Edwards Lifesciences Corporation
First Quarter 2024 Results
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Presenters
Mark Wilterding, SVP & IR
Bernard Zovighian, CEO
Scott Ullem, CFO
Daveen Chopra, Global Leader of TMTT
Larry Wood, Group President of TAVR and Surgical Structural Heart
Katie Szyman, Global Leader of Critical Care

Q&A Participants
Robbie Marcus - JPMorgan
Travis Steed - Bank of America
Larry Biegelsen - Wells Fargo
Matt Taylor - Jefferies
Joanne Wuensch - Citi
Matt Miksic - Barclays
Shagun Singh - RBC Capital Markets
Chris Pasquale - Nephron Research
Philip Chickering - Deutsche Bank
Richard Newitter - Truist Securities
Danielle Antalffy - UBS
Joshua Jennings - TD Cowen

Operator
Greetings, and welcome to the Edwards Lifesciences First Quarter 2024 Results.

At this time, all participants are in a listen-only mode. A brief question-and-answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press "*", "0" on your telephone keypad.

As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Mark Wilterding, Senior Vice President, Investor Relations. Thank you, you may begin.

Mark Wilterding
Thanks a lot, Diego, and good afternoon, and thank you all for joining us. With me on today's call is our CEO, Bernard Zovighian, and our CFO, Scott Ullem. Also joining us for the Q&A portion of the call will be Larry Wood, our Global President of TAVR and Surgical Structural

Heart; Daveen Chopra, our Global Leader of TMTT; Wayne Markowitz, our Global Leader of Surgical Structural Heart; and Katie Syzman, our Global Leader of Critical Care.

Just after the close of regular trading, Edwards Lifesciences released first quarter 2024 financial results. During today's call, management will discuss these results included in the press release and accompanying financial schedules and then use the remaining time for Q&A.

Please note that management will be making forward-looking statements that are based on estimates, assumptions and projections. These statements include, but are not limited to, financial guidance and expectations for longer growth opportunities, regulatory approvals, clinical trials, litigation, reimbursement, competitive matters and foreign currency fluctuations. 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 and important product safety information may be found in the press release, our 2023 annual report on Form 10-K and Edwards' other SEC filings, all of which are available on the company's website at edwards.com.

Finally, unless otherwise noted, our commentary on sales growth refers to constant currency sales growth, which is defined in the quarterly press release issued earlier today.

Reconciliations between GAAP and non-GAAP numbers mentioned during this call are also included in today's press release.

With that, I'd like to turn the call over to Bernard for his comments. Bernard.

Bernard Zovighian
Thank you, Mark. We are pleased with our total company performance with first quarter sales growth of 10% to $1.6 billion versus the year ago period. As a result, we are raising our 2024 sales guidance to the high end of 8% to 10%.

As we look ahead, I'd like to share some perspective about the strategic direction of our company.

Edwards is well-positioned to extend our leadership and deliver sustainable growth, driven by the strategic investments we have made across our transcatheter platforms to address the large and growing needs of patients impacted by aortic, mitral and tricuspid disease.

We remain confident in the many opportunities to grow TAVR over the long term. In addition, TMTT is becoming an increasingly significant contributor to Edwards growth, and we expect this will continue.

An important element in our valve innovation leadership is our advanced tissue technology. We have been an innovator in tissue technology for more than 50 years, and we are pleased with our latest technology, RESILIA. With differentiated evidence of advanced durability, this technology is used across our comprehensive portfolio with a focus on lifetime management of the patients we serve. We are pleased that 0.5 million patients will benefit from this tissue technology by the end of 2024.

As the global leader in structural heart, we remain deeply committed to bringing the highest quality evidence, groundbreaking technology and world-class physician support to advance science and, meaningfully, improve patient care.

This year, we are already making significant progress on multiple clinical trials and next-gen technologies. In January, we achieved an important milestone with the completion of patient treatment in progress, a pivotal trial studying the treatment of moderate aortic stenosis patients, a population estimated to be twice as large as severe aortic stenosis.

In February, EVOQUE became the first transcatheter therapy to receive U.S. FDA approval for the treatment of patients with tricuspid regurgitation. EVOQUE is a groundbreaking treatment option that not only has the potential to improve quality of life, but also shown favorable clinical trends in all-cause mortality, reintervention and heart failure hospitalization.

