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EW.N - Q1 2026 Edwards Lifesciences Corp Earnings Call

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OVERVIEW:

Company Summary

LSEG DATA & ANALYTICS

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PRESENTATION

Operator

Greetings and welcome to the Edwards Lifesciences first-quarter 2026 results. (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 Corp - Senior Vice President, Investor Relations*

Good afternoon, and thank you for joining us. With me on today's call is our CEO, Bernard Zovighian; and our CFO, Scott Ullem. 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 first-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. 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 Corp - Chief Executive Officer, Director*

Thank you, Gerianne, and welcome, everyone. Building on a year in 2025 marked by solid financial performance and strategic progress, we delivered another strong quarter in Q1, achieving 12.7% sales growth, which reflects the impact and durability of our differentiated strategy.

Our focus on structural heart disease solves large, urgent, and complex patient needs. It allows us to pursue unique opportunities to innovate and lead. None of this will be possible without the exceptional talent of our employees who bring our culture to life each day through their dedication to patients.

We've built a workplace where our 16,000 employees around the world can stay and grow with us. I want to thank each of them for being aligned to our vision, inspired in their work, and committed for the long term, which is essential to our continued impact for patients.

Our strategy is underpinned by speed, agility, and disciplined execution, which enables our differentiated sustainable growth. Developing safe and effective valve therapies requires unwavering focus, deep expertise, and the generation of world-class evidence capabilities that distinguish Edwards as a trusted partner. While it takes time to pioneer new therapeutic areas and change the practice of medicine, our innovative therapies have transformed care for many patients and positioned Edwards to continue to lead for many years to come.

Looking forward, we are reinforcing our foundation with multiple strategic investments focused on clinical evidence generation, technology advancements, indication expansions, and resources to support patient care. We continue to pursue additional meaningful growth opportunities in each therapeutic category that will have a positive impact on our performance in 2027 and beyond.

In TAVR, there is a renewed focus on the therapy across the healthcare ecosystem. This has been reinforced by definitive 7-year PARTNER 3 and 10-year PARTNER II data, which validate the durability and consistent performance of SAPIEN. Our platform is distinguished by high-quality, long-term evidence grounded in decades of scientific rigor.

In addition, the practice-changing early TAVR trial results are resonating with the clinical community, validating the movement away from the outdated practice of watchful waiting, and further highlighting the importance of intentional referral and treatment earlier in the disease pathway for severe aortic stenosis. Together, our SAPIEN innovation and evidence have once again elevated the standard for current and future TAVR valve performance, durability, and lifetime management of patient with aortic stenosis.

In TMTT, our many years of patient-focused commitment, pioneering development, and strategic investments have resulted in a unique comprehensive portfolio of therapies that enables physicians to offer options to the clinically diverse population of patients suffering from mitral and tricuspid diseases.

With a complementary portfolio of repair and replacement technologies across both valves, we have expanded the population of patients who can benefit from these technologies. We remain deeply committed to ongoing innovation and the generation of high-quality clinical evidence to reach even more people affected by these diseases.

In Surgical, we continue to expand our portfolio to address the needs of the many structural heart patients best treated surgically. Our portfolio of resilient tissue technologies including INSPIRIS, KONECT, and MITRIS is backed by years of durability data and continue to support enhanced patient care globally.

The success of our structural heart strategy is evidenced by the significant opportunities across surgical, TAVR, mitral, and tricuspid, and we are in a unique position to advance new technologies, next generation of existing technologies, and to expand indication to benefit even more patients.

In addition, we are executing our proven innovation strategy to expand into structural heart failure and aortic regurgitation, which represents significant longer-term growth opportunities. We remain steadfast in our commitment to address patients in need by advancing novel therapies to extend lives, improve quality of life, and provide greater impact and efficiency for health systems.

Turning to our financial performance. Edwards continues to be well-positioned to invest in innovation while also generating attractive financial results. In 2027 and beyond, we believe our strategy will enable average annual sales growth of approximately 10% as well as operating margin expansion. We expect variability in sales growth rates over time based on the timing of catalysts. Our financial strength and strategic clarity give us confidence in the future.

In the first quarter, we generated 12.7% sales growth and strong earnings performance for Edwards, both ahead of expectations, driven by broad-based growth across our product groups. Based on our first-quarter outperformance, we are raising our full-year 2026 sales growth guidance to 9% to 11% and adjusted EPS guidance to $2.95 to $3.05, which demonstrates solid earnings leverage.

Now I will provide more detail about product group performance. TAVR first-quarter global sales of $1.2 billion increased 11% over the prior year. Globally, procedural growth benefited from a heightened clinical focus on proactive disease management of severe AS, along with long-term evidence, demonstrated the proven durability and valve performance of a SAPIEN platform.

