are today.

This has been a company strategy for years to bring evidence, to grow the market, to make sure that many underserved patients can have access to this best therapy. And it is why one we are confident, but we are also very pleased about our leadership in the space.

Operator

Larry Biegelsen, Wells Fargo

Are you on the line?

He dialed in a second line. Let's try that one moment.

Larry Biegelsen - *Wells Fargo Securities - Analyst*

It's Larry.

Operator

We can hear it now on this line. Go ahead.

Larry Biegelsen - *Wells Fargo Securities - Analyst*

All right. I'm sorry about that. Bernard, congratulations on a strong quarter here. You're guiding to -- I just wanted to ask a follow-up question on Travis' question there. You're guiding to TAVR growth of 9% to 9.5% in 2026.

You talked about positive procedure trends exiting Q3, but less share gains going forward. So are you signaling that TAVR growth will slow next year? And how should we think about the contribution from the NCD and progress next year? And I have one follow-up.

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

Yeah. I think it is a little bit too early to talk about next year, Larry. I'm not signaling that a slowdown or whatsoever. I'm signaling confidence and signaling a difference in mix. But there is one thing we have is confidence.

And I'm trained we are trained to provide you detail into the mix here and which is truly aligned with our strategy that we have been talking for years.

Larry Biegelsen - *Wells Fargo Securities - Analyst*

I mean, so can you -- I mean, people are trying to understand what your expectations for the NCD and PROGRESS next year? Do you expect any benefit from those two, and I'll drop.

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

Yeah. Thanks, Larry. No, I understand every one of us, one to try to update the model, we are so close to investor conference. We are going to talk about that at the investor conference. Are we going to have some impact from the NCD and from symptomatic next year?

Yes, probably, we have an NCD. It is official, but we also know that it takes time for all of the centers to implement a new NCD. We have a new indication with this symptomatic. We know we might have some impact also, but it is going to be a gradual impact, a progressive impact year-over-year, and it is the beauty of its two catalysts here. It is not going to be a peak and then a value a year after.

We are going to see a progressive trend year-over-year. So yes, confidence yes, some impact, progressive impact, but -- and the mix is going to change a little bit less about share more about market, and we are going to give you more clarity in December.

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

And I would just add Bernard that one of the reasons why we provided the longer-term mid- to high single-digit expectation for TAVR over the longer term is it does incorporate a lot of these factors that we're talking about. And so to Bernard's point, we'll be able to provide more specificity around '27 in a few weeks, but all of this gives us confidence in that mid- to high single-digit growth rate for TAVR over the longer term.

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

In summary, I know what you're asking yourself, are we confident about 2027? Yes, we are. We are -- think about -- look at 2026, we are going to exit the year as a company. growing about 11.5%. And with EPS leverage with multiple catalysts.

So yes, we are confident and we are going to provide a reasonable guidance in December.

Operator

Robbie Marcus, JPMorgan.

Robbie Marcus - *JP Morgan - Analyst*

Great. Congrats on a good quarter. Two for me. Just wanted to ask on moderate now that it is -- you had great data earlier this week on Monday. How should we think about timing of submission and expected approval for that? And then I have a follow-up.

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

Let me start and will ask Dan to bring some clarity about the timing since his very close to the action here. I will say one is, yes, thanks, Robbie. Great quarter. Very pleased about what we did across the company and for the company. Two is PROGRESS is a big study.

It's a big moment for us, pivotal moment, turning point for so many patients here. So very excited about it. You had a chance to listen to the PIs on Monday night but I'm going to let Dan give a little bit more clarity about what's in front of us here.

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

Yes, thanks Bernard. Clearly, it's a turning point. This data is important, it's powerful. And the indication is important. The work can't be done without it.

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So it's an important indication for us. It's a priority for us, for sure. We don't usually comment on exactly where we're at. with indications, the conversations being had with the FDA, et cetera, and we won't do that. But I think in a few weeks at investor conference, we will be able to give a broader update on how we're thinking about the timing of that indication and how that impacts both how we're looking at 2027 and beyond in our longer-term thinking. So hopefully, more to come.

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

What I want you to know, in my mind, the big message, and I know Doretta talk about it, but I think it is important to remind everybody. A few years ago, we gave this a long-term guidance for the company, about 10% EPS leverage and we said, what we need from TAVR is about mid- to high single digit.

It was a clear message. And two years later, so today, all of the things that we wanted to achieve to deliver that has happened. And this is one, it is exciting.