In March, at the annual CRT Conference, we announced compelling results from two large real-world studies demonstrating continued excellent outcome for patients treated with the Edward SAPIEN valve platform. And earlier this month, at the American College of Cardiology Conference, we announced data from the HUDDLE study. Initiated by Edwards in 2021 with our partner at NFL Alumni Health, the study examine the prevalence of structural heart disease among groups historically known to experience disparities in access to care.

Edwards is committed to helping identify and dismantle barriers to access for communities that are under served, due to race, gender and socioeconomic status. Each of these reflect our deep commitment to advancing patient care through our differentiated strategy and reinforce our confidence in sustaining the growth of transcatheter based structural heart intervention.

Now, I will provide some additional detail on Q1 results, by product group. In TAVR, first quarter global sales of $1 billion increased 8%, year-over-year, when adjusted for billing days. Q1 marked the first quarter that Edwards TAVR sales exceeded $1 billion, an exciting milestone for our team and a testament to clinicians' confidence in our leading technology. Performance was driven by growth in the U.S. and Japan, Edward's global competitive position, and selling prices were both stable.

In the U.S., our year-over-year first quarter TAVR sales growth rate was higher than our global constant currency growth rate. We estimate total procedure growth was comparable. Procedure volumes increased, as the quarter progressed.

We remain pleased with the continued performance of our best-in-class TAVR platform, SAPIEN 3 Ultra RESILIA, which builds on Edwards long-standing leadership in tissue technology and durability. This innovative technology now makes up the majority of our sales in the U.S. This platform is supported by the robust real world data for more than 10,000 patients in the TVT Registry that demonstrated excellent outcomes, across hundreds of centers.

The technology's optimized tissue treatment is designed to extend durability of a valve, a feature that will be increasingly important, as the therapy continues to treat patients with longer life expectancy. We are also proud to continue our deep commitment to advancing science for AS patients, through the progress and early TAVR trials.

As discussed in January, we completed enrollment and treatment of patients in progress, approximately two years of expectation. We also expect to release the results of early TAVR at the TCT Conference, this year.

Symptom assessment is one of the most significant barriers to referral, and the early TAVR trial evaluates the impact of TAVR on asymptomatic patients with severe AS. We believe if data are compelling, early TAVR may have a meaningful impact on deciding when to treat patients, while also streamlining referral and patient care for all severe AS patients.

Outside of the U.S., in the first quarter, our constant currency TAVR sales growth was slightly below our global TAVR growth. Strong growth in Japan and the rest of the world was partially offset by slower than expected growth in Europe.

In Europe, our results were softer than expected in Q1. But we expect full year 2024 performance to normalize. We are actively preparing for the launch of SAPIEN 3 Ultra RESILIA in Europe, and we anticipate introducing the technology into the European market in Q2.

In Japan, we continue to see strong TAVR adoption driven by SAPIEN 3 Ultra RESILIA. We believe AS remains a significantly undertreated disease among the substantial elderly population and continue to focus on expanding the ability of an evidence supporting this therapy.

In closing, we are confident that Edwards is positioned for healthy and sustainable TAVR growth well into the future, driven by our development of differentiated TAVR technology, our deep commitment to advancing patient care through high-quality clinical evidence and our investment in patient activation initiatives.

Importantly, we are proud of our groundbreaking research into the treatment of AS through our early TAVR and PROGRESS trial, which could, fundamentally, change how AS patients are treated.

We remain confident in our full year TAVR sales growth of 8% to 10%. We expect higher year-over-year second half growth rate than in the first and second quarter.

Turning to TMTT. We drove positive momentum with our unique and broad portfolio strategy for both repair and replacement therapies for mitral and tricuspid patients. We made significant progress in advancing important technologies, including the PASCAL repair system, the EVOQUE tricuspid replacement system, and the SAPIEN M3 mitral replacement system. We are the only company with multiple approved mitral and tricuspid therapies backed by world-class evidence to improve patient care.

In Q1, we achieved positive results with sales of $73 million, representing a 72% increase versus the prior year. The majority of our Q1 sales were driven by expanded adoption and new site activation of PASCAL, supported by continued double-digit tier market growth in the U.S. and Europe. We are also pleased with strong physician feedback and excellent procedural outcome with the EVOQUE tricuspid valve in both the U.S. and Europe.

With this replacement technology, we see the unique elimination of tricuspid regurgitation, significant quality of life improvement for patients and favorable trend in all-cause mortality and heart failure hospitalization.