SAPIEN growth in the US was healthy, and it was even faster outside of the US. Edwards' global competitive position in the first quarter increased slightly year over year, mainly due to the exit of a competitor in Europe. Average selling prices were stable globally. Recent clinical trial results on long-term TAVR performance continue to support patient treatment with SAPIEN TAVR. We are encouraged by the broader momentum that the EARLY TAVR study data has generated across the clinical community for both symptomatic and asymptomatic patients.

There has been a shift towards proactive disease management with an increased focus on evaluation and intentional referral of patients with severe aortic stenosis earlier in the disease pathway. This evolution in patient management, combined with a large and growing body of long-term SAPIEN outcomes data, reinforces our confidence in the durable multiyear growth opportunity ahead.

Over our 70-year history of continuous valve innovation, we have devoted our deep knowledge, experience, and learning to the complex research and development, clinical studies, and manufacturing of surgical and transcatheter heart valves. Each innovation represent a unique challenge. We know the impact of these advanced technologies. and over time, we have seen multiple examples of other valve platforms showing variable performance, which is the reason why long-term clinical evidence from rigorous FDA trials must continue to guide therapy choice for patients.

We are confident in our SAPIEN TAVR therapy with distinguished valve performance, proven long-term clinical evidence, including the 7-year PARTNER 3 data and 10-year PARTNER II data and an asymptomatic indication, all of which are meaningful differentiators. Later this year, we will also learn more about patients with moderate AS when the PROGRESS trial results are presented at the TCT conference.

Let me now turn to some commentary on US TAVR. In Q1, procedure growth continued to benefit from the heightened clinical focus on proactive management of severe AS, as the clinical community continues to digest and incorporate new evidence into patient care. We believe Edwards' competitive position also benefited slightly year over year.

We are also pleased that CMS is conducting the process to reconsider NCD for TAVR. This decision has the potential to improve timely access to life-saving TAVR therapy. The initial 30-day public comment period closed on January 14 of this year, and we look forward to the next steps in the process, including the release of a draft decision memo by June 15 of this year.

In Europe, first-quarter results demonstrated continued strong commercial execution and sustained physician demand for the SAPIEN platform. The Q1 growth rate also benefited from the exit of a competitor in the prior year. Updated guidelines from the European Society of Cardiology and the European Association for Cardiothoracic Surgery are reshaping clinical discussion around proactive business management, reinforcing the role of TAVR for a broader patient population.

Outside of Europe, our sales growth was strong across multiple geographies, including Japan, driven by procedural growth and adoption of our SAPIEN 3 Ultra RESILIA platform.

In summary for TAVR, based on our Q1 results, we are raising our full-year TAVR sales growth guidance to 7% to 9%. As we look ahead to '27 and beyond, we see compelling mid- to high-single-digit growth opportunities in TAVR, supported by our patient access strategy, expanding clinical evidence, and a differentiated innovation pipeline designed to meet the needs of millions of patients around the world that suffer from aortic stenosis. Together, this will have lasting impact on the continued expansion and success of a SAPIEN platform globally and support a durable, multiyear growth opportunity.

Now, let's turn to TMTT. Our unique portfolio of repair and replacement therapies to treat mitral and tricuspid diseases drove first-quarter sales of $173 million, an increase of approximately 42% year over year. We believe that mitral and tricuspid procedural growth globally was in the double digits.

In tricuspid, we have seen strong adoption of repair and replacement technologies globally. At the recent ACC scientific session, two-year TRISCEND II data we have presented demonstrated significantly lower all-cause mortality with EVOQUE versus medical treatment when accounting for patient crossover.

This new data demonstrated that the EVOQUE replacement system provides significant and sustained elimination of TR, improvements in health status and quality of life, and no added device-related risk. We are also increasing patient access to transcatheter tricuspid valve replacement and driving further adoption of EVOQUE by expanding into new centers. We believe the growing body of clinical evidence, including reductions in all-cause mortality and heart failure hospitalization, will support physicians' continued treatment of patients with tricuspid regurgitation.

Moving to PASCAL. Adoption continues to increase, driven by physician enthusiasm for its unique design and differentiated outcomes and underscored by the significant needs of these patients. Our progress on the PASCAL pipeline remains on track with the next-generation technology expected in Q4 for both mitral and tricuspid in the US and Europe.

We also continue to expect the launch of PASCAL in the US for tricuspid patients in Q4 of this year, which will expand the population of patients that can benefit from this impactful technology. The recent FDA approval of SAPIEN M3 expands our mitral portfolio in the US. Our commercial experience, while early, validates the need for this mitral replacement solution for patients who are not well suited for mitral TEER. Physicians' feedback on patient outcomes and procedural experience with SAPIEN M3 has been positive.

