

Edwards Lifesciences Corporation
First Quarter 2025 Results
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Presenters

Matt Wilterding, SVP, Global Finance
Bernard Zovighian, CEO
Scott Ullem, CFO
Daveen Chopra, Global Leader, TMTT
Larry Wood, Global Group President, TAVR and Surgical

Q&A Participants

Larry Biegelsen - Wells Fargo
David Roman [sp] - Goldman Sachs
Travis Steed - Bank of America
Robbie Marcus - JP Morgan
Vijay Kumar - Evercore ISI
Matt Taylor - Jefferies
Joanne Wuensch - Citibank
Pito Chickering - Deutsche Bank
Chris Pasquale - Nephron
Patrick Wood - Morgan Stanley

Operator

Greetings and welcome to the Edwards Lifesciences first quarter 2025 results. At this time, all participants are in a listen only mode. A question-and-answer session will follow the formal presentation. If you require operator assistance during the conference, please press star zero on your telephone keypad. As a reminder, this conference is being recorded. It is now my pleasure to introduce you to your host, Mark Wilterding, Senior Vice President, Global Finance. Thank you, Mark. You may begin.

Mark Wilterding

Thanks, Alicia, and thank you, everyone, 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, and Wayne Markowitz, our Global Leader of Surgical. Just after the close of regular trading, Edwards Lifesciences released first quarter 2025 financial results. During today's call management will discuss those results included in the press release and accompanying financial schedules and then use the remainder of 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](https://www.edwards.com).

Edwards' guidance reflects its current estimates of the impact from tariffs that are in effect or has been announced as of the time of this press release and assume such tariffs remain in place for the remainder of 2025. Any modification to such tariffs or new tariffs could have a material impact on the company's future, financial results, and guidance. 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 this call are also included in today's press release. Quarterly and full year growth rates refer to continuing operations and do not include discontinued operations. With that, I'd like to turn the call over to Bernard for his comments.

Bernard Zovighian

Thank you, Mark. Welcome, everyone, thank you [technical difficulty]. Total company sales grew 8% to \$1.41 billion in the first quarter, reflecting the benefits of our broad and differentiated portfolio of therapies to treat patients with structural heart disease. The many milestones achieved in Q1 are the result of our focused strategy and our decades of unwavering dedication to driving breakthrough innovation in pioneering and leading categories. Collectively, these milestones mark the significant progress we have made to unlock this large and growing opportunity to transform care for millions of structural heart patients around the world. I'd like to thank our 16,000 global employees for their many contributions to advancing patient care.

TAVR growth in the quarter was better than expected as clinicians continue to adopt our best-in-class SAPIEN technology. Looking ahead to the rest of the year, we continue to believe that the results of EARLY TAVR trial represents a multiyear growth opportunity that will begin with the expected indication approval in the second quarter and expand with the evolution of policy and guideline changes in the U.S. and globally. And in late 2026, we look forward to the presentation of the results of a groundbreaking progress trial, which has the potential to further expand the therapy to many new patients with moderate AS. I am proud of our commitment to TAVR innovation and high-quality science that is increasing the access to treatment options for all AS patients.

We continue to be pleased with TMTT's strong momentum, reflecting our portfolio of differentiated repair and replacement technologies, and we are raising our 2025 TMTT sales guidance range to \$530 million to \$550 million. As a reminder, our successful TMTT strategy position us to become the first to develop and launch a transcatheter tricuspid valve with EVOQUE in 2024. Today, I am also very proud of the recent approval of our SAPIEN M3 in Europe, the world's first transcatheter mitral valve replacement system, which will benefit

many patients with mitral regurgitation who have limited treatment options. This breakthrough technology demonstrates our team's long-term and steadfast commitment to solving large, unmet patient needs. Edwards with EVOQUE, M3, and PASCAL is uniquely positioned to meet the broad and diverse needs of patients with tricuspid and mitral valve diseases. In surgical, our category-leading business continues to benefit from increasing adoption of our premium RESILIA portfolio in INSPIRIS, MITRIS, and KONECT. Edwards continues to invest in surgical innovation and evidence as we expand access to our therapies globally.

Last week, at the Heart Valve Society meeting, eight-year data were presented, demonstrating the excellent durability of a company's novel RESILIA issue, which is used in a wide range of Edwards surgical platform as well as SAPIEN 3 Ultra RESILIA. The results represent the longest follow-up study on the durability of valves, which highlights our dedication to pioneering unique innovation. With patients of all ages living longer and seeking higher quality of life, the importance of lifetime management has never been greater. We also continue to make steady progress advancing our portfolio of emerging opportunities, which we discussed at our investor conference in December. Our team continued to build capabilities to reach the millions of patients around the world who suffer from structural heart failure. And AR, in aortic regurgitation, we're enrolling patients in joining the pivotal trial for the Edwards J-Valve AR system.

Turning to our 2025 financial outlook. We are confident in our full year total company sales growth guidance of 8% to 10%, and we have plans in place to offset the estimated impact of a currently announced tariffs and the estimated dilution from the JenaValve acquisition, which we are planning to close midyear. As a result of our plans, we are in a position to deliver on our original EPS guidance of \$2.40 to \$2.50. Our priorities continue to be serving the patients who count on us and maintaining the highest level of service and support to our physician partners around the world.

