Edwards Lifesciences
Second Quarter 2025 Results
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Presenters
Mark Wilterding - SVP, Global Finance
Bernard Zovighian - CEO
Scott Ullem - CFO
Larry Wood - Group President of TAVR & Surgical
Daveen Chopra - Global Leader of TMTT
Dan Lippis, Corporate VP

Q&A Participants
Robbie Marcus - JP Morgan
Travis Steed - Bank of America
Larry Biegelsen - Wells Fargo
David Roman - Goldman Sachs
Matt Taylor - Jefferies
Anthony Petrone - Mizuho Group
Vijay Kumar - Evercore ISI
Matt Miksic - Barclays
Chris Pasquale - Nephron Research

Operator
Greetings and welcome to the Edwards Lifesciences second quarter 2025 results conference call. At this time, all participants are in a listen only mode. A question-and-answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press star zero on your telephone keypad. Please note this conference is being recorded. I will now turn the conference over to your host, Mark Wilterding, Senior Vice President, Global Finance. Thank you. You may begin.

Mark Wilterding
Thank you very much, Diego, and thank you all for joining us this afternoon. 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 Larry Wood, our Global Group President of TAVR and Surgical, Daveen Chopra, our global leader of TMTT, Wayne Markowitz, our Global Leader of Surgical, and Dan Lippis, Corporate Vice President. Just after the close of regular trading, Edwards Lifesciences released second quarter 2025 financial results.

During the call today, management will discuss the results included in the press release and accompanying financial schedules and 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 were 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. Information concerning 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.

Edwards' guidance reflects its current estimates of the impact from tariffs that are in effect or have been announced to date and assume such tariffs remain in place for the remainder of 2025. Any modifications to such tariffs or any new tariffs could have a material impact on the company's future financial results and guidance. Finally, unless otherwise noted, our commentary on sales growth refers to constant currency sales growth, which is defined in the quarterly results press release issued earlier today. Reconciliations between GAAP and non-GAAP numbers mentioned during the call are also included in today's press release. Quarterly and full year growth rates refer to continuing operations. With that, I'd like to turn the call over to Bernard for his comments.

Bernard Zovighian
Thank you, Mark, and welcome, everyone. Thank you for joining us today. Before getting into the numbers, let me highlight the many significant achievements we have made across the company. When we introduce our sharpened focused strategy, we did so in anticipation of an asymptomatic AS approval, the expansion of EVOQUE launch, the expected introduction of SAPIEN M3, and our strategic entry into structural heart failure and aortic regurgitation, which represents remarkable synergies to our 65 years of valve leadership. These areas represent large and growing opportunities, and we are just getting started. Our focus on structural heart has positioned the company for agile execution of our strategy and provides the foundation for sustainable growth. It is supported by our conviction in mid- to high single-digit TAVR growth over the long term given the undertreatment globally. The potential of our market-leading surgical valve franchise based on compelling [inaudible] RESILIA data. And finally, the significant patient benefits of our pioneering TMTT technologies. While TAVR is and will remain an important growth driver for our company, Edwards is increasingly defined by a balanced portfolio of differentiated therapies across aortic, mitral, and tricuspid that will position us for leadership for many years to come as we help even more patients around the world.

During the call today, we will go into more details on the company's strong second quarter performance across product groups and geographies and our confidence in the outlook for Edwards in the years ahead. We are pleased to report double-digit sales growth in the second quarter, driven by broad-based growth across our unique portfolio of structural heart therapies. Total sales of $1.53 billion grew 10.6%, which was better than expected. Based on our strong first half performance and the many catalysts across our portfolio, we are increasingly confident in our full year outlook and are raising our full year 2025 sales growth guidance to 9% to 10% and adjusted EPS guidance to the high end of our original range of $2.40 to $2.50.

Now I will provide some additional detail by product group for Q2. In TAVR, our second quarter global sales of $1.1 billion increased 7.8% over the prior year. Growth was comparable in the US and OUS. On a global basis, Edwards competitive position and pricing remains stable. TAVR growth in the quarter was better than expected as clinicians continue to adopt our best-in-class SAPIEN technology. We are encouraged by the renewed focus on TAVR across the clinical community since the early TAVR data released last October. We are pleased with the recent approvals that make the SAPIEN free platform the first and only TAVR to receive US and European approvals for the asymptomatic indication. These two approvals enable all patients diagnosed with severe AS to be evaluated and considered for treatment with TAVR regardless of symptoms.

The evolution of policy and guideline changes together with the potential of a new US NCD will provide important catalysts resulting in a multiyear growth opportunity for TAVR overall. And we remain focused on continuing our deep commitment to advancing evidence for AS patients with three important studies. In May at the EuroPCR conference, results of the Optum real-world study of more than 24,000 patients demonstrated that intervening on aortic stenosis before symptoms develop reduces the economic and resource burden on the healthcare system and improves patient outcomes. Additionally, compared with asymptomatic severe AS, delaying treatment until the disease progressed resulted in a higher rate of death within one year after aortic valve replacement. Alongside data from the early TAVR trial, these results reinforce the value of early referrals and evaluation by our heart valve team for all patients with severe AS.