In summary, for TMTT, strong and increasing utilization of our differentiated therapies, EVOQUE, PASCAL, and SAPIEN M3, combined with double-digit mitral and tricuspid procedure volumes globally, positions Edwards for continued growth. Our portfolio of repair and replacement therapies is allowing physicians to select the best possible technical solution for their patients to get the optimal clinical outcome. This, combined with an expanding body of high-quality clinical evidence, expansion into new indications, and the advancement of next-generation technologies, support our path towards $2 billion of revenue in 2030 and additional growth beyond.

In 2026, we remain on track to achieve $740 million to $780 million in sales in TMTT, representing 35% to 45% growth. In Surgical, first-quarter global sales of $276 million increased 6% over the prior year, driven by continued adoption of our RESILIA therapies that offer extended durability.

INSPIRIS adoption continues to increase globally. KONECT, which facilitates Bentall procedures for patients in need, recently launched in Europe with strong adoption. With the launch of MITRIS in additional markets around the world, we have seen strong uptake of this technology in surgical mitral valve replacement procedures.

The 10-year data from our COMMENCE trial studied long-term durability of our best-in-class RESILIA tissue will be presented at the upcoming AATS conference. We continue to expect that our surgical tricuspid valve, TRIFORMIS, will launch in the second half of the year. Our surgical left atrial appendage closure program is on track for preliminary introduction later this year.

In summary, we continue to expect mid-single-digit sales growth in Surgical in 2026.

And now, Scott will cover the details of the company's financial performance.

Scott Ullem - *Edwards Lifesciences Corp - Chief Financial Officer, Corporate Vice President*

Thanks, Bernard. Our better-than-expected Q1 sales performance reflected strength across all product groups and regions. Total sales of $1.65 billion grew 12.7% year over year. We are raising our full year total company sales guidance to 9% to 11%, up from 8% to 10%, and our TAVR sales guidance to 7% to 9%, up from 6% to 8%, driven by strong Q1 results. Edwards now expects total company sales of $6.5 billion to $6.9 billion and TAVR sales of $4.7 billion to $5.0 billion at current exchange rates.

As a reminder, the first quarter of 2025 was a lower growth rate quarter, and our results in 2025 set a higher bar for 2026, especially in the second half. We continue to expect $740 million to $780 million in TMTT sales and mid-single-digit sales growth in Surgical in 2026. We are also updating our full-year earnings per share guidance to be between $2.95 and $3.05 per share as a result of our first-quarter results.

And now, I'll cover additional details of our Q1 results, starting with earnings per share. Adjusted EPS of $0.78 in the quarter benefited from solid operational performance and planned phasing of strategic investments during the course of this year. Our GAAP EPS for the quarter was $0.66. A full reconciliation between our GAAP and non-GAAP measures, including adjusted EPS and other items, is included with today's release.

For the first quarter, our adjusted gross profit margin was 78.2% compared to 78.7% in the same period last year. This year-over-year change was driven by a weakening dollar as well as additional manufacturing expenses related to the expansion of new therapies. We are maintaining our full-year 78% to 79% gross margin guidance.

Selling, general, and administrative expense in the quarter was $522 million or 31.7% of sales compared to $466 million in the prior year. This was in line with our expectations and reflects continued funding of resources we provide to support patient care as well as a higher translation of our OUS expense base from the weakening dollar.

Research and development expense was $263 million in the first quarter or 16% of sales compared to $255 million or 18% of sales in the same period last year. This decrease in research and development as a percentage of sales and the increase in total expense reflects our strong top-line growth as well as strategic prioritization of investments in our expanding structural heart portfolio. We continue to expect 2026 R&D as a percentage of sales to be approximately 17%.

First-quarter adjusted operating profit margin was 31.4%. Our margin benefited from the better-than-expected top-line performance as well as planned phasing of strategic investments during the course of the year. We expect full-year operating margin to be at the high end of the original 28% to 29% guidance, resulting in approximately 150 basis points constant currency operating margin expansion for the full year.

In 2027 and beyond, we continue to plan for 50 to 100 basis points of underlying operating margin expansion.

We continue to expect our 2026 tax rate, excluding special items, to be between 16% and 19%. The midpoint of this guidance assumes adoption of a side-by-side safe harbor taxation model alongside Pillar Two while the higher end accommodates the event that this legislation does not come into effect before the end of this year.

Foreign exchange rate changes in the first quarter increased reported sales by approximately $15 million versus guidance we provided originally for Q1. On a constant currency basis, sales in the first quarter were near the top end of our guidance range. Year-over-year reported sales growth benefited $49 million or 400 basis points from foreign exchange.

FX reduced our first-quarter gross profit margin by 30 basis points compared to the prior year. At current rates, we now expect foreign exchange to have an approximately $55 million upside to full-year 2026 sales compared to the prior year, and the majority of this benefit already occurred in the first quarter.