Looking ahead to 2026 and beyond, Edwards is positioned to transform care for the many structural heart patient needs. We are confident that our strategic focus, unique innovation strategy, and exceptional work of our employees around the world will deliver significant value to patients, to health care ecosystem, and shareholders. Now I will provide some additional detail by product group for Q1. In TAVR, our first quarter global sales of \$1.05 billion increased 5.4% over the prior year or 6.5% when adjusted for billing days, which was a little higher than expected. Growth was comparable in the U.S. and OUS.

Edwards' strong competitive position and pricing remained stable globally with some regional variability. I am proud of our team's commitment to leading with science, supported by a decade of clinical research that set the standard for quality evidence and physician decision-making. This significant body of high-quality science from rigorous FDA trials underscores the excellent clinical outcomes delivered by Edwards' premium SAPIEN technology. Last month, at the American College of Cardiology Conference, new clinical data from the EARLY TAVR trial studying patients with asymptomatic severe AS were released. The data highlighted that

delayed aortic valve replacement in this patient population was associated with worse outcomes.

Additionally, a new study using cardiac biomarkers reveal that the rapid and unpredictable progression of disease. Both studies underscore the need for urgent referrals for treatment, evaluation for severe AS patients regardless of symptoms. Also at ACC, new groundbreaking data from the DETECT AS study were presented. DETECT AS is the first randomized trial evaluating the impact of physician notification or equivalents [sp] for their patient with severe AS that meet treatment guidelines. The study found that these equivalents increased both treatment and survival rate for patients with severe AS. In the U.S., our leading SAPIEN 3 Ultra RESILIA platform continues to demonstrate strong performance. We are advancing initiatives to help hospitals treat structural heart patients efficiently and manage increasing procedure volumes.

We are encouraged by hospitals that have demonstrated the ability to scale to accommodate for severe growth. We are encouraged by discussion with key clinicians on the long-term impact of EARLY TAVR data to streamline patient care. In addition, we expect asymptomatic indication approval in the second quarter. Outside of the U.S., we continue to focus on the value of our differentiated technology and increasing therapy adoption, especially in areas where TAVR remains underutilized, and many patients go without care.

In the first quarter, sales growth was supported by the continued expansion of SAPIEN 3 Ultra RESILIA in Europe. SAPIEN 3 Ultra RESILIA continues to deliver exceptional clinical outcomes, reinforcing the differentiation of this best-in-class platform. In Japan, we continue to face weaker procedure growth environment and competitive pressure. We remain dedicated to addressing the significant undertreatment of AS among the substantial elderly population in Japan. In summary, for TAVR, we are maintaining our full year sales growth guidance of 5% to 7%. Long-term, we are enthusiastic about the durable mid to high single-digit growth opportunity in TAVR, supported by the upcoming EARLY TAVR indication approval, guideline and policy changes, and the potential to serve patients with moderate AS.

Turning to TMTT. Our unique and increasingly differentiated portfolio drove another quarter of impressive growth with a meaningful contribution to overall company performance. We are pleased with first quarter sales of \$115 million, representing growth of about 60% and led by increased adoption and balanced contribution from PASCAL and EVOQUE in the U.S., Europe, and globally. We continue to see strong therapy adoption and expansion across both mitral and tricuspid. Globally, mitral tear procedures continue to grow double digits, and the developing tricuspid opportunity is growing even faster across both repair and replacement. PASCAL continues to demonstrate its value for patient care. It's differentiated features are driving distinguished clinical outcome, and adoption is increasing at both new and existing sites around the world.

The EVOQUE commercial launch is progressing well in the U.S. and Europe, with continuing excellent patient outcome. At the end of March, we were pleased to see the finalization of the NCD for transcatheter tricuspid valve replacement for patients suffering from tricuspid disease. With the new NCD, EVOQUE is now covered for all Medicare beneficiaries who meet the criteria outlined in the final coverage policy, expanding patient access to this important therapy. We are pleased with the recent approval of SAPIEN M3 mitral valve replacement system in Europe. This revolutionary transcatheter valve therapy is built on the proven SAPIEN platform, which has been used in more than 8,000 procedures in the mitral position. We continue to expect that results from the ENCIRCLE pivotal trial studying M3 will be presented at the TCT Conference in October 2025.

In addition, as part of our deep commitment to advancing science for patients with structural heart disease, a European post market follow-up study is planned to continue evaluation of SAPIEN M3, following patients out to five years. As previously shared, we expect U.S. approval of SAPIEN M3 to follow in 2026. The launch plan for SAPIEN M3 in Europe is focused on creating a new category as we have done many times before and achieving excellent patient outcomes. With our decades of experience, we are uniquely positioned to bring SAPIEN M3 to the many patients in need across Europe. We will work with all stakeholders to ensure patient access to this novel therapy, providing physician training and working with policymakers to establish proper therapy coverage.

Edwards is the only company that offers the transcatheter portfolio that includes both replacement and repair treatment option for both the mitral and tricuspid valves, meeting the complex needs of underserved patients. We are committed to bringing this portfolio to patients in need around the world and expect meaningful impact from these advanced therapies in '26 and beyond. In our surgical product group, first quarter global sales of \$251 million increased 3% over the prior year. We continue to see positive procedure growth globally for the many patients, best treated with Edwards premium RESILIA portfolio including MITRIS, INSPIRIS, and KONECT.