Second, at the New York Valve conference last month, 10 years outcome from the PARTNER II study were presented, underscoring the excellent long-term outcomes and durability of Edwards TAVR platform. This is the first FDA-approved TAVR study to report 10-year follow-up and represent the largest TAVR patient cohort studied through 10 years. Finally, new data from the detect AS study were also presented. The sub analysis demonstrated that electronic provider notification, or echo alerts, increased both treatment and survival rates in all patients with severe AS. Looking ahead to TCT in October, we expect to be the first company to present seven-year data studying a low surgical risk cohort of TAVR patients. I am proud of our team's commitment to advancing robust dividends to improve outcomes for patients with severe aortic stenosis supported by a decade of clinical research. This significant body of high-quality science underscores the excellent clinical outcomes delivered by Edwards' premium SAPIEN technology, which has benefited over 1 million patients around the world since its launch.

In the US, we are pleased that the clinical conversations about the successful early TAVR trial have brought a renewed focus to streamlining the management of patients with severe AS, enabling closer follow-up and more timely treatment of patients with aortic stenosis. Outside of the US, we continue to focus on the value of our differentiated technology and increasing therapy adoption, especially in areas where many patients go without care. In Europe, the exit of competitor resulted in a rebalancing of market share and a modest contribution to our sales.

In Japan, TAVR sales grew in the mid-single digit, an improvement over last quarter and consistent with the company's total sales growth in the region. Rest of the world growth remains strong. In summary, we are raising our full year guidance to 6% to 7%, up from previous guidance of 5% to 7%.

Longer term, we are enthusiastic about the mid- to high single-digit growth opportunities in TAVR supported by the recent early TAVR indication approvals, future guideline and policy changes, including an updated NCD. And finally, you have a potential to serve patients with moderate AS. I also want to take this opportunity to share with you that Larry Wood, who has been leading the TAVR team, has made the personal decision to depart Edwards in early September and pursue a leadership opportunity outside of cardiovascular. We sincerely thank Larry for his 40 years of dedication to Edwards and our patients. During that time, Edwards TAVR has helped more than 1 million aortic stenosis patients around the world. As we're here today, TAVR is well positioned for continued growth and success, and we are pleased to announce that Dan Lippis will assume leadership of TAVR franchise globally. We are fortunate to have a very well-prepared successor who has more than 50 years of deep TAVR experience in the US and Europe. Most recently, Dan has also been leading our JPAC [sp] region with responsibility for our full portfolio of technologies. I'm very confident that the TAVR leadership team will build on our momentum and deliver long-term success. Dan and Larry will work together on a smooth transition through early September.

Now let's turn to our TMTT product group. Our unique portfolio of repair and replacement therapies to treat mitral and tricuspid diseases drove another quarter of impressive growth with a meaningful contribution to overall company performance. Second quarter sales of $133 million grew 57%, reflecting the strength and differentiation of our portfolio of repair and replacement technologies and demonstrating our team's long-term and steadfast commitment to solving large unmet patient needs. PASCAL and EVOQUE were both significant contributors to growth as they continue to scale. With the addition of SAPIEN M3, Edwards is uniquely positioned to meet the broad and diverse needs of patients with mitral and tricuspid valve diseases. Mitral tier procedures continue to grow in the double digits globally, and the developing tricuspid opportunity is growing much faster across both repair and replacement. Adoption of our differentiated PASCAL technology remains strong in both new and existing centers around the world. We continue to see growing interest in the therapy, reinforcing the significant unmet needs of these patients. We are also pleased to announce the completion of enrollment in our 1,000-patient European MiCLASP post approval study in patients with both DMR and FMR.

Publications and presentation of data from this study continue to demonstrate the excellent clinical results delivered by the state-of-the-art PASCAL technology. The EVOQUE commercial launch is progressing well in the US and Europe with excellent real-world outcome for patients in line with the successful TRISCEND II clinical trial results. Consistent with Edwards' science-based approach to establishing categories for the many patients in need, we are continuing to generate evidence for EVOQUE. At the recent New York valve conference results from a real-

world 176-patient study across 12 centers and 5 countries in Europe demonstrated excellent clinical outcomes that were similar or better than the results shown in TRISCEND II [inaudible] receiving EVOQUE, and we look forward to an EVOQUE late breaking substudy at next month European Society of Cardiology Conference. We have also begun enrollment in the large TRISCEND III clinical trial in Europe. This prospective multicenter study of up to 500 real-world patients with TR disease will track clinical outcomes out to five years.

In summary for EVOQUE, there is a great demand for the therapy, and we are continuing to develop important evidence to support expansion globally. We are pleased with the addition of our latest TMTT technology, the pioneering SAPIEN M3 valve, which received CE Mark approval in Q2. Clinical feedback, while early, has been positive. We will deploy our differentiated high-value model to support therapy expansion with a continued focus on ensuring access and excellent outcome for patients. We continue to expect that results from the in-circle pivotal trials studying SAPIEN M3 will be presented at the TCT conference later this year. And we now expect US approval of SAPIEN M3 to follow in the first half of 2026.

In closing, with PASCAL, EVOQUE, and the recent CE Mark of SAPIEN M3, our vision for TMTT has developed into a growth portfolio of groundbreaking transcatheter repair and replacement technologies, meeting the complex need of underserved patients with mitral and tricuspid diseases. We are committed to bringing these impactful therapies to the many patients in need around the world. We are pleased with our year-to-date performance in TMTT and remain on track to achieve our full year sales guidance to 530 million to 550 million.