Turning to the balance sheet. We continue to maintain a strong and flexible balance sheet with approximately $2.4 billion in cash and cash equivalents as of the end of the first quarter.

During the first quarter, the company entered into an accelerated share repurchase agreement to buy back $500 million in shares. Edwards has approximately $1.5 billion remaining under our share repurchase authorization. Average diluted shares outstanding during the quarter were 581 million. We now expect average diluted shares outstanding for 2026 to be between 575 million and 580 million.

For the second quarter, we're projecting sales of $1.66 billion to $1.74 billion, and we are expecting adjusted earnings per share in Q2 of $0.70 to $0.76.

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

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

Thank you, Scott. In summary, our Q1 performance demonstrated the strength of our focused structural heart strategy as well as the impact of our ongoing investments in large opportunities that will continue to support long-term sustainable growth and distinguished value creation.

Before we move to Q&A, I'd like to share that we will be hosting our annual investor conference on Friday, December 4, at the New York Stock Exchange. Additional details will follow as the event gets closer, but we hope you will mark your calendars to join us in New York City as we discuss our patient-focused innovation strategy and the opportunities ahead.

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

Gerianne Sarte - *Edwards Lifesciences Corp - Senior Vice President, Investor Relations*

Thank you, Bernard. We're ready to take your questions. (Event Instructions)

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) David Roman, Goldman Sachs.

David Roman - *Goldman Sachs - Analyst*

Hi. Good afternoon, everyone. I appreciate your taking the questions. Maybe I could just start with TAVR. There was a lot going on during the quarter with respect to industry data around longer-term performance of one of your competitor products. You talked about the increased focus on lifetime management on the last call and at last year's analyst meeting. Can you maybe just help us think through some of the drivers here from some of these data? Are you seeing a class effect on TAVR? Is this questioning device selection for lifetime management? Is this a balloon versus self-expandable valve dynamic? Just help us think through some of the different moving parts here, and what operational considerations are reflected in your guidance.

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

Thank you, David. This is a very comprehensive question here. So let me try with first some big picture comments here.

I believe we should look at the TAVR category way beyond what happened in the quarter. If you look at what happened in the last, let's say, months, years, what we have done as a company, we produced a ton of data, high-quality data, all of them being highly positive.

So think about EARLY TAVR for asymptomatic patients. Think about the 7-year data with PARTNER 3. You have a 10-year data PARTNER II. So all of this together and obviously, additional data from a competitor -- but it is not just one thing.

I believe as a company, what we have produced is pretty amazing. This gave you confidence that SAPIEN has distinguished valve performance, benchmark durability. And your physician, we are confident already, but this gave extra confidence.

And everybody knew that you have a timeframe for valve vulnerability when the valves are failing. It is usually around four or five or six years. So everybody also was obviously clearly looking at PARTNER 3 7 years and 10 years. And to see this kind of data, this gave you the confidence for this renewed focus in TAVR as a category and also is explaining the fact that last year, because of the second part of the year, we had a great result in TAVR. And in Q1, we continue to get a great result in TAVR.

But maybe I'm going to ask Daniel to add a few comments about this. Dan?

Daniel Lippis - *Edwards Lifesciences Corp - Corporate Vice President - TAVR*

Yeah, thanks, David. Like again, great quarter. Pleased with the results. Encouraged to see the momentum that was built in the back half of 2025 continue into '26, and that contributes a lot, right? Independent of what's going on with our competitors, we expected a good quarter. All the things that Bernard said.

It's always nice when it's a little better than expected, and that's the case here in Q1. And that certainly gives us a little extra confidence, and that's reflected in our new guidance.

But I think it's also important just to like -- the competitive data that was dropped, it happened like mid/late February, and so it's really difficult to parse out exactly what is contributing to what at this time. And it was partial data as well.

And so we still have to -- and the clinical community still have to understand the full dataset, including all the echo follow-up on patients, et cetera. So I think it's a little early to sort of like get into the details and trying to understand exactly how much of that is contributing. But for sure, the totality of data that has been in play and being presented the clinical community over the last 12 months is contributing. All leading towards patients benefit when treated earlier in the disease pathway with TAVR.

Hopefully, that answers your question a little bit.

David Roman - *Goldman Sachs - Analyst*

That's helpful. I'll be quick on my follow-up here. Just on TMTT, I think if you look at the sequential dollar growth here, Q4 to Q1, one of the more significant step-ups that you've seen just on a dollar basis. Are you -- is this -- what are you seeing just sort of a share gain perspective and then also any early perspective on how M3 might be impacting the business?

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

Sure. David, this is Daveen. Thanks so much for the question. I think overall, in TMTT, obviously, we continue to be excited about TMTT. We're seeing that this comprehensive portfolio of repair and replacement is really enabling personalized therapy which helps get the best clinical results for patients.