We continue to generate high-quality evidence on our RESILIA tissue technology. As shown in the eight-year data presented at the recent Heart Valve Society meeting, RESILIA tissue valves had significantly improved freedom from structural valve deterioration and freedom from reoperation compared to non-RESILIA valves. Also in the quarter, our surgical team made progress advancing important innovations around the world. MITRIS launched in China with positive surgeon feedback, and we anticipate receiving CE Mark approval for the KONECT aortic valve conduit in Europe before year-end. And now, Scott will cover the detail of the company's financial performance.

Scott Ullem

Great. Thanks a lot, Bernard. As Bernard mentioned, we are pleased with our first quarter total company sales performance and progress on our strategic milestones, which gives us confidence in our full year outlook. We are raising our original sales guidance range for TMTT to

\$530 million to \$550 million, driven by more favorable foreign exchange and continued business momentum. Total company, TAVR, and surgical sales growth guidance ranges remain unchanged, but the company is increasing our original total company sales dollar guidance range by \$100 million to account for recent movement in FX rates. Edwards now expects total company sales of \$5.7 billion to \$6.1 billion in 2025. So, now I'll cover additional details of our Q1 results, starting with earnings per share. We generated adjusted EPS of \$0.64 in the quarter with solid operating performance. Our GAAP EPS for the quarter was \$0.62. A full reconciliation between our GAAP and non-GAAP measures, including adjusted EPS and other items, is included with today's release.

Moving on to other elements of the P&L. For the first quarter, our adjusted gross profit margin was 78.7% compared to 78.5% in the same period last year. We are maintaining our full year 78% to 79% gross margin guidance at this stage. However, we do expect some pressure from the weakening dollar, the impact of announced tariffs, and the expected close of the JenaValve acquisition. Selling, general, and administrative expenses in the quarter were \$466 million or 33% of sales, which was better than our expectation for the quarter, driven by lower sequential spending and deferral of certain strategic investments originally planned for Q1. Research and development expense of \$255 million in the first quarter was equivalent to 18% of sales, a reduction from 19.6% of sales in the previous quarter. This lower ratio of spending reflects the company's prioritized investments in our structural heart portfolio in areas where we believe there are significant opportunities for breakthrough innovation and profitable growth.

Adjusted operating profit margin in the first quarter of 29.1% was driven by better-than-expected sales and favorable mix as well as some variable expenses delayed beyond Q1. We expect pressure on our operating margin as a result of the weakening dollar, the impact of announced tariffs, and the expected midyear close of the JenaValve acquisition. However, we are implementing plans to mitigate these anticipated costs, and we maintain our full year operating margin guidance of 27% to 28% and our EPS guidance of \$2.40 to \$2.50. We continue to expect our 2025 tax rate excluding special items to be between 15% and 18%.

Foreign exchange rates decreased first quarter reported sales growth by 170 basis points or \$22 million compared to the prior year. FX rates positively impacted our first quarter gross profit margin by 40 basis points compared to the prior year. Relative to our February guidance, FX rates had a nominal impact on first quarter earnings per share. At current rates, we now estimate no impact from foreign exchange on reported sales in 2025 relative to 2024 versus our investor conference guidance of a \$100 million reduction. As a reminder, our hedging strategy is designed to mitigate the impact of foreign currency fluctuations on the original EPS guidance we provided in December.

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 the end of the quarter. During the first quarter, the company entered into an ASR agreement and repurchased stock through a pre-established plan totaling \$300 million. Edwards has approximately \$1 billion remaining

under our share repurchase authorization. Average diluted shares outstanding during the quarter were 588 million. We continue to expect average diluted shares outstanding for 2025 to be between 585 million to 595 million. So, I'll finish with one final guidance comment. For the second quarter, we're projecting sales of \$1.45 billion to \$1.53 billion and adjusted earnings per share of \$0.59 to \$0.65. And with that, I'll pass it back to Bernard.

Bernard Zovighian

Thanks, Scott. Before I close this afternoon, I want to take a moment to acknowledge an important anniversary for the company. It was 25 years ago this month that we rang the bell at the New York Stock Exchange and officially began our journey as Edward Lifesciences. Since then, we have transformed care for millions of structural heart patients around the world, solving large and complex patient needs and pioneering therapeutic categories. And our future is bright. Our foundation remains strong, and we will continue to bring new innovation to the many structural heart patients in need around the world. With that, turn it back to Mark.

Mark Wilterding

Thank you very much, Bernard. We are ready to take your questions. As a reminder, please limit the number of questions to one plus one follow-up to allow for broad participation. If you have additional questions, please reenter the queue, and management will answer as many participants as possible during the remainder of the call. Alicia, I'll turn it over to you.

Operator

Thank you. We'll now be conducting the question-and-answer session. If you would like to ask a question, please press star one on your telephone keypad. A confirmation tone will indicate 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 headset before pressing the star keys. One moment, please, while we pull for questions. Thank you. Our first question comes from the line of Larry Biegelsen with Wells Fargo. Please proceed.

Larry Biegelsen

Good afternoon. Thanks for taking the question. Congrats on a good start to the year here. And, Scott, you can probably anticipate the first question. You're maintaining the EPS guidance despite the tariffs and the JenaValve acquisition and maybe even currency. So, obviously, people would love to hear you parse out how much each of those impact 2025. And how much lower could the gross margin be relative to the guidance? And I have one follow-up.

Scott Ullem

Sure. So, let's go through the three elements, Larry. Thanks for the question. On FX, our hedging program is designed to mute the impact of foreign exchange changes on our EPS. So, the real impact is from tariffs and the JenaValve acquisition. For tariffs, it's probably about \$0.05 to EPS based upon the tariffs that are already in place. And just a little color --

commentary on tariffs. We may not be as complex as some others because we operate just a handful of production facilities that are strategically located with our key business regions.