In our surgical product group, second quarter global sales of $267 million increased 6.8% over the prior year. We continue to see positive procedure growth globally for the many patients best treated surgically with our premium resilient technologies, including INSPIRIS, MITRIS, and KONECT. Our surgical team is making progress around the world advancing important innovation for patients. We continue to see the impact across the clinical community from the recent presented RESILIA eight-year data demonstrated excellent durability and better freedom from reoperation due to structural valve deterioration compared to non-RESILIA valves. We are also pleased to have received CE Mark approval for KONECT in Europe during the quarter. For the full year, we continue to expect mid-single-digit sales growth in our surgical product group. And now Scott will cover the details of the company's financial performance.

Scott Ullem

Thanks a lot, Bernard, and good afternoon, everyone. As Bernard mentioned, we are pleased with our better-than-expected Q2 performance and the progress we made during the quarter advancing our strategic initiatives. Our double-digit sales growth drove adjusted earnings per share of $0.67. Our GAAP EPS for the quarter was $0.57, which included a onetime charge related to our portfolio of external investments. A full reconciliation between our GAAP and adjusted earnings per share for this and other line items is included with today's release. And now I'll cover additional details of our P&L. For the second quarter, our adjusted gross profit margin was 77.6%, in line with our expectations, compared to 80% in the same period last year.

This year-over-year change was driven by additional manufacturing expenses related to the expansion of new therapies as well as foreign exchange.

We continue to expect our full year 2025 adjusted gross profit margin to be within our original guidance range of 78% and 79% our guidance continues to assume some pressure from the weakening dollar and the impact of announced tariffs, albeit less than initially expected, as well as the acquisition of JenaValve, which is not closed yet. Selling, general, and administrative expenses in the quarter was $502 million or 32.8% of sales compared to $448 million in the prior year. We expect increased SG&A spending in the second half of the year due to deferral of certain spending year-to-date as well as anticipated spending related to JenaValve.

Research and development expense was $276 million in the second quarter or 18% of sales compared to $272 million or 19.8% of sales in the same period last year. This increase in spending and decrease in R&D as a percentage of sales reflects our strategic prioritization of investments in our expanding structural heart portfolio. The year-over-year improvement in second quarter adjusted operating profit margin of 28.2% benefited from our better-than-expected sales performance and the deferral of certain spending to the second half of the year. As mentioned on the Q1 earnings call, we continue to expect lower second half operating margin levels compared to the first half, reflecting expenses associated with the planned acquisition of JenaValve. We continue to expect full year 2025 operating margin of 27% to 28%. We remain committed to annual constant currency operating profit margin expansion in 2026 and beyond consistent with our guidance at our investor conference in December.

Turning to taxes. Our reported tax rate this quarter was 16.1% or 16.8% excluding the impact of special items in line with our expectation for the quarter. We continue to expect our 2025 tax rate, excluding special items, to be between 15% and 18%. Turning to the balance sheet. We continue to maintain a strong and flexible balance sheet with approximately $3 billion in cash and cash equivalents as of June 30th. Edwards currently has approximately $1 billion remaining under its share repurchase authorization. Average diluted shares outstanding during the quarter were 588 million. Based on year-to-date share repurchases, we now expect lower full year shares outstanding to be between 585 million to 590 million versus original guidance of 585 million to 595 million.

Foreign exchange rates increased second quarter reported sales growth by 130 basis points or $15 million compared to the prior year. FX rates negatively impacted our second quarter gross profit margin by 60 basis points compared to the prior year. Relative to our April guidance, FX rates had a nominal impact on second quarter earnings per share. At current rates, we now expect FX to have an approximately $30 million upside to full year 2025 sales compared to the prior year. I'll finish with comments related to the sales and EPS guidance. As Bernard mentioned, we are increasing our underlying growth rate guidance for TAVR to 6% to 7% driven by strong performance and our sales guidance range for TAVR to $4.3 billion to $4.5 billion to also reflect stronger OUS currencies. We are also increasing our total company sales growth guidance to 9% to 10% with sales of $5.9 million to $6.1 billion.

We now expect full year adjusted earnings per share guidance at the high end of our original range of $2.40 to $2.50. Regarding JenaValve and the potential impact on our P&L this year, we are reaching the end of the regulatory review process and expect a decision soon. We remain hopeful that we will be able to close the acquisition during the third quarter. For the third quarter, we're projecting sales of $1.46 billion to $1.54 billion and adjusted earnings per share of $0.54 to $0.60. And with that, I'll pass it back to Bernard.

Bernard Zovighian
Thank you, Scott. We are pleased with our strong performance in the first half of 2025 and our outlook for the full year. The milestones achieved showcase the strength of our focused strategy to drive breakthrough innovation in pioneering and leading categories. Looking ahead to '26 and beyond, Edwards is positioned to transform care for the many structural heart patients in need. We are confident that our unique innovation strategy supported by the many important catalysts across our portfolio and the exceptional work of our 16,000 employees around the world will deliver significant value to patients, the healthcare ecosystem, and shareholders. With that, I turn it back over to Mark.

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

Operator
Thank you. And to ask your question, please press star one on your telephone keypad. A confirmation tone will indicate that your line is in the question queue. You may press star two if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. And once again, please limit yourself to on question plus one follow up. Our first question comes from Robbie Marcus with JP Morgan. Please state your question.