So I think overall, as we look across the portfolio across the different platforms, as you said, maybe in PASCAL, we continue to see its products being differentiated, physicians are seeing that differentiating -- differentiation, and that's probably why they're choosing it.

EVOQUE continues to scale up well. People are seeing, as we talked about, new data coming out, more all-cause mortality improvements of this therapy, which continue to drive its growth.

And SAPIEN M3 is the newest kid on the block, where we just launched this in the US at the end of the year, and we're starting to see a lot of physician excitement for this product because it's a product for patients where they didn't really have a great solution before. And I think for many of their patients, SAPIEN M3 is getting great clinical results and allowing them to have a great solution for their patients.

Operator

Larry Biegelsen, Wells Fargo.

Lawrence Biegelsen - *Wells Fargo Securities LLC - Analyst*

Good afternoon. Thanks for taking the question. Congrats on a really strong start to the year here. I guess I have to ask one follow-up question, Bernard, on David's question on the six- and seven-year data. It was obviously the big news in the quarter. So what are you -- he asked about the guidance. What are you assuming in the guidance from a share standpoint, from an impact from the low-risk data? If you took share because of that, would that be upside to the guidance you're providing today? And I had one follow-up.

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

Thank you, Larry. And thanks, yeah, we had a great quarter. It is always great to start the year strong, especially after having finished last year strong also. So to have this kind of a momentum in the business gives us a lot of confidence.

So if you step back, first, globally, for TAVR, the majority of our performance is coming from market growth. So this renewed focus, all of the data, we talk about Dan and I. So the majority is about your market growth globally and also with some share mainly from the exit of a competitor in Europe.

So yes, we have seen a slight benefit also in the US from a share standpoint. But we try -- you know us very well. We try not to focus too much on share because share is a lagging indicator. Share is never driving a business. We, as a company, we bring data, we bring evidence, we bring best innovation to bring to physicians best tools, best solutions so they can take care of their patients. And therefore, everybody is benefiting. So that's the way we are thinking about it.

Now, everything that you have seen in the -- everything that we talk about is in the guidance today. And what we try to do with our guidance is to give you a realistic guidance based on what we know today.

So what you talk about happened in mid-February, and we gave you the best of what we know today. providing a realistic guidance is very important to us, Larry.

Thank you for the question.

Lawrence Biegelsen - *Wells Fargo Securities LLC - Analyst*

All right. Bernard, just for my follow-up. It's been a while since it's been since December since we heard about SAPIEN X4. Could you give us a little bit of an update? You talked about confirmatory clinical work. Where does that stand? Thanks for taking the question.

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

Thank you, Larry. So I'm going to ask Daniel. He is very close to this one to give you an update on this platform.

Daniel Lippis - *Edwards Lifesciences Corp - Corporate Vice President - TAVR*

Yeah, hi, Larry. Thanks for the question. Clearly, we're pretty excited about our TAVR pipeline in general, which includes X4.

X4 is a potential game changer for us, especially on the concept of personalized valve sizing. You know that we've set a very, very high bar with S3UR. That continues to differentiate, and we see that in the data that we're just talking about, not only our own data, but also relative to competitive data.

We talked about in December that when we put X4 in a clinic, we immediately started to see things that we would think like, hey, if we had the opportunity to enhance that product, we should take it, and we are. And that has to go into a confirmatory trial.

And so we're going to be collecting that evidence through 2026. And when we've completed that, we'll have more to say about the X4 product and the timelines and all those sorts of things. So that's exactly where we're at.

Lawrence Biegelsen - *Wells Fargo Securities LLC - Analyst*

Thank you.

Operator

Travis Steed, Bank of America.

Travis Steed - *Bank of America - Analyst*

Hey, congrats on a good quarter. Maybe ask about capacity. You've had more left atrial appendage closure procedures shifting towards EP. What are you seeing from a capacity standpoint for structural heart doctors when you're in the field? And are you seeing any kind of benefit on the numbers in the market?

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

Yeah. Travis, thanks for the question. Capacity has not been an acute matter in the last few quarters. What we have seen is health systems in the US have done a great job managing capacity. They look at their processes, they look at their staffing, they look about how to turn faster the room in between patients.

So we have been quite impressed by all what we have been doing. And obviously, we are there also to support them.

But maybe I can add, Daveen and Dan, to add some color here, if you have seen anything.

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

Yeah. This is Daveen. I'll just make one comment. I think the agility that you talked about, Bernard, is especially true as you start a new therapy like TMTT, right? When you start something like M3 or EVOQUE, you start taking up lab space.

But what we've seen is, at least from our standpoint, is that as they put in new lab time, they've worked across the system to ensure that they're not taking away from a place like TAVR or something else from what we've seen. They've continued to be agile and figuring out, hey, how do we get an extra shift in? How do we get an extra lab running? How do we do other things like that. So that's been pretty consistent in what we've seen as centers get going in TMTT.