And we also already have a lot of production in the U.S. And so, think \$0.05 associated with the 10% tariffs. Now, that's just for 2025. The tariff impact is higher than that. But as you know, they get capitalized into inventory and recognized in our P&L as finished goods are sold. So, the bigger impact is in 2026, but it's premature to be offering any guidance or speculation about what tariffs could look like when we get out there. For JenaValve, we think the impact is probably in the range of \$0.05 to \$0.10. Keep in mind, we don't have current information. We haven't closed the deal yet. But based upon our estimates and the preliminary plans we have for integration, that's probably a good modeling assumption at this point.

Larry Biegelsen

That's very helpful. And a follow-up for Daveen on tricuspid. Congratulations on the NCD for EVOQUE. How do you see the NCD impacting the ramp of EVOQUE? Thanks for taking the questions.

Daveen Chopra

Thanks, Larry. Thanks so much for the question. Right? We -- yeah. We continue to be excited as EVOQUE as a new category for us, right? It's a great product. And the NCD, as you know, was effective now in March of 2025, and this is a transcatheter tricuspid valve replacement NCD. The NCD ensures that both the standard Medicare as well as the large Medicare Advantage patient groups have access to EVOQUE as outlined in the final coverage policy. This coverage policy was very much in line with our expectations, so it's kind of built into our guidance this year. We love the components of this NCD, including within an FDA-approved indication under a heart team and in the context of CED or coverage with evidence development to collect additional data on the therapy. So overall, it is in line with our expectations of 2025 being full steam with activating new sites and continuing to treat more patients with EVOQUE who are getting excellent outcomes. And this is the start of a great multiyear kind of growth opportunity for treating more patients.

Larry Biegelsen

Thanks so much.

Operator

Thank you. Our next question comes from the line of David Rowan [sp] with Goldman Sachs. Please proceed.

David Rowan [sp]

Thank you. Good afternoon. I wanted just to start on the TAVR business. And maybe you could talk us through a little bit what you're seeing on the ground as it relates to either referral patterns or physician engagement post the presentation of EARLY TAVR now that we're kind of six months-ish following TCT. And then maybe walk us through specifically what happens once

you get the indication expansion approved and what the plan is to start to support market development effort and when we should see that show up in numbers. Then I have one follow-up.

Larry Wood

Thanks, David. Yeah, that's a great question. Well, first of all, I think the data set was very, very strong that we presented at TCT, but it does take physicians a little bit of time to work their way through the data and really understand the important nuances. We followed up those -- the TCT with a very strong deep dive at ACC, and there was a few things that came out of that. One was the unpredictable nature of these patients that have asymptomatic aortic stenosis. And I think one of the things that a lot of people have been utilizing and have been focused on is the use of biomarkers and the thought being that biomarkers would be predictive and would help physicians understand what asymptomatic patients they should refer and what patients they could safely wait on.

And I think the surprising data that came out at ACC said the biomarkers were actually not predictive. They did not predict which patients had more serious events versus which patients just had a progression to more mild symptoms. So, I think it just really stresses that these patients need to get referred. They get worked up by the heart team. And we've continued to work with the clinical community and our physicians to make sure we amplify that message. But, of course, all we can do right now is just to educate people on the publications on the data. We can't actually promote in any way, shape, or form treating patients who are truly asymptomatic because we don't have the indication yet. We do expect that to come before midyear, so we're on track for that. And the minute we get the indication approval, we have a very detailed education plan. We can then begin reaching out to the referral base and doing all of the other things that we want to do to help amplify this message. But again, we expect the approval to happen in Q2.

David Rowan

Got it. Thanks for the detail there. And then on the TMTT side, as you kind of look 12 to 24 months forward, I believe you'll have tricuspid repair and replacement, mitral repair and replacement available U.S. and OUS. So, can you maybe help us just think about market segmentation a little bit in that category? How should we think about mix between repair and replacement today and going forward? And whether this category is more of a sort of quote, toolbox approach for physicians or you think it converts to a one size fits all be it in mitral or tricuspid?

Bernard Zovighian

Thanks, David. Let me start, and then I will ask Daveen to add some additional details. I want to start where we were a few years ago. We knew that TEER technology and repair technology were not going to be sufficient to unlock the full potential of a mitral and tricuspid space. So, it is why we went in with the toolbox. And we brought first PASCAL highly differentiated. And you have seen the kind of impact in the way [inaudible] to patients with PASCAL. But we know that

many patients cannot be treated with TEER. So, therefore, we launched -- we were the first to launch EVOQUE, which is going very well, and we see -- we are putting more patients than just TEER patient, tricuspid patients with EVOQUE. With M3, it is the beginning of the same journey here. It is going to take us multiple years to train physicians, expand. So, to give you a sense about segmentation right now, it is a little bit early. But Daveen is very close to that, so maybe I'll ask Daveen to bring some color here.