Two, it is the result of our flawless execution. And three, we are confident. We are confident about next year. We are confident about the next many years here because all what we do here, it is changing the practice of medicine.

And we know that changing our practice of medicine it takes time, it is progressive. So we are going to benefit from it every year for many years.

Robbie Marcus - *JP Morgan - Analyst*

Great. Maybe a follow-up for Doretta. And you're newer to the company. I think a lot of people are still trying to learn your guidance philosophy. The guide on second quarter implied not a whole lot of sequential growth into the second half.

You put up a pretty meaningful beat over 200 basis points on TAVR, a big TMTT beat and total company organic sales growth beat along with EPS well above the implied a consensus.

So I look at the fourth quarter guide here, it looks even to get to the high end of the TMTT range as step down sequentially on a dollar basis, not a whole lot of growth in TAVR. Maybe just I think it'd be helpful to touch on that and just your guidance philosophy overall as investors get used to this moving forward? Thanks a lot.

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

Great. Thanks so much for the question, Robbie. And it's very important. And I would say at a high level, my approach, our approach to guidance really remains grounded in the same principles that we've had as a company. The priority is really the ability to give you and our investors an appropriate and credible outlook.

Will continue, and we continue to update our outlook as we see our performance and we look at our underlying trends. But always it's grounded in that view of making sure it's appropriate, it's credible, and we're really guiding to the midpoint.

To the point, as it relates to the fourth quarter, I would echo a lot of the comments that Dan made earlier. We feel good about the underlying fundamentals of the business. But we believe going forward, our growth is going to come from market versus share. But all of this is grounded and confidence to be able to deliver on what we say.

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

Thank you. Maybe I just make one comment because -- this is Daveen. Jumped a little bit over on the TMTT side of things. I'll just make one nuance comment on this saying with TMTT, obviously, we're in a high-growth situation. Where for us, we think a lot about the year-over-year portion of TMTT versus the quarter-over-quarter. It is a better indicator of the health of the businesses because catalyst can happen anytime during the year.

And when you're in a high-growth business like TMTT, it kind of throws you off a little bit. But you pull back up and you say, hey, man, how are we looking year-over-year, increasing sequential dollar growth that's at least how we think about TMTT as we move forward within the context of what Doretta said.

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

I think closing on the topic, it is an important topic. We pay attention at guidance altogether as a team, as a leadership team. I will add only one thing. I want to make sure that we are delivering on our commitments always. And I want you to have trust and confidence. So good question, Robbie. Thanks.

Operator

Matthew Taylor, Jefferies.

Unidentified Participant

Hi, good afternoon. Thanks for taking my question. This is Matthew on for Matt. I just wanted to start and ask and as you expand into asymptomatic and in the future, expand into moderate, do you expect to kind of maintain a similar share to these historical indications? Or do you see an opportunity to take even more competitive share? And then I have one follow-up.

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

Thank you. Maybe I can start at the high level, and then Dan again, we can provide some additional comments here. What we have said over the years is that, over time, we can expect us losing slightly some share more competition is coming and we all know that.

So if you ask me in the next 10 years, a slight loss of share, but largely offset by what we are doing to grow the market. What we are doing to have a more indication, what we are doing to get into to make sure the penetration of TAVR is also improving. So that's still the way to think about the various level. We have been saying that for a long time, and it is going to be the same, again, largely offset, but Dan go for it.

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

Yes. I think if we look where we are now and where we have been historically, we've always had differentiation on indication. We've always and we have always had differentiation on durability.

And I think that these things are interesting but not necessarily what drives market position. It's a complex combination of lots of things that go into your market position as you might well know, including your premium that you might offer and all other things.

What I would say, though, is the indications are super important, right, especially for the indications like asymptomatic and moderate because these indications don't have a predicate for treatment. These are new indications, right?

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For the last 15 years, whether it be high-risk indication or intermediate risk indication or low-risk indication. These are all indications where the predicate with surgery and you've got a transcatheter option that is being considered as a reasonable or better alternative to a predicate.

Now we're getting into indications that require market development. And those indications are important to put muscle behind to build markets to educate physicians to understand the data better, to allow us to treat patients who are underserved. And so I see that more of an opportunity to expand the market and to continue to build on positive underlying fundamentals but probably less of a competitive differentiation, I guess, lever in the short or medium or even long term.

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

And let me add something purely from a strategic standpoint, we have been working hard to be where we are, asymptomatic indication. Now you have a PROGRESS data. a new NCD in the US and if you think about your strategy, if you think about focus, it's team focus, this is where we are going to spend our time. This is where we are going to have a resource allocation to make sure we are going to educate, train, bring awareness, drive the adoption.