Daniel Lippis - *Edwards Lifesciences Corp - Corporate Vice President - TAVR*

And if I just add from my side, I think it's the right point. It's different from hospital to hospital.

But from a TAVR perspective, I think what really helps is that it's clearly a priority procedure. And that's based on the evidence. And so there is that ability to navigate some of the acuteness of various hospital challenges.

We're on the ground every day with the hospitals trying to understand what their specific issues are, if they have them and how, if anything, we can help, but it's something that we pay close attention to all the time.

Travis Steed - *Bank of America - Analyst*

Helpful. And then maybe a follow-up on the NCD. There's a lot of stuff in the proposed NCD centers heart team. Just curious if you think it will all go through as proposed and how important are each of those things in the NCD proposal. And I had a lot of questions on is -- did US TAVR, was it high-single digits or double digits, if you'd answer that, too?

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

So it is very tough to predict what the final NCD will be. You know that we are very pleased. CMS opened over process. The first phase is over. So basically, now we are waiting for, I think, in mid-June to get what the draft NCD will be are positioned, I believe, is fact-based in the interest of a patient to make sure they have a fast access to care. But again, the decision we rely on CMS. That's on the NCD.

What's the second part of your question, Travis?

Travis Steed - *Bank of America - Analyst*

The US TAVR, was it high-single digits or double digits this quarter, and if you have tight rates between the two?

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

Yeah. We don't like to give this kind of specifics. So globally, TAVR grew 11%. What we said is that TAVR in the US was healthy and that the OUS TAVR grew even faster. So I'm sure you can do some math here.

Travis Steed - *Bank of America - Analyst*

Sure, thank you.

Operator

Robbie Marcus, JPMorgan.

Robert Marcus - *JPMorgan Chase & Co - Analyst*

Great. Thanks for taking the questions, and congrats on a nice quarter. Maybe one on guidance. Really strong quarter here, beat on TAVR, TMTT across-the-board margins. Just wanted to ask sort of the philosophy and the rationale. You took TAVR up 1% for the year, had a big beat in TMTT and left that unchanged. I realize there's a pretty wide guide to start with. And then EPS beat by $0.05, and raised the low end by $0.05. Maybe just give us the rationale, and I realize it's still first quarter, so I imagine conservatism is a big chunk of it.

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

Thanks, Robbie. So I would say, let me maybe start with the philosophy here on the guidance. I want to be always transparency with you guys and with everyone here to provide a very realistic guidance based on what we do at the time we are providing the guidance. And this is what we are doing here by providing this range.

Now, if you look at Q1, yes, indeed, Q1 came on strong -- stronger than expected. And it is why we raised the guidance for the year for TAVR and for the company.

Now, there are a couple of things that you need to be aware of is the comp. So if you look at Q1 in 2025, so last year, it was a little bit lower growth rate for us as a company and for TAVR. And so that's one.

Two is we had a great year last year in 2025, especially in the second part of the year. So Q3 and Q4. So this is setting a higher bar for us in 2026 in Q3 and Q4. So we took all of that into consideration.

Q1 2025 being low, at 2025, H2 being high, a strong beat in Q1. And based on what we know today, that we give you the best guidance we can, being a realistic guidance. We feel confident about us delivering on this new guidance for TAVR and for the company.

I hope it is helping you, Robbie.

Robert Marcus - *JPMorgan Chase & Co - Analyst*

Great. Maybe just one follow-up. And I realize this is a follow-on to a follow-on. But we did see your main TMTT competitor talk about healthy market growth, but then losing share to you in both mitral and tricuspid.

And we did hear yesterday, I guess, from another one of your competitors talk about their left atrial appendage closure was being utilized a bit less stand-alone by interventional cardiologists as they're shifting focus over to mitral and tricuspid. You're clearly benefiting from all of those trends in commentary. So I was wondering if you agree with those comments that you're seeing in the market and how you're helping to drive that. Thanks.

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

That's a very interesting question, Robbie. And I -- what I tried to do here is maybe again, look at the big picture here. So for some of our competitors, it is about share. We look at this one as we are creating a category.

When 10 years ago, we had the vision and I should say, of a bold vision to go deep into the two disease states, mitral and tricuspid, and decided to invest in a big way in building a portfolio of therapy to be able to solve these unmet patient needs. At the time, 10 years ago, 5 years ago and even today, it was not about share. It was about the patient. It was about the opportunity.

Now fast forward in 2026, guess what? We have a portfolio. We committed. We have made the investment. And now we are benefiting from it.

So now you ask position what do we have? We have multiple solutions, and they can choose which one is best for what patient.

And that's the difference. This is what's happening. So that's still our view of what's happening here.