Daveen Chopra

Yeah. As Bernard said, it's hard to give exact segmentation, but I'll try to give you at least some thoughts we have. Today in Europe now, as Bernard said, we have now repair and replacement for each mitral and tricuspid. So, we believe with the two technologies together, we can treat a larger group of patients. Clearly, in the mitral side again in Europe, M3 has just gotten approved. And for SAPIEN M3, it will be over time to really build out this category, to train physicians, to get appropriate payments, et cetera, over time. And for that, we see -- we remember that the M3 that this is a product that's geared toward the TEER and mitral surgery unsuitable patients, so for patients who don't have TEER or surgery options. So, over time, we still believe TEER for coming years will be the largest part. And then eventually over time, mitral will continue to grow -- mitral replacement will continue to grow in its treatment of people offering that new option.

In tricuspid in Europe -- again, it's a little difference in the U.S. -- than U.S. where tricuspid TEER has been around for many years. And now the new category of EVOQUE has been recently created in Europe where we're now adding more patients to the pool who are both tricuspid surgery and tricuspid TEER ineligible. So, now we're adding new patients who don't have an option in producing these amazing results. And so, that's how we see the European market progressing in the next couple of years. The U.S. will have a little bit different dynamics, but you'll still see that because TEER has been very well established in the mitral space, we see mitral replacement as an additive therapy, bringing patients off the sideline and offering a solution that they didn't have before.

In the tricuspid space, as you know, both repair and replacement entered the U.S. market at similar times. So, the clinical community right now is learning together about, hey, which is the best repair patient and which is the best replacement patient. We've seen from experience in Europe so far that having a repair and a replacement solution is really important for treating the maximum number of patients. But the exact ratio, we're going to figure that out together with clinicians in the coming years.

David Rowan

Great. Thanks so much.

Operator

Thank you. Our next question comes from the line of Travis Steed with Bank of America. Please proceed.

Travis Steed

Hey. Congrats on the quarter. First question I wanted to ask on TAVR capacity constraints and the potential for the TAVR, NCD to loosen some of the requirements or essentially broadened some of the number of centers available to treat and some of the some of the ways that capacity constraints could be eased over time.

Larry Wood

Sure. Thanks for the question. Yeah, we certainly feel it's the time to reopen the NCD. We think there's a number of things that need to be updated. The first is the NCD needs to specifically cover asymptomatic patients just to ensure national coverage is standardized for all the patients that that need therapy. I think the second thing is we know that adding hospitals that could offer this therapy would improve care and give more people access. And I think that that's another important element.

In terms of more broadly on capacity, I think some of the acute capacity issues that we dealt with last year, I think we're through the worst of that. We still see centers working actively to add capabilities. And we try to partner really closely with them. We offer valve clinic coordinator training courses. So, if that's the constraint, we can certainly help them train their staff. Some places, it's more about anesthesia, and so we can bring in experts to help them adopt conscious sedation. If they're just limited to two or three cases a day, we can bring in things like our benchmark program that can allow them to do more cases in the same time and the same footprint. So, we continue to work with them. I think the reality is we have a lot of new technology. We have a lot of new indications coming. I think hospitals realize that, and I think they are investing. We've seen that, and they'll continue to do so.

But the reality is they need to keep doing that because the indications -- right now, it's going to be in the near term, asymptomatic, but we know we already have EVOQUE. We know we have M3 coming. And then we're only year and a half away from seeing the PROGRESS data, which could be another indication expansion. So, I think the hospitals are more in tune with what the requirements are going to be on a go forward. So, I think it's going to be all those things coming together. I think it's going to be policy. I think it's going to be guidelines, and I think it's going to be those investments that are going to be the long-term solutions to capacity.

Travis Steed

Great. That's helpful. And then I have a follow-up, just a modeling question on Q2 TAVR. I think the Street said 5.8%. Just curious if there's any color you want to provide on how to model Q2 TAVR in the -- in the remainder of the year in the second half. And any days benefit to kind of call out over the course of the year for the remaining portion of the year.

Scott Ullem

[Technical difficulty] 5.4% growth in the first quarter. And to get to the midpoint of our 5% to 7% growth rate guidance for the year, it tells you we need something in the 6% range for each

of Q2, Q3, and Q4. Obviously, there's going to be some differences. We've got some changes coming during the course of the year, including the symptomatic indication. But probably the right place to model, Travis, is in that 6% range with some expected variability quarter-to-quarter.

Travis Steed

Great. Thanks a lot.

Operator

Thank you. Our next question comes from the line of Robbie Marcus with JP Morgan. Please proceed.

Robbie Marcus

Great. Good quarter. Thanks for taking the questions. Two from me. Scott, maybe just on the EPS offsets. Offsetting \$0.10 to \$0.15 for Edwards is a big move and really impressive. Maybe speak to sort of the undertaking you're doing to be able to offset that kind of headwind between tariffs and JenaValve dilution.

Scott Ullem

Yeah. Thanks for the question. Obviously, we've been anticipating the approval of the JenaValve and running a bunch of scenarios in the event that we're successful in getting it closed, which we think we will. Our guidance for the year did not anticipate an impact from JenaValve, but we've had plans to be able to take action when we got some confirmation and more confidence that we're going to get it closed. So, we're ready to go. We do think that spending will step up a bit in the second quarter because it was lower than what we originally had planned and expected in Q1, and that's really the reason why we ended up with \$0.64 a share in EPS in the first quarter.

We're going to be looking at things like investments that we are planning to make that are more discretionary in 2025 that will not impact our sales guidance for this year. But at this point, we're not going to get into a lot more of the detail about where those items are. I mentioned in the prepared remarks that we're really focusing hard on prioritizing our R&D investments and really focusing things that can drive top line organic growth and profitable growth and earnings over the long-term. And we're going to keep doing that. And again, I think we can continue to execute our focused strategy while also doing what we need to do to offset those headwinds that we're facing now in 2025.