But having said that, we obviously, we are very proud about the SAPIEN. Best value performance by far, there is no one competing with it and best durability. There is no one competing with it. But that's our, basically, our 10-year strategy coming to reality this quarter and this year. So this gives us big confidence for sure.

Unidentified Participant

Great, thank you. And maybe now that you've had some time to digest the PROGRESS results and the initial physician feedback. What do you think is most either underappreciated or misunderstood about either the opportunity within moderate or the result itself?

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

Thanks.

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

Dan, you want to take it?

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

Yeah. I think, first of all, the feedback from physicians who every day dealing with structural heart patients and running valve clinics. I think from their perspective, this is very positive results and results that they would tell you after the fact that, that was expected, and congratulations, and they're amazing.

And one of the reasons why it's super positive for them is because this is a patient population whose echocardiographic severity doesn't match their clinical severity or their clinical prognosis. And so without the data and without knowing, it's hard to change guidelines, and it's hard to make treatment decisions.

And now that data exists and there is a clear understanding of who would benefit with an Edwards TAVR and the performance of the TAVR in the arm was so positive.

This is reassuring, reassuring and generates confidence for both physician and patient. I think what's underappreciated is further upstream, right?

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Because now it's about not only recognizing the moderate patient, but how to recognize the at-risk features within this moderate patient population. And that's not easily done in a community setting, right?

And so now I think what is being digested and underappreciated is there's a difference between passive clinical surveillance in the normal setting of patient care, whether that be in primary care physician or even general cardiology settings to advance surveillance, whereby you have multiple sources of information, and you can go into further detail to make the correct assessment about what that relative risk is for each individual patient. And I think this is what is being digested now. And I think that's something that's going to advance patient care over time.

Operator

Vijay Kumar, Evercore ISI.

Vijay Kumar - *Evercore Inc. - Equity Analyst*

Hi, Bernard. Good evening, and thank you for taking my question. I guess my first one was on PROGRESS, right. Next year, you'll have the approval, FDA approval, post-approval Edwards will be in a pretty unique position, right? You'll have the broadest label in TAVR covering severe symptomatic asymptomatic and AS. How will that -- having the breadth of label, right, change your contracting process? Like why shouldn't Edwards continue to gain share for the foreseeable future?

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

I like your question, and I like how excited you are about it, and we are, too. And indeed, it is -- you are right, asymptomatic because we got the indication already. And we have been the only company running this kind of high-level evidence, disease study to be able to have this kind of indication.

On PROGRESS, we don't have yet the indication for moderate. But we might be in a similar situation later next year. It's too early to speculate on this one yet. But yes, we feel good about it. And I think, again, I understand your question, but we are clearly focusing like we have been doing on making sure TAVR is better adopted.

If you think about where we are today for severe symptomatic patients, 15 years later, all the data we are having, the penetration in the US is about [15%]. We have a lot to do here, then you asymptomatic, then potentially moderate. Yes, there is a lot of work. There is a lot of opportunity, and this is where we are going to spend our time here.

And I know that many people are asking us about share. We are very pleased also about the differentiated feature of SAPIEN. And because of that and the durability we gained share, but it is not the way we are going to be focusing. Maybe things will happen on share, but we are not going to push for it.

And Dan with obviously other one right now, putting all the thinking behind the plan for '27, '28, '29, '30 because this is what we have in front of us, four, five, six amazing years. So Dan, do you want to add anything here?

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

Yes, it's a similar question to the previous question on this topic. But I think it's important to recognize that as we go further upstream and go with these indications.

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And earlier in the disease pathway, the concept of lifetime management does come into play a lot and we're not necessarily talking about always younger patients, right, even with the PROGRESS trial, these were seven, eight-year olds, even in asymptomatic early TAVR patients, they're not like super young.

But the concept is as we are going earlier in the disease pathway and lifetime management does make a big difference. I think the conversation around share is more about trust in the platform whether it be for the acute result or the durable result more than how many indications you have.

But it all is -- gives us a lot of confidence. I think we have an enormous amount of confidence in our platform. We're very, very pleased with our acute performance as well as our longer-term data, which continues to differentiate. And so we feel pretty good about our relative competitive position.

The indications themselves, I'll come back to it. these new indications are symptomatic and moderate pending gives us the opportunity to put our muscle and our effort behind educating the market, developing the therapy, developing the market and creating access for patients who are underserved. And this is also very, very important from our durable strategy of growth.