The increasing physician demand for EVOQUE is a clear indication of unmet need and the potential for this therapy to treat a very large patient population. We continue to invest in expanding our high-touch field organization, globally, to support this therapy in order to continue to achieve excellent outcome for each patient.

Given the strong adoption of our differentiated technology, PASCAL and EVOQUE, we are raising full year TMTT guidance to $320 million to $340 million versus previous guidance, which was the higher end of $280 million to $320 million range.

We are confident that our unique portfolio strategy with repair and replacement options for both mitral and tricuspid will offer clinicians the broad set of therapies necessary to, effectively, treat many patients in need. This strategy positions us for global leadership, sustainable long-term growth and an increasing contribution to overall Edwards growth.

In Surgical, first quarter sales of $266 million increased 8%, over the prior year. Growth was driven by strong global adoption of Edwards premium surgical technologies INSPIRIS, MITRIS and KONECT. We continue to see positive procedure growth, globally, for the many patients, best treated surgically, including for both undergoing complex procedures.

We continue to expand the overall body of evidence in multiple technologies and multiple valves and now expect U.S. and Canada enrollment of our MOMENTIS clinical trial studying RESILIA performance in the mitral position to be completed in Q2 2024, one year ahead of expectation. The study will continue to open new sites in Europe and Latin America with global

enrollment continuing into 2025. We are now raising our full year surgical sales guidance to 6% to 8% and versus previous expectation of mid-single digit growth.

In Critical Care, variability of demand led to better-than-expected first quarter sales of $251 million, which increased 14% versus the prior year, driven by contribution from all product lines. Growth was led by our smart recovery technologies, including the Acumen IQ sensor. Demand was also strong for our Swan-Ganz catheters and pressure monitoring devices used in the ICU.

Critical Care remains focused on driving growth through smart recovery and smart expansion, which are designed to help clinicians make more informed decisions and get patients home to their family, faster.

We are now confident in raising our full year critical sales guidance to 8% to 10% versus previous expectation of mid-single digit growth. Since announcing the spin-off of Critical Care in December, our team has made significant progress, and I want to thank all of them for their hard work and dedication. Scott will provide additional details.

And now, I will turn the call over to Scott.

Scott Ullem
Thanks a lot, Bernard, and good afternoon, everyone. As Bernard mentioned, we are pleased with our first quarter total company sales performance and progress on our strategic milestones. In addition, we achieved $0.66 of adjusted earnings per share.

Our GAAP earnings per share of $0.58 included one-time expenses associated with our planned spin-off of Critical Care. A full reconciliation between our GAAP and adjusted EPS for this and other items is included with today's release.

For the second quarter, we're projecting sales of $1.62 billion to $1.70 billion and adjusted earnings per share of $0.67 to $0.71.

And now I'll cover additional details of our P&L. In Q1, our adjusted gross profit margin was 76%, compared to 77.5% in the same period, last year. This expected year-over-year reduction was driven by a more favorable impact from foreign exchange in the prior year. We continue to expect our full year 2024 adjusted gross profit margin to be between 76% and 78%, driven by high value technologies that yield strong gross profit margins.

Selling, general and administrative expenses in the quarter were $490 million, or 30.6% of sales, compared to $436 million in the prior year. This increase was driven by an expansion of transcatheter field based personnel in support of our growth strategy. We expect full year 2024 SG&A as a percent of sales to be approximately 30%, as we continue to invest in field based personnel and patient activation initiatives.

Research and development expense in first quarter grew 9% over the prior year to $285 million, or 17.8% of sales. This increase was primarily the result of continued investments in our transcatheter aortic valve innovations, including increased clinical trial activity.

For the full year 2024, we continue to expect R&D to be 17% to 18% of sales, as we invest in developing new technologies and generating evidence for our structural heart disease initiatives, with the goal of treating even more patients.

Turning to taxes. Our reported tax rate this quarter was 14.3%, or 14%, excluding the impact of special items. Our favorable non-GAAP rate in the first quarter includes a higher-than-expected benefit from stock-based compensation. We continue to expect our 2024 tax rate, excluding special items, to be between 14% and 17%.

Foreign exchange rates decreased in first quarter reported sales growth by 40 basis points, or $5 million, compared to the prior year. Foreign exchange rates negatively impacted our first quarter gross profit margin by 160 basis points, compared to the prior year. Relative to our January guidance, FX rates had a nominal impact on first quarter earnings per share. At current FX rates, we now expect a $70 million or 1% negative impact to full year 2024 sales versus the prior year.