Bernard Zovighian

So, just to add on that -- Scott, well said. I will say we are very pleased about the way we are starting the year. Strong Q1. Sales slightly better than expected. EPS, top end of our range. We are -- we have achieved so many milestones in Q1. You have seen all of them where we are going to be able to create a new category for us. Think about a multiyear growth opportunity ahead of us based on these new milestones. Then full year outlook, confident 8 to 10. Raising of

the TMTT guidance and being able to offset JenaValve dilution and basically the tariff impact. We feel good about the year. We feel good about how we are running the company.

Robbie Marcus

Thank you. Great. Maybe just a quick follow-up. The TMTT guidance range. Part of it is FX, part of it's underlying. First quarter was good but still pretty much in line with the Street. How are you thinking about the split between FX and underlying and sort of the key drivers of progression in the raise guide through the rest of the year? Thanks a lot.

Scott Ullem

Sure. I'll just confirm on FX and then pass it over to Daveen to talk about just the operational performance and our outlook for the rest of the year. For FX, think about this \$100 million benefit that we're getting through the movement in FX rates and just spreading that across our businesses. Probably about half of the increase in TMTT guidance comes from FX and the other half from operational. And then the balance of that \$100 million would be spread across the other businesses. Of course, TAVR would be the biggest place for that to go. Daveen, do you want to talk about the other half of the guidance increase?

Daveen Chopra

Yeah. On the operational side of things, as you can imagine, we continue to see great momentum on both PASCAL as well as EVOQUE. So, both are kind of key driver, both in Q1 and going forward as we just treat more and more patients from maybe -- even I'll give you just a geography components. So, it was good to look at that way, as well. We see both coming from both the U.S. and Europe. And in both these markets, PASCAL continues to show its differentiation. And EVOQUE as a new category continues to treat new patients that don't have great outcomes. So, we see continued growth happening from that side, as well.

Robbie Marcus

Appreciate it. Thank you very much.

Operator

Thank you. Our next question comes from the line of Vijay Kumar with Evercore ISI. Please proceed.

Vijay Kumar

Hey, guys. Thanks for taking my question. Scott, I had a couple of guidance clarifications, if you will. Maybe on the EPS guidance here, you called out the tariff headwinds in JenaValve. Are we expecting to offset that increment, \$0.10 to \$0.15 of headwinds completely, or should we be perhaps looking at the bottom half of the guidance range? Just maybe walk us through on what the offsets are.

Scott Ullem

Yeah. So, it's a little premature to be more precise about where within that 2.40 to 2.50, we may fall, and the reason is because we haven't closed JenaValve yet. So, part of this depends upon the timing of that close and when we start picking up some of that burn, and part of it depends upon what the integration plan looks like and what we're actually going to execute. That's why we gave a range, and that's why we think that the 2.40 to 2.50 range in EPS can accommodate different scenarios.

Vijay Kumar

Understood. Maybe one on international. Japan was a little light. Maybe talk about trends within Japan.

Bernard Zovighian

Yeah. Thanks, Vijay, for the question. So, for sure, our results in the quarter and even in the last quarter was less than expected. A little bit disappointing for us. But we are very optimistic about Japan. What we have seen is a couple of things happening. Weaker procedure growth environment. And we need to better understand that, what's happening there and also some competitive pressure. So, what we are doing is a couple of things is -- one is enhancing our capability in the region in Japan to accelerate market growth, one -- and better position our technology. You know that when -- our technology are very differentiated. When we bring our technology to patients, evidence demonstrating that they live longer, better quality of life, they avoid hospitalization, complication. So, this is the kind of value we bring. We have a good story to tell. And I believe we are going to have all the Japanese physicians responding very well to this. We are also enhancing our capability in Japan to address the situation. So, overall, long-term in Japan, we see a big potential. Aging population. There is a lot of AS patients, Mitral patients, tricuspid patients. So, clearly, an opportunity for us and opportunity to change patient care there.

Vijay Kumar

Understood. Thank you.

Operator

Thank you. Our next question comes from the line of Matt Taylor with Jefferies. Please proceed.

Matt Taylor

Hi. Thanks for taking the question. I did want to follow-up on TMTT. I heard your comments, and I guess I just wanted to confirm that none of the guidance range was really around M3. And also, just wanted to think about how to maybe compare and contrast the launch of the Mitral replacement versus what you've seen with EVOQUE in tricuspid. Should we expect it to be similar? And can you talk about when the European launch will start to contribute and what to expect from the U.S.?

Daveen Chopra

Yeah, sure. This is Daveen, Matt. I can take that question. So, first -- to the first part of your question, yes, you're correct that we had built in M3 into our original range for the year already, and the change in guidance did not have to do with the specific CE Mark or the timing of the CE Mark. We'd already kind of built it in. And as we look at this kind of therapy, we're beginning with a very controlled launch that's emphasis on this really high-touch model that we have of supporting physicians and patients to ensure the highest quality outcome. The indication, though, of Mitral replacement in Europe is different -- is more similar to EVOQUE in Europe and different than what we see EVOQUE in the U.S., meaning, as I mentioned, Mitral replacement is for patients who are unsuitable for Mitral surgery or for TEER. So, for that, yeah, we expect a gradual buildup.