Vijay Kumar - *Evercore Inc. - Equity Analyst*

Understood. And maybe one quick follow-up on -- do you see moderate AS expanding the TAM? Or is this -- is this more of a -- because AS is progressive. Are we just pulling forward patients? How do you see it?

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

Yes. Thanks for that question. I've been getting that one a bit and you can give yourself a bit of a headache on it. But the way that I look at it is very, very simply is you can either look at this through the lens of the data and the contemporary literature, which says that the moderate patient population is 1 to 2x bigger than the severe population or you can look at it through the lens that the severe population is 2 to 3x bigger than what we thought it was. Either way, it's the same math.

And so we look at it as a sizable number of patients who have unmet clinical needs and largely underserved today. And so however you look at it, it's a lot of opportunity.

Operator

Pito Chickering, Deutsche Bank.

Pito Chickering - *Deutsche Bank AG - Research Analyst*

Hey, good afternoon, guys. Thanks for putting me in here. Can I ask a bit more on Europe. If you look at the constant currency growth in the first half of the year, about 13.3% and 3Q is about 8.2%. So should we think about the first half of the year as market share gains plus the market growth and going forward, Europe is going to be more of a high single-digit growth now that there's no more market share gains?

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

I am not sure about the number you are quoting here, Pito. What I can tell you is that in the quarter, between US and Europe, we don't see any difference to us about the same. In Europe, the only thing that they have that we don't have in the US is they have a new guidelines that happened a few quarters ago.

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But we have seen a heightened focus also in Europe. We have seen the same some modest share gain year-over-year. But I'm not sure I can give you detail here. Maybe I'm going to ask Dan here. Dan?

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

And if the question is regarding front half growth, back half growth, whether it's Europe or one of the things that we -- at least from a TAVR perspective, we have to recognize that we had a highly unusual seasonality last year over the summer. We saw more seasonality this year, wasn't as expected, it was slightly better than expected. And interestingly, over the last 3 years, we've seen 3 different types of seasonality over the summer.

But the front half, back half growth, as we've been saying all along, we knew that it was going to be stronger in the front half than the back half because of those comps. And there's other factors at play here as well, which you've noted.

Pito Chickering - *Deutsche Bank AG - Research Analyst*

Okay. Fair enough. Like any early feedback from docs have been using [TriClip] and how long they are to try PASCAL for TR. I guess how is the training backlog looking there? And looking at the new four catheters that can speed up these procedures significantly in the Class 2 trial, do you think that's going to act as an inflection point for you guys in the near term?

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

Hey, thanks, Pito, this is Daveen. I'll first out by saying, obviously, with the addition of PASCAL tricuspid we're exiting in the US that we've now completed our portfolio of both repair and replacement technologies for each of the mitral and tricuspid and now specifically in the tricuspid having both repair and replacement, I think we can really partner with physicians to personalize the therapy for the patient and get the right technology for you the unique anatomy and clinical situations for each patient.

We obviously just got PASCAL recently approved, not that long ago in the US, though we had been doing clinical trials, obviously, in the US for a longer period of time. And basically, what we're seeing is that people continue to be excited about the technology.

And we've had this technology in Europe for quite a few years with quite a bit of usage. And we see that there are certain features that PASCAL has the ability to elongate in the dense cord of the tricuspid valve that make it potentially really beneficial.

And I think we also saw in the Class 2 TR data, the randomized data set that we just saw that PASCAL performed very well with high TR reduction, great improvement in health status and obviously, a very safe procedure.

So I think so far, I'd say is that, yes, physicians who have used it recently commercially or previously in clinical trial settings. Our believers in the technology. They enjoy differentiated features, and they really think it's a complementary technology to evoke to really treat their tricuspid patients with the best possible solution.

Operator

Thank you. I will now turn the call over to Bernard Zovighian for closing remarks.

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

Thank you, everyone. So clearly, we had a great quarter. And also, we are on track to have a phenomenal year. We increased the guidance for the company to be about 11.5%. So this, in my mind, you presented top-tier performance in medtech.

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In addition to the financial aspect, we are having we achieved so many milestones, clinical, regulatory, commercial milestones that put us in a position to having this kind of sustainable top-tier performance. Again, we are very confident about the years to come. Thanks for your continued interest in Edwards. Doretta, Gerianne and I welcome any questions by telephone. Have a great day, everyone. Thank you.

Operator

Thank you. This concludes today's conference. You may now disconnect.

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