Regarding the previously announced spin-off of Critical Care, preparations are ongoing. We anticipate completing the unaudited carve-out financial statements next month, and we are on track to obtain a tax-free ruling from the IRS, by year end. We are currently assessing capital structure options for the spin-off company, and we plan to share details with investors later this year.

During the first quarter, we incurred $41 million of one-time costs associated with the spin-off. Additional one-time costs will be incurred throughout 2024.

Free cash flow for the first quarter was reduced by a $305 million deposit contingent upon the resolution of a tax dispute and $20 million of payments associated with the spin-off of Critical Care. Excluding the impact of these items, adjusted free cash flow was $206 million, and we continue to expect full year 2024 adjusted free cash flow will grow to between $1.1 billion and $1.4 billion.

So before turning the call back over to Bernard, I'll finish with an update on our balance sheet. We continue to maintain a strong and flexible balance sheet with approximately $1.7 billion in cash, cash equivalents and short-term investments, as of March 31.

We continue to expect average diluted shares outstanding for 2024 to be between $600 million and $610 million. We have approximately $1 billion remaining under our current share repurchase authorization.

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

Bernard Zovighian
Thank you, Scott. We are pleased with a strong start to the year, as we continue to focus on helping even more patients, worldwide, and driving growth with leading innovative technologies. We remain confident in our increased 2024 financial outlook and look forward to launching breakthrough technologies and progressing multiple important clinical trials, while aggressively investing into our future.

In closing, we believe Edwards is uniquely positioned to deliver sustainable growth, driven by our significant investment focused on structural heart to address the large and growing needs of patients impacted by aortic, mitral and tricuspid disease.

With that, I pass it back to Mark to open up Q&A.

Mark Wilterding
Thank you very much, Bernard. We're ready to take questions now. In order to allow for broad participation, we ask that you please limit the number of questions to one, plus one follow-up. If you have additional questions, please reenter the queue and management will answer as many participants as possible during the remainder of the call.

Diego, please go ahead with additional details on accessing the Q&A portion of the call.

Operator
Thank you. And if you would like to queue up for a question, please press "*", "1" on your telephone keypad. A confirmation tone will indicate that your line is in the question queue. You may press "*", "2", 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, that's one question and one follow up for each time you queue.

And our first question comes from Robbie Marcus with JPMorgan. Please state your question.

Robbie Marcus
Great. Thanks for taking the question and congrats on a nice quarter. Two for me. I wanted to start first with EVOQUE. Clearly, TMTT had a really strong quarter, came in well above consensus and some of the most optimistic numbers I was hearing. So I wanted to get a sense of what you're seeing, how much of the TMTT was EVOQUE. And clearly, you raised guidance. I imagine this is just the early stages of adoption here. Thanks.

Bernard Zovighian

Thanks, Robbie. This is a good question. So we are obviously very pleased about the early physician feedback, which has been very, very strong on EVOQUE. We were able to achieve an excellent procedural outcome. Now back to your question about our performance in Q1, very little about EVOQUE.

We have seen a very clear momentum on PASCAL, PASCAL in Europe, PASCAL in the U.S. And we are very pleased about our expansion and adoption of PASCAL globally, basically. But I'm going to ask Daveen to add some details here.

Daveen Chopra
Yeah. Thanks so much, Bernard. Thanks for the question, Robbie. Yeah. And to follow up with Bernard's comments, obviously, the vast majority of our growth came from PASCAL, just because EVOQUE is so new. And overall, though, we continue to be really pleased with the initial launch of EVOQUE both in Europe and the U.S. Right now, we're just starting to steadily kind of activate sites.

We've had really good clinical outcomes, very consistent with what we saw in the clinical trial. And we see really predictable times, and predictable procedure times is something that, obviously, physicians really love to see and we see that both at old sites that were enter TRISCEND II, as well as new sites that we've opened up kind of in Europe.

The only other comment I'll make is, it's really early in our journey, but our experience in Europe, especially where we've had PASCAL approved for tricuspid since 2020, really reinforces the fact or the need that we want to have a portfolio of both, repair and replacement technologies because tricuspid patients are so complex and so diverse. So I'll stop there.