But I'm going to add, Daveen, you are here, you are close to the action here. So what do you think?

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

Yeah. No. I'll just add a little bit on to what you said, Bernard. Clearly, we think that the patient treatment for mitral and tricuspid disease, two diseases that are massively under diagnosed, under awareness, under referral, lots of opportunity for so many more people to get these treatments to help their lives, right? They're still growing. The procedure growth is still growing at double digits across both mitral and tricuspid.

And so for us, clearly, if you look across the board at our therapies, whether you're talking about PASCAL with TEER or EVOQUE or SAPIEN M3, which is brand, brand new, we're growing at a higher rate than we think the market, and that there's tons of opportunity to create massive new categories to treat people, whether you think about it from a mitral side or a tricuspid side or from a repair side or a replacement side.

And we think that all this when you add this together, and as Bernard talked about, having the portfolio to best treat patients, to give them the best possible solution, really will help us drive to that $2 billion in 2030 that we've talked about and continued growth beyond that. So we are continuing to be very excited about how our portfolios come together to help treat more patients overall.

Robert Marcus - *JPMorgan Chase & Co - Analyst*

Perfect. I appreciate the thoughts. Thanks a lot.

Operator

Vijay Kumar, Evercore ISI.

Vijay Kumar - *Evercore Inc - Equity Analyst*

Hey, guys. Congrats on a nice sprint, and thanks for taking my question. I guess one on maybe a guidance kind of question, Scott. You did the ASR. Can you just talk about how you think about share count here for second quarter? And whether there was any weather impact here in Q1, how Q1 played out?

Scott Ullem - *Edwards Lifesciences Corp - Chief Financial Officer, Corporate Vice President*

Sure. So we completed the accelerated share repurchase. We also did a little bit more repurchase. So something like $520 million total in the quarter. So that brings down the share count a bit. You see the weighted average for the full year is coming down 5 million shares from our original guidance.

The accretion dilution is kind of a push. It doesn't have a big impact on the bottom line short term. But obviously, we're buying back shares because we think longer term, it's the right investment.

Weather impact in Q1, really nominal. I know there was a question back in February when there was some weather that hit the Northeast. And we said back then, a lot of times, it's -- you just don't know whether procedures are going to get rescheduled during the quarter or after the quarter, into the next quarter or whether they go away. In this case, we didn't really see a big impact by the time we got to March 31.

Vijay Kumar - *Evercore Inc - Equity Analyst*

Great. And then maybe, Bernard, one for you on the PROGRESS trial. I think last call, there was some concerns on -- maybe you're less bullish on PROGRESS. So can you just maybe talk about -- express your bullishness and progress? And how are you handling crossovers? Are crossovers allowed in this trial? If so, when are crossovers being allowed in PROGRESS?

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

Thanks, Vijay. We tend -- in general, and you know us well. We tend not to talk about trial before we can talk about trial results. So most of our trials are FDA-approved trial, third-party adjudicated. And we treat them very seriously because it does matter to our long-term strategy. They are not marketing trial or so on.

So right now, the only thing I can tell you about moderate is what I said in the past, which is we are looking for the presentation at TCT this year. And as a matter of fact, we are going to have other trial TCT this year. But this one is going to be a TCT this year.

We were very pleased at the time of enrollment a couple of years ago where this trial enrolled very fast. And usually, it is a good deal of proxy when physicians, treating physicians, they are enrolling the trial. So we see the benefit. But again, I don't know anything about the results, and we usually keep it like it is until the end.

So every one of us are going to discover the trial at TCT. And believe me, we are going to go deep with the PI, with the investigators, with all of you at TCT. So you will have a full analysis. We will understand all of the learning and all of this. But as of now, yes, we started the trial for a reason, but I don't know more than that.

I hope it is helping, Vijay.

Vijay Kumar - *Evercore Inc - Equity Analyst*

Yes, that's helpful, Bernard. Thank you.

Operator

Joanne Wuensch, Citibank.

Joanne Wuensch - *Citi Infrastructure Investments LLC - Analyst*

Good afternoon, and thank you for taking your question. And I also say a very nice quarter. Two questions. I'll just ask them upfront.

The expense management, particularly as I looked at research and development, a little less. So SG&A was really strong in the quarter. How should we think about your maybe new view towards expense management or continued view?

And then forgive me, Scott, for asking this, but where are you in the progress towards finding a new CFO? Thank you.

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

Thank you. So let me start with R&D. We are very much committed into our R&D investment, organic innovations. And we are -- the guidance for the year is around 17%. So clearly, we are committed.

A couple of things is happening. One is we want to have the right priorities. So you have seen the ratio going down from what it was a few years ago, around 19% to 16% in Q1, but 17% for the full year 2026. And we are going to continue looking at making sure we have big investment because structural heart disease have many opportunities, at the same time, managing the priorities and having a ratio continuing to go down.