Robbie Marcus
Oh, great. Good afternoon and congrats on a very nice quarter. Maybe to start, two for me. First one, US TAVR looks like when I try and back in based on the color you gave, it was a little better than The Street expected. So, what really drove that? Was there asymptomatic already coming into play? Or any other trends or color you could add would be helpful. Thanks

Bernard Zovighian
Hey, Robbie. Thanks for the question. Yes, the quarter really came better than expected for TAVR, and we are very pleased about what we have seen. If you -- big picture, we are the leader in TAVR. We have been focusing a lot, a lot on bringing evidence, and this early TAVR study drove a lot of conversation among the clinical community. So, what we have experienced since

the approval is a renewed focus on TAVR, a renewed focus on how to better manage these patients, how to make sure that these patients are timely taken care of. So, all of that together, basically, we created a catalyst in the TAVR space. And the good news about that, it is just starting. We are waiting for a big catalyst. We are waiting for guidelines. We are waiting for NCD, which are yet to come. So, that's great to see this kind of positivity in the space, the reaction of the clinical community, and at the end of the day, for a leader like us to be leading this conversation. I'm going to ask Larry to provide additional details here also.

Larry Wood
Yeah. Thanks, Bernard, and thanks, Robbie, for the question. Yeah. I don't think we're seeing a lot of asymptomatic patients come in. I think in centers that participated in the early TAVR trial, we probably see a little bit of it, so there might be some in there. But I think as Bernard kind of alluded to, I think what we're seeing is just a renewed attention on the management of patients with severe aortic stenosis. And I think this data set was very powerful. And we know in the system from a lot of the work that [inaudible] has done that even patients with mild symptoms often get held in the process and don't move forward for referral for therapy. And I think people are paying a lot more attention to these patients, and I think this new data set is just reprioritize these patients within the structural heart programs. And so, I think that's a little bit of what we're seeing. And obviously, we're very pleased with the quarter.

Robbie Marcus
Great. Maybe a follow-up for me. US TAVR obviously gets a lot of attention, and we hear less about outside US trends. So, maybe you could talk about what you saw outside the US in Japan and particularly Europe with the exit of your competitor? Thanks.

Bernard Zovighian
Yeah. Thank you, Robbie. Maybe I'm going to take this opportunity to ask Dan to answer this question. We are very fortunate to have amazing talent that it was, and Dan Lippis is going to come here in the US and lead the TAVR franchise. So, maybe, Dan, you want to answer this question.

Dan Lippis
Sure. Thanks, Bernard. Hopefully, you can hear me well. First of all, it's been a real privilege working alongside Larry so closely for the last 15 years. First in the US, then in Europe, and now most recently in Asia. And given that I led the TAVR team in Europe, maybe I'll start with Europe. The rollout of our S3 platform is progressing really nicely, and the feedback from physicians continues to be very positive. But I guess what we're most optimistic about is the recent asymptomatic indication, and we think that's going to be a real game changer for the longer term. Switching to Japan. This is an important market for us. We remain very dedicated to expanding our therapy there. The undertreatment is significant, and the overly population there is very substantial. And while we're market leaders there, we are working really hard to regain some of the ground we've lost as new competitors have entered the market. And

beyond that, we continue to grow in a very nice manner internationally beyond Europe and Japan. So, hopefully, that answers your question.

Bernard Zovighian
Thanks, Dan, and thanks for the question, Robbie.

Operator
Thank you. And your next question comes from Travis Steed with Bank of America. Please state your question.

Travis Steed
Hey. Thanks for the question and congrats on a good quarter. I wanted to ask about EPS, both more kind of shorter term, why not maybe raise the EPS even more at this point. Tariffs are probably, what, a couple of cents better, and you beat the Street by $0.05. And then kind of longer term, when you think about EPS leverage, do you think you can grow EPS faster than the 10% revenue growth that you kind of laid out going forward?

Scott Ullem
Yeah, Travis. It's Scott. Thanks a lot for the question. We had a nice second quarter, and we saw the benefits of that drop through to the bottom line. We ended up coming in above the top end of our guidance range, which was not expected. At the same time, we've got some headwinds that we talked about last quarter, and those have not necessarily all abated. And so, especially things like JenaValve where we expect to have a negative effect on our earnings per share. When it closes, that gives us some cause for pause. But overall, we're feeling good about the trends in earnings per share this year. That's why we raised our guidance from 2.40 to 2.50 all the way to the high-end of 2.40 to 2.50. In terms of longer-term EPS expectations, you know our plan, which is to, on average, grow the top line double digits and to get some leverage on the bottom line beyond that. So, our expectations and our intentions have not changed, and we're going to stay focused on not just delivering short term in 2025 strong earnings per share but longer-term, consistent, sustainable, growing EPS, as well.

Travis Steed
Great. Thank you. Maybe just a question on the international competitor that's exited the market. When you think about the share you're capturing there, is it kind of in line with your international share above or below? Just kind of get a sense for kind of that opportunity.

Larry Wood
Yeah. Thanks for the question, Travis. What I will say is our first order of business when our competitor exited the market was to make sure we reached out to the centers that we knew were heavy users of their technology and make sure that we had inventory there, that we had people there, that we were able to train folks and make sure that they were -- the patients didn't get delayed or denied access to high-quality care. So, that was sort of really our focus, and that's we drove a little bit of the benefit that we saw there. I think longer term, they sold at

a different price point than we did. So, I think it's on us to speak to the value of our technology and why it's worth our price point, and that's what the team is focused on right now. And so, we'll see how that plays out over the longer term. But certainly, we're optimistic that our platform has showed really well, and we continue to put data on the board that I think highlights the advantages and why our platform is worth what we charge for it.