And in Europe, as you can imagine, we're drawing on our therapy and our experience in how to create categories because each country in Europe is very unique. The different ways of getting incremental payment and coverage for our therapies. And we've got to work on that that one at a time, and that takes time. Additionally, we've got to train physicians, train our own team, and build it up. So, we really see SAPIEN M3 in Europe being more of a gradual long-term, important category of adding new patients with Mitral disease to be treated. And hopefully, that helps.

Matt Taylor

That's great. And then maybe you could just finish with the U.S., how that will be different?

Daveen Chopra

Yeah. So, in the U.S. from -- different than EVOQUE in the U.S., as you can imagine. Mitral replacement, again, in the U.S. will also have an indication unsuitable for TEER or mitral surgery. So again, these patients are already in the funnel. They may not be appropriate for surgery or TEER. They don't have any other option. And now for many of those POD patients, M3 will be an option. EVOQUE, as you know, when we launched it, had a different, broader indication for people for health status improvement for people with tricuspid disease. So, there's not this layer of first, are you appropriate for TEER or surgery. So, with that, we would expect that the U.S. mitral launch in general would be at a slightly slower rate probably -- would be at a slower rate than we think we saw with EVOQUE. But either way, we really see that the great news about this is that this technology replacement is really complementing TEER and adding patients to allow us for that kind of multiple years of growth as we add more patients with this new treatment.

Matt Taylor

Thank you so much.

Operator

Thank you. Our next question comes from the line of Joanne Wuensch with Citibank. Please proceed.

Joanne Wuensch

Good afternoon and thanks for taking the question. I just want to pause on the early TAVR label expansion and NCD, because I think there's a couple of different things that are happening here. And correct me if I'm wrong. One is the label expansion. The second one is the NCD. The NCD could expand the number of centers. It could expand maybe something else. And I've also heard from some physicians may be an expectation that it might eliminate the need for a cardiac surgery team in the OR. So, could you just sort of like clarify what you think may happen? And then how long after all of that starts to layer on do you think procedures start to ramp? Thank you.

Larry Wood

Yeah. Thanks, Joanne. I think there's a multitude development here. The first thing is the label expansion, which obviously is under FDA's control. And again, we expect that to happen in Q2. So, that's kind of step one. The national coverage decision, that's under the purview of CMS, and they'll decide when they want to reopen that and when they want to reevaluate it. And given the safety of TAVR, that's been demonstrated in the national registry that we have that really confirms the outstanding results across all of the centers that we've opened. We do expect there to be an expansion in the number of centers. How many will that be? That's going to be up to how they write the policy and how that plays out. And we'll see how they decide to streamline the team and try to make the healthcare system more efficient.

The third big element is guidelines, which fall under the society purview. And how do they take this data? How do they update the guidelines, so that patients with severe aortic stenosis but haven't yet pursued to symptoms, how do we make sure that they move through the healthcare system, they're properly screened, and they're treated in accordance with what the data suggests. And I think we're still in that education process with a lot of folks. There are -- sometimes people think that asymptomatic patients are automatically younger patients, but what we saw in the trial is I think the average age was 76, where for a low-risk trial, it was 73. So, these aren't necessarily younger patients. We're not necessarily treating them at a much younger age. So, I think these things are all important things that we just need to keep reiterating. And again, once we have the approval, it really takes the shackles off of being able to really advance our education platform and advance our ability to promote this. But until we get the FDA approval, we're just kind of at a standstill beyond what the physicians themselves, the investigators, and people do it at the big medical meetings.

Joanne Wuensch

Very helpful. Thank you.

Operator

Thank you. Our next question comes from the line of Pito Chickering with Deutsche Bank. Please proceed.

Pito Chickering

Hey, guys. Following up on these NCD questions, our call is that the physicians -- is that CMS is actually in sort of final discussions with the societies and the health systems about relaxing this entity to be certified to our centers and that this change could actually be coming in May or in June. Is this timing something that you guys have heard, as well?

Larry Wood

There is no predetermined timing. It opens whenever CMS decides that they want to open it, and that is completely within their purview. And no one, frankly, has any influence over that. It's completed within their realm of control. So, anybody that provides specific timing, they're simply speculating as to when they think that that could happen. So, I don't have any insights beyond what I've already stated, and it's going to be up to them. Again, we do expect that a new policy -- I think we have plenty of experience with the technology now. I do think the new policy will reflect the safety that we've demonstrated. And I do expect that at some point the policy is going to reopen. And I think one of the catalysts in front of CMS is going to be the asymptomatic approval.

And one of the things we've seen historically -- when we first got approval for SAPIEN, it was under local coverage, and it did lead to some inconsistencies with how things were done. And that really drove CMS to open the NCD because they wanted to make sure that patients across all of their constituents could be treated under a national policy. So, I expect that to happen again. When exactly is going to be completely up to them. But when they do, then we get to we get to engage with them, we get to start that process and hopefully end up with a policy that is going to allow more patients access to life-saving therapy.

Pito Chickering

Great. Then a follow-up here. Can you guys give us an update on how the demand for training for EVOQUE is going? And any color on how many sites have been trained? And -- or in a process to be trained? Thanks so much.

Daveen Chopra

No, sure. This is Daveen again. Yeah. So, first, in terms of EVOQUE sites, as you can imagine, as I think I mentioned before, we started originally with those first 50 or 60 clinical trial sites. And then from that that continuing to invest in new sites are -- work with sites that are investing in Tricuspid disease. So, that number is a growing number. We continuously are booking our trial sites out for several months in advance. So, right now, if you're interested in a trial site, it's at least a couple of months away. So, it's been consistently like that where the demand from physicians to get trained has been always a little bit greater than maybe our ability to open sites just in the ramp.