We are also helped by the top line increasing. So the top line increasing as managing priority. So this is what we are doing in a very intentional manner and strategic manner.

With regards to the CFO, the process is going. And I should say it's going well. But as soon as I have news to report, I will say it in the press release, obviously, because it is an important hire. But good news is Scott is very committed to make sure it is a very successful transition. He has been a very successful CFO for the company over the last 12, 13 years, and he has been a great partner to me and to many of the executive team. So I feel good about the process here. And as soon as I know more, you will hear from me.

Joanne Wuensch - *Citi Infrastructure Investments LLC - Analyst*

Thank you very much.

Operator

Matt Taylor, Jefferies.

Matthew Taylor - *Jefferies LLC - Equity Analyst*

Hi, thank you for taking the question. So I just wanted to follow up on the thread before and get some clarity from you on the guidance. When you're increasing the TAVR guidance this year, are you assuming any increase in your competitive position or share gains? Could you characterize that, or is that mostly market growth and your stability with it?

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

Thanks, Matt. So the main reason for having increased the guidance was based on our Q1 outperformance based on our earlier expectation. That's the main reason.

Now, if you look at our Q1 performance, this was led by market globally, given our renewed focus on TAVR, led by all of the clinical evidence that we have produced in TAVR with SAPIEN 3, and you know all of them, and also a little bit of share. Share in Europe from the exit of a competitor and also some slight share gain in the US.

So this is the way we build the guidance based on what we know today, Matt. And obviously, as we know more for the Q2 earnings call, we will provide more analytics if we have to.

Matthew Taylor - *Jefferies LLC - Equity Analyst*

Thank you. And maybe as a follow-up, could you comment on just the healthcare environment in general. There's been some chatter about concerns with changes in the macro environment and coverage. I think that would impact US because you're levered to Medicare, and these are very necessary procedures, but I'd love any thoughts that you have on the overall environment.

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

Yes. We -- I would say we don't see an intense environment. And again, what you need to realize, as a company, all of our technologies are technologies helping to extend life of patients or improvement of the quality of life of patients.

So there are -- most of them are life-saving technologies. And there are technologies that patient needs urgently. So we don't feel maybe what you are talking about. And we got some good news also this morning from the new administration.

I don't know if you did follow, but together with CMS and FDA, basically a partner to bring a new policy for breakthrough therapies. And it is exactly what we are doing as a company. And the goal here for this new policy, the name of it is rapid, is basically to make sure that patients have an early and timely access to care in the US. So we look at it.

The environment for breakthrough therapy is positive. And the news from this morning, we look at it as even more positive. We have been working with FDA and CMS for decades. And it is great to see that they want to enhance a process which was already working. And I'm sure this process is going to be even better. So we are fully behind it. So very positive about it.

Matthew Taylor - *Jefferies LLC - Equity Analyst*

Okay, thank you so much.

Operator

Matt Miksic, Barclays.

Matthew Miksic - *Barclays Services Corp - Analyst*

Hi, thanks so much for taking the question. So one follow-up on mitral and one quick follow-up on tricuspid kind of a review forward.

So I think you know one of the competitors in mitral talked a little bit about the share activity share pressure, which, of course, it in mitral for some time, you can share repair with PASCAL total great some step-up of that activity.

And maybe you could talk a little bit about like what the rollout of M3 looks like in terms of training, in terms of adoption and how, if at all, that is either expanding the accounts that you're in or enhancing engagement with those accounts? Any kind of color like that would help.

And then I'd like to just one quick follow-up on tricuspid.

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

Sure, Matt. This is Daveen. So some quick background. I think we see in the treatment of mitral patients that, as I mentioned before, PASCAL really offers differentiated technology, which the physicians are seeing, and that's why they want to use PASCAL for their patients.

As you look about SAPIEN M3, this product is one for where you may get suboptimal results for either TEER or surgery. So this is offering a potentially solution for patients who don't necessarily have a great surgical or transcatheter solution today.

And as you can imagine with any new technology, again, only a quarter into the launch, you start off by really working closely with the centers that were a part of your clinical trial. And those are usually our first wave that we start working on and then eventually you start building on to other kind of large mitral centers.

But we're so early in the rollout because we're only a quarter in that you're just kind of starting that process and with a limited number of centers overall.

Operator

Matt, do you have a follow-up?

Thank you. We'll move on. As that was our last question, I'll hand the floor back to management for closing remarks. Thank you.

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

Thank you, everyone, for your continued interest in Edwards. Scott, Gerianne, Dan, Daveen, and I, obviously, welcome any additional questions by telephones, and I wish you a great rest of your day. Thank you, everyone.

Operator

Thank you. This concludes today's call. All parties may disconnect. Have a good evening.