Travis Steed
Makes sense. Thanks a lot, and congrats.

Operator
Your next question comes from Larry Biegelsen with Wells Fargo. Please state your question.

Larry Biegelsen
Good afternoon. Thanks for taking the question and congrats on the nice quarter. Larry, congratulations on all your success at Edwards. You're going out on a high note, and it's hard to imagine Edwards without you. It was a pleasure working with you, and I wish you the best of luck in your new role. So, I'll start with a question for you. Larry, when do you expect CMS to reopen the NCD? And what's the likelihood of moving to a single operator? And if that happens, what do you think the implications are? And I had one follow-up.

Larry Wood
Yeah. Thanks, Larry. Thanks for your kind words, and thanks for your question. We think the time to open the NCD is now. The ball is really in CMS's court, but we're going to continue to work with them and provide information to them, and hopefully it opens sooner rather than later because there's a number of changes that need to be made. The first one is making sure that asymptomatic gets covered so that all asymptomatic patients are eligible for therapy across the country. And so, that's really important. But this technology has advanced so far at this point that I think everybody agrees we could streamline the operator requirements and the facility requirements. And that's going to open up access for patients and improve care for patients because we know there's waiting list and there's other challenges, and that will relieve a lot of the capacity in the system challenges that we have now.

I think the big advantage to if we go to one specialty doing the procedure is, in essence, you would have two teams now that could do procedures. You could have a surgeon led TAVR team and you can have a cardiology led TAVR team, which would allow people to optimize their patient flow through. So, I think that'd be a big benefit. And when we look at the data, the conversion now from TAVR to surgery is the same rate as the conversion rate between PCI and surgery. And obviously, we don't have all these restrictions and requirements. So, we think the time is now. We just need to continue to work with them and make the case for it. And hopefully, they open it sooner rather than later.

Larry Biegelsen

That's helpful. And Bernard or Scott, you set a goal of 10% -- it's a follow-up to an earlier question. You set a goal of 10% annual top line growth, I think 50 to 100 basis points of margin improvement and double-digit EPS growth in 2026 and beyond. You have a lot of momentum now. You have catalysts coming like M3 and hopefully JenaValve. Is there anything you're aware of today that would cause you to be below those goals next year? Thanks for taking the question.

Bernard Zovighian
No, I can -- thanks, Larry. Let me start and I'm sure Scott can add any details here. No, we are confident, Larry. Like you said, we are -- we passed on a great quarter. We are on track to have a great year, better than expected. We have so many catalysts across the company in TAVR, in TMTT, in surgical. We have some new businesses also coming our way. There are so many things to do in the US, outside of the US. So, I feel very confident. And it is very much aligned to what I shared with you at the investor conference last year. We saw that coming. We knew it was coming. And we are making all of this happen. I am super proud of the team we have. This team is amazing. We have a very bold strategy altogether. We are the only company having this kind of bold strategy, a very unique innovation process, and we are executing in a very flawless fashion. We make things happen. And that's truly who we are as a company, and so I'm very confident about our commitment here for ’25, ‘26 and beyond. Scott, anything to add?

Scott Ullem
I share that view. We feel positive about not just the top line but what contributes to the bottom line, as well. At the same time, there are all kinds of different scenarios that can unfold. And so, part of this has to do with uncertainties like tariff exposure that none of us can predict. Part of this is just what happens to the baseline against which we're comparing 2026. But we're just -- based upon all the different scenarios, we're feeling pretty good at this point in July of '25 as we look ahead to the full year 2026 and the ability to meet those annual average targets that we laid out in December.

Operator
Thank you. And your next question comes from David Roman with Goldman Sachs. Please state your question.

David Roman
Thank you and good afternoon, everybody. I wanted to start on the TMTT business and maybe very specifically around EVOQUE. There have been a variety of publications. I wouldn't call them studies necessarily -- questioning some of the safety and real-world outcomes around EVOQUE. But I think when we last engaged with you, you talked about the impact that learning curve has had on centers and those centers that had greater experience were seeing better outcomes. Can you maybe just elaborate a little bit on what you're seeing from a real-world evidence standpoint as it relates to adverse events surrounding EVOQUE and when we might be able to see some of that data in a more public setting?

Daveen Chopra
Yeah. No, sure, David. I really appreciate the question. I think for EVOQUE, we continue to see a lot of excitement around EVOQUE. We see a lot of physician excitement, and we see a lot of patient excitement how the technology is changing their life. I think we saw in TRISCEND II that there's -- that's the baseline clinical data we have for this product. And what we've seen in the real world is actually results that are similar or better than TRISCEND II. So, for instance, even at the very recent New York Valves conference, we saw coming out of our European almost 200 patients. We saw initial results coming from that study at 12 centers across 5 European countries, results that were equal to or better than TRISCEND II. Beyond that, we also -- New York Valves had a one-year study on echo gradients that continue to show how the right ventricle and the heart gets so much better with EVOQUE. And you'll see, I think, coming up both at ESC, some more sub-analysis on EVOQUE and going in the future, you'll see TVT registry analysis. But I think for us, it's a continued -- continued data set after data set showing similar real-world outcomes that we've seen from TRISCEND II.