And this really, as you know, has to do with the value proposition where people are seeing how the elimination of TR with EVOQUE is really changing patients' lives, and as a result, both physicians and patients are asking for the technology. And so, in general, though, as you can imagine, as Larry just mentioned, there are, what, 850 TAVR centers or so. I mean, it's a very big

number. And our goal is some number of those would be great for Tricuspid treatment, including EVOQUE, and we continue each year just to keep opening and training new centers for many years to come, just like TAVR did over the course of many years.

Pito Chickering

Great. Thanks so much.

Operator

Thank you. Our next question comes from the line of Chris Pasquale with Nephron. Please proceed.

Chris Pasquale

Thanks. The 2.6% surgical growth this quarter was the slowest we've seen from that business in a while. I know selling days had a bit of an impact. Can you just talk about your confidence in being able to sustain mid-single-digit growth in that segment, especially now the RESILIA platforms have really become dominant in many of your big markets that you don't as much of a tailwind from mix?

Scott Ullem

Yeah, Chris. Thanks for the question there. In Q1, we did have some challenging comps when we considered -- compare it to prior year when the business was growing in the high-single-digit range. And I think looking forward in 2025, as you heard from Bernard, we're launching MITRIS in China. We've got some other potential tailwinds later on this year with the approval of KONECT in Europe. And so, we are remaining confident in our current guidance in the mid-single-digit range for 2025.

Chris Pasquale

Great. That's helpful. And I know this may be a bit difficult to answer, given that the deal hasn't closed yet, but we saw some updated data from the ALIGN AR trial at ACC. Continues to look solid. We're about 18 months out now from the original data presentation. Just any help you can give us in terms of what we should expect for a regulatory pathway and approval timing for that product?

Larry Wood

Yeah. Actually, we don't have anything that we can talk about on that. We're sort of pencils down until the deal closes. So, we don't have any direct knowledge. We're not in conversation with them. Until the deal closes, we're on the outside looking in. So, I don't have any more information than what you saw presented at ACC.

Chris Pasquale

Alright. Thanks.

Operator

Thank you. Our next question comes from the line of Patrick Wood with Morgan Stanley. Please proceed.

Patrick Wood

Beautiful. Thanks so much guys. I guess maybe on PASCAL, doing pretty well. Where are we at in terms of accounts breadth versus depth? I'm thinking like, is the utilization sort of where you would like it to be? I'm trying to work how wide you all versus how deep within individual accounts.

Daveen Chopra

Yeah, sure. If you think about PASCAL overall, we continue to see that this product has future differentiation that we believe is leading to really predictable and positive outcomes for patients. And that -- and you see that in accounts who currently have access to PASCAL that, as they use PASCAL more and more, they see those great patient outcomes, and then they want to use it more. And then as you can imagine, they then tell their friends through different types of programs and at congresses so that sites who today who don't use PASCAL are interested in trying to use it. And so, that's how we see it spreading in both increased depth in certain centers as well as opening new centers. In terms of the number of centers, maybe specific, I'll just speak to the U.S. Again, maybe I'll use the generic [inaudible]. If they are 850 TAVR centers, give or take in the U.S. or so, our goal is to grow into as many of these that make sense. But today, we're definitely in less than fewer than 50% of them. So, there's still a lot of opportunity for growth both in new accounts as well as increasing penetration and seeing those great patient outcomes in the sites that currently use PASCAL.

Patrick Wood

Thanks. That's helpful. And then very quickly, there's been a lot of shuffle around at the FDA overall and people fire, rehire that sort of things. Is there any expectation from you guys that approval time lines long-term could be affected or anything like that? Or is this a short-term noise that we can ignore?

Bernard Zovighian

Yeah. Obviously, the situation is a fluid one, and we are watching. But so far, we don't see any. any change with the FDA approval time line, response to maybe submission, all of that. So, we feel like the people at the FDA are very professional. They are very committed to the space, and we don't see any impact, and we don't believe we will see an impact. But obviously, it is a fluid situation that we need to monitor.

Patrick Wood

Awesome. Thanks, Bernard

Operator

Thank you. At this time, this concludes the allotted question-and-answer session time. I would like to pass the call back over to management for any closing remarks.

Bernard Zovighian

Yes. So, thank you, everyone, for your interest. So, beyond the strong start of the year, I'm very excited about what we were able to achieve in Q1 with this very strong catalyst. If you step back and you look at them, we are on track to get an early TAVR indication approval in Q2. We had an NCD for EVOQUE, SAPIEN M3 CE Mark, which basically represents the start of a new category for us, RESILIA eight years. Amazing outcome. So, all of that together gives us confidence in what we told you in December at our investor conference. We believe we are very well positioned to transform care for the many structural heart patients, and we are continuing to target total company sales growth of 10% annually on average. So, again, very pleased about the year, the numbers, all of the catalysts. I think all of our people, 16,000 employees, are doing amazing work, and I want to thank them for that. Thanks for your interest in the company. And if you need any questions, do not hesitate you to call [inaudible] Mark, Scott, or myself. Have a great rest of your day. Thank you.

Operator

That concludes today's teleconference. You may disconnect your lines at this time. Thank you for your participation.