Bernard Zovighian
Maybe, David, to add something on what Daveen just said. And in a typical adverse fashion, Daveen's team is continuing to innovate. So, we have a Gen 1 today. We are very pleased with Gen 1. But the same way we did with SAPIEN, we are Gen 5 today. You can expect EVOQUE Gen 2, Gen 3, Gen 4, and each platform will be better. The physicians will have more experience. We will bring more evidence. We will have more innovation. So, you can expect the same kind of trajectory where we are going to create this amazing category for so many patients in need. But right now, the demand like Daveen said is very high. We can barely fulfill the demand.

David Roman
Okay. Very helpful. And then maybe, Scott, I appreciate the continued emphasis on the P&L. And maybe just kind of summarizing things longer term. I think if you look back over Edwards the past several years, at one point in time, the company was generating 10% plus top line growth with low 30s operating margins. Is it realistic to think that that is the direction you aim to take the business now and that the company did operate at 30% plus at one point and 10% and given the totality of drivers you have here that, that's a reasonable profile to think about longer term?

Scott Ullem
Yeah. I think at this point, we're not going to set a specific target. 30% is a nice round number, but we're not really focused on hitting the three handle so much as we are focused on increasing our operating profit margin by 50 to 100 basis points annually going forward starting in 2026.

Operator
Thank you. And your next question comes from Matt Taylor with Jefferies. Please state your question.

Matt Taylor
Hi. Thanks for taking the question. I just wanted to ask a couple of follow-ups on some of the nuanced TAVR dynamics that were asked about before. One is, would you venture a guess at what proportion of the Boston Scientific exited sales you could get? What's kind of your fair share of that? And then Larry was asking before about the NCD, and I understand the motivations to open that up. But what actual impact do you think that could have on capacity and volumes if it were to change to one operator and to reduce the volume requirements, et cetera?

Larry Wood
Yeah. Thanks, Matt. Thanks for the question. It's really too early to comment on both, but I'll try to give you some directional comments. I think as it relates to Boston, the biggest thing is that there's a difference in price point here. And I think this has been one of the things that we've been talking about for a while that I'm sure everybody is aware of. Our platform is backed by the most evidenced by long-term data by our long-term clinical trials. I mean, we just put out 10-year data from our PARTNER II trial that shows the incredible durability of our platform and low reintervention rates. And what we really need is people to value that long-term data and value all the things that our platform brings to the table rather than making their decisions based on price. But we're going to have to see how the market plays itself out. If they stay price focused, then they'll just move to another similarly priced product. If there's a lesson to be learned from this, hopefully it's that evidence matters and these long-term trials matter. And so, we'll see what our fair share is when we get to the end of that.

As it relates to the NCD, it's impossible to know what they're going to do with operator requirements, and it's impossible to know what they're going to do with facility requirements. But given where this procedure has come and how safe it is in the long-term data -- and we've already proven that we can roll it out to more than 850 centers really successfully and drive high-quality outcomes. There really is a time to open up a lot more centers that would be able to do this procedure that had the expertise. How many they allow us to open will determine how much it will impact capacity, and we'll see how that goes. But if we look at the other NCDs that have been done recently, there seems to be directionally taking a lot of these operator requirements away and taking a lot of these facility requirements away. And so, given the evidence we have on TAVR, well over 1 million -- 1.2 million patients treated with our platform alone, we seem to have a lot of data and a compelling case to make for reducing a lot of these restrictions. But we'll just have to see how that plays out when it opens.

Matt Taylor
Thanks, Larry. Congratulations.

Operator
Your next question comes from Anthony Petrone with Mizuho Group. Please state your question.

Anthony Petrone
Thanks. And I'll echo, Larry, congratulations. Great working with you and good luck on the next chapter year. Maybe a little bit on the US TAVR backlog. It typically sits at around somewhere in the three- to six-month range, and with asymptomatic not being in there in this quarter, it seems like at least something changed that the backlog was able to be mined a little bit more efficiently. So, maybe just a little bit on TAVR backlog in the US. And maybe did you see any workflow improvements? And I'll have one quick follow-up on mitral.

Larry Wood
Well, thanks, Anthony, and thanks for your kind words. I think what you're calling a little bit of backlog there I don't know that we would necessarily use that terminology. I think as patients move through the system, there's just a lot of steps they have to go through. They have to see two specialties. They have to be scheduled for multiple visits. They have to get a CT, and there's all those things that they have to go through the process. And depending on the center and depending on what their image capacity is and the waiting times to get imaging, it can easily take a patient three to six months to work through that system, and that's just what it takes to do. I think what I referenced earlier and what I think we are seeing now is just a real renewed focus on these patients. I don't think we've seen a marked reduction in the time that patients are moving through the system. I think we're probably -- hopefully seeing an uptick in referrals and just a renewed focus on making sure these patients get timely referral and timely treatment. So, I think that's what we're seeing now. But it's going to take a couple of quarters to really quantify this, and that's what we're waiting for. But clearly, we've seen some momentum here and a lot of attention. If you were at the New York Valve meeting, they opened the meeting with the early TAVR data. There was a huge debate about how patients should be referred. And then [inaudible] talked about the tech AF [sp] and that completely normalized the gender bias that we see in treatment rates. So, there's just a tremendous amount of attention on this, and I think that's what's really driving things from a mind share standpoint.

Anthony Petrone
And then a quick follow-up on mitral is just, when you think about mitral following TAVR, severe symptomatic is kind of the on-label indication. The penetration in severe asymptomatic is marked in the low single digits, and Abbott's out there with the repair MR study, which I think reads out early next year. And so, where do you see severe asymptomatic for mitral from minimally invasive in terms of penetration? And what do you think can happen when we get more data potentially from competition here early next year? Thanks.

Unknown
No, sure. I appreciate the question. If you look at the treatment of mitral disease, we see that the -- there's a huge number of patients with mitral disease, very similar to what we see in the severe symptomatic aortic stenosis numbers in the US, but the actual number of treatments are much, much smaller. As a result, we're much, much earlier than TAVR as we think about, hey, how do we just penetrate -- how do we penetrate or how do we help more patients with this

technology. And you spoke about it from a little bit of a tier angle, but I think we look about it a little bit more broadly, meaning that mitral disease today, there are so many different patient anatomies where we actually really believe having multiple modalities, both here and mitral replacement, will help us help treat the most number of patients.

And again, probably a little bit differently than aortic stenosis, we have both degenerative unfunctional etiologies where different technologies like repair and replacement can help these technologies a little bit more differently. And so, what we're starting to see in Europe, and we've just got M3 now into our European market, is that M3 is really adding treatment to patients who didn't have treatment before. And I know you're speaking a little bit about it from a asymptomatic or other kind of thing. I guess I'll just speak about it from a severe symptomatic group where they're tons of patients out there who tier unfortunately, is not a great solution for, and it's uneligible [sp]. And with M3 now, we have -- can treat a larger number of people.

And we're excited that with M3 now in Europe will eventually be bringing it to the US now in the first half of next year so the US can fulfill that next part of having both a repair and a replacement technology to help treat mitral. So, for us, I understand how you took it from different angle, I guess I'll put it on to, we have so many patients coming through the pool right now. There's such undertreatment that people today with mitral disease don't have a treatment that as we get repair and replacement, we have a whole great number of patients to just help with these new solutions.

Operator
Thank you. And your next question comes from Vijay Kumar with Evercore ISI. Please state your question.

Vijay Kumar
Hey, guys. Thanks for taking my question, and, Larry, I wish you all the best in your transition. Maybe my first question, Scott, for you on the back half margins here is -- I know there are moving parts between FX tariff. Can you just walk us through what the implied back half gross margin is? And I think the EPS guidance for 3Q in place maybe a 25-ish kind of operating margins. Am I looking at the right way on margins? And if 25% is the right number, are you assuming a full quarter of JenaValve impact?

Scott Ullem
There are several questions in there. Let me try to hit them. I'll start with the last one. So, for JenaValve, our hope is that we get to closed in August. So, we'd see some impact in Q3, a full quarter of impact in Q4. That's in the assumption for 2025. In terms of margins, FX has hurt our gross profit margin rate. It's actually benefited earnings per share because we're getting more sales and profit from outside of the US translated into the weaker US dollar. So, it's sort of the two edged sword. Lower gross margin rate but higher EPS dollars. And I think -- what was the rest of your question, Vijay?

Vijay Kumar
Tariff -- what is the tariff impact essentially --

Scott Ullem
And operating margin. So, for tariffs, we said think a $0.05 for the full year back last quarter. It's probably less than half of that now is our current expectation, which is similar to what you probably heard from other companies. In terms of operating margin, yeah, mid-20% operating margins for the second half of this year is the right modeling assumption. It's lower than the first half of this year both because of some deferred expenses that we expect to incur going forward as well as the JenaValve impact that you'd see. This has not changed from last quarter. Last quarter, the same math for the second half around 25-ish percent and same expectation now at this point.

Vijay Kumar
That's helpful, Scott. And if I may, one more. You said double-digit revenues and EPS for '26. Do you expect operating leverage for 2026?

Scott Ullem
Well, first of all, we did not say double-digit revenue for 2026. We said that we feel good about the prospects as we look ahead to 2026. Certainly, our target, as you know, because that's our annual average revenue target, but don't assume that 10% is going to be the bottom of our guidance range when we get to the December investor conference. In terms of operating leverage, yeah, as we've said, we're targeting 50 to 100 basis points of -- of EBIT margin on a constant currency basis increase starting in 2026.

Vijay Kumar
Thank you.

Operator
Thank you. And your next question comes from Matt Miksic with Barclays. Please state your question.

Matt Miksic
Hey. Thanks so much for taking the questions and congrats on a really strong quarter. Echo everyone's comments, Larry, and it's been great working with you. Hope we could continue to connect in your new ventures. So, maybe following up on some of the questions on average strength in the quarter, how should we think about that Q2 strength as we move into what's kind of a typical seasonal Q3? And then also just any comments on -- Japan has bounced back nicely. Europe is strong, but rest of world really looked like it accelerated this year from last year. Maybe any comments on that. And I have one follow-up on TNT if I could.

Larry Wood

Yeah. Thanks, Matt. Thanks for your kind words. I think we adjust our guidance accordingly, so we tried to account for all of the things that we know right now and where our confidence is. And so, we do typically see seasonality in Q3 probably more pronounced in Europe than it is in the US, but we tend to see it a little bit globally. But all of that is factored near our guidance, and I think we feel great about the momentum and where we're going. And so, hopefully that continues, and that's what we expect. Japan, we remain focused on a little bit of share recapture there and reaccelerating that market. And that's really where we are there, and we're continuing to work on that, and I think we're all committed to driving that in that manner.

Matt Miksic
Sure. Yeah, in rest of world? That was the part that I saw really popped up here this year.

Bernard Zovighian
Yeah. TAVR is a global business, Matt. We are very pleased about that. We are present almost in every country. It is a global business. It's growing everywhere. Going well. So, yes, we mentioned the rest of the world because it is not just about the US, even though the largest region for us are the US, Europe, and Japan. But rest of the world matter and is doing very well.

Matt Miksic
Great. And then just cut on TMTT. A lot of enthusiasm coming out of New York Valve. It's obvious that you have a lot of runway here as you'll be the only provider I think for some time on repair replacement in tricuspid or mitral. I know you're getting a lot of attention to those accounts. Maybe talk about what -- it is not competition at the moment anyway across all of those indications. What are some of the places you're spending your time? Is it new centers? Is it imaging and radiology support training? Maybe help us understand what are the gating factors to growth as you kind of -- as you say, work as fast as you can to meet that demand. Thanks.

Bernard Zovighian
Matt, let me start. I love your comments. Indeed, we are going to be the only provider of repair and replacement technology for many years. And this is the result of who we are as a company and our unique innovation strategy. We are bold. We are long-term focused, and we invest where nobody else is investing. So, eight years ago, we believe in this portfolio. And today, indeed, we have this portfolio, and we are the only one who is going to have this kind of portfolio for many years. So, thanks. We are going to take care of patients we are going to help train physicians to make sure they can take care of these patients. But, Daveen, you want to talk about where are you spending your time and all of these --

Daveen Chopra
No, I'll add a little bit more to it. Clearly, there are a lot of angles to therapy development, and that's what we're doing here. We're taking new therapies and bringing it to patients. And so, for us, right, yeah, there's a part about technologies we've been talking about. How do we launch

these new technologies for the first time and get them to patients to add new treatment? And then, yes, there's new geographies around the world. We're launching PASCAL for the first time in countries around the world and eventually EVOQUE and eventually M3 will then follow up. And then there's new clinical data that's coming out. We look forward to the ENCIRCLE clinical data at TCT, et cetera. And to do all this, you've got to have that great market access, making sure you have not only regulatory approval, reimbursement and to your point is great physician training, et cetera, to ensure that our field force has trained well, and physicians are trained well. So, it's hard to pinpoint just one area, but I think -- the hope that I give you is that we're added -- we're putting these different layers on top of each other, and they're going to lead to layer or catalyst -- [inaudible] catalysts of growth as we keep moving forward across therapies, geographies, et cetera.

Operator
Thank you. And ladies and gentlemen, we have time for one final question, and that question comes from Chris Pasquale with Nephron Research. Please state your question.

Chris Pasquale
Hey. Thanks for squeezing me in. I wanted to circle back to the MCD and how that could change things from a practical perspective when it does come. I'm curious what you're seeing so far from the local MACs when asymptomatic cases do get submitted. Are they getting paid for smoothly? Or is that a meaningful friction point in certain regions? And then maybe help frame the situation over in Europe for us. Does having the indication over there ensure broad access? Or are there other states -- steps that need to take place? And if it's the latter, what's the time line we should think about for those?

Larry Wood
Yeah. Thanks for your question, Chris. In terms of how things could change from a practical perspective, I think it's a lot of things we talked about before in terms of operator requirements, in terms of the patient flow, in terms of the facility requirements. And so, I don't know I have a lot more to add to that. In terms of how the local MAC cover this, when something is not covered in a national coverage decision, people submit on a case-by-case basis, and those get evaluated individually by local MAC. I will say, in the early TAVR clinical trial, I'm not aware of anybody having difficulty getting their patients covered. So, I don't know how much of a headwind it is. But that being said, we do know that there are some big hospital systems that are saying we're going to wait until the NCDs updated because we simply don't want to take the risk of having cases rejected by a local MAC. And so, this is why we've always said that asymptomatic is going to be a little bit of a slow burn.

First, you're going to get the indication. The next thing that we need to do is the NCD and guidelines, and we'll see which of those go first. But each one of these things I think is incrementally going to change how patients get managed. And that's why we've always said that we think this has -- it's not going to be a step function, but it's going to be a long-time contributor to what we're doing as we streamline these things. In terms of Europe, they --

talking about Europe, it's not a homogeneous place. Every country has their own different reimbursement systems. I think much like the US, getting the indication first is the number one thing. And so, we do have the CE Mark. We just recently received that. And so. that really is what starts the process. And so, having those approvals, both FDA and CE Mark, give us a unique opportunity to engage on guidelines. It gives us the opportunity to engage with the reimbursement groups and make sure this gets covered for patients. But we just got this approval literally like a week ago, so it's probably a little early in the process for us to be very definitive, but it gives us a license to go start having those conversations because it's now on label.

Chris Pasquale
Great. Thanks, Larry, and best of luck with your next adventure.

Operator
Thank you. And we have reached the end of the Q&A session. I'll now hand the floor back to Bernard Zovighian for closing remarks.

Bernard Zovighian
Okay, everyone. Thanks for your continued interest in Edwards. Scott, Mark, [inaudible], and I welcome any additional questions by telephone. Thank you so much and have a great day.

Operator
Thank you. And this concludes today's call. All parties may disconnect.