Robbie Marcus
Great. Maybe a follow-up. I caught the comments that the U.S. TAVR grew faster than the global organic TAVR growth rate and that procedure has accelerated, throughout the quarter. So, how are you thinking about TAVR growth for the rest of the year? And do you feel like the U.S. has finally recovered after some of the setbacks you saw during the disruptive years of COVID? Thanks a lot.

Bernard Zovighian
Thanks, Robbie. Let me start and again, I will ask Larry to add some insights here. So we knew, when we put together our guidance for the year, the TAVR guidance 8% to 10%, we knew that the growth will ramp throughout the year and that Q1 will be our lowest growth quarter. So we feel confident about our 8% to 10%. We feel confident about what's happening in the U.S., our share and price are stable. So we feel good about all of that. Larry, you want to add anything?

Larry Wood
Yeah. I don't have a lot to add. We saw good progression throughout the quarter. It's always a little slow in January as we come out of the break, but we are pleased with how the quarter

went overall, and we remain excited about the year. We have a lot of activities on patient activation. We have a huge data set coming out of TCT that I think all of us are going to be excited to see what that says, what those data say and how they inform the field. And so, I continue to believe we have a long runway long-term with TAVR, and it is good to see the U.S. kind of put COVID, I think, finally in the rearview mirror, and we can just focus on accelerating patient care.

Robbie Marcus
Thanks a lot.

Operator
Our next question comes from Travis Steed with Bank of America. Please state your question.

Travis Steed
Hey. Thanks a lot. Congrats on a good quarter. Maybe on TAVR again, curious why European growth was lower than expected? And then on the billing days, were those U.S. or OUS and did those come back in any quarter?

Larry Wood
Yeah, thanks. Yeah, overall, we felt good about the quarter, and we just talked about the U.S. We saw a lot of strength in Japan, but Europe was--it grew year-over-year and it grew sequentially, and we lost a couple of billing days. But even with that, we were a little bit disappointed with our overall growth in Europe.

We saw some pretty aggressive pricing from competitors that I think led to some trialing. But we're really excited that we're launching S3UR that actually starts this month, and we're excited to bring that technology to Europe, and we expect these to normalize, throughout the course of the year.

Scott Ullem
I can give a little bit more commentary on the billing days. So outside of the U.S. is where we really felt it. We saw two billing days difference in Europe and Japan. Overall, globally, we saw one billing day difference, and so it had an impact. To your question about do we see any more impact in later in the year? Yeah, in Q3, we've got a billing days impact that goes the other direction, as well.

Travis Steed
All right. That's helpful. And then on TAVR and some of the things you've been doing with egnite and kind of helping drive center growth and diagnosis. Curious to see how that's going and at what point do you start to kind of scale those programs out and an impact on, see the impact on TAVR growth?

Larry Wood

Yeah. We have a lot of patient activation activities where there's a lot of work that we do. We have multiple fronts, and egnite is just one part of our strategy there. But we're excited about what these technologies can do. And there are so many patients, if you look at the Thieme and (inaudible) publication, and I know he's spoken to you guys before, there's just a lot of patients upstream that aren't moving through the system at the speed in which they should. And I think there's a patient identification aspect, there's a referral aspect.

So we have multiple work streams working on this. But I think the appreciation and understanding for the undertreatment of aortic stenosis is growing. And I think as that grows and people start to understand the magnitude of the problem, I think it gives more opportunity for our patient activation strategy to take hold.

Bernard Zovighian
And maybe in addition, Larry, I'm very proud about what we are doing. We are the only one, basically, having a deep commitment to advancing science for AS patients through the progress and early TAVR trial. So this is truly our commitment, but we feel that there is a ton of potential, especially our underdiagnosed, undertreated, and we are committed to offer treatment for these patients. So as a company, very proud about how we do all of this.

Travis Steed
Great. Thanks a lot.

Operator
Thank you. And our next question comes from Larry Biegelsen with Wells Fargo. Please state your question.

Larry Biegelsen
Good afternoon. Thanks for taking the question. I just wanted on TAVR, I wanted to confirm, Bernard said that Q2 TAVR growth will be better than Q1, in response to Robbie's question. And why do you expect TAVR growth to accelerate in the second half, and how are you guys factoring in the SMART trial results? And I have one follow-up.

Larry Wood
Yeah, we do expect to have procedures to ramp. That's always been a part of our plan, and so we continue to expect that to happen. And I think it's a lot of things, Larry, I think it's a lot of our patient activation work. But it's also just the market continues to improve, and we're very pleased with where we finished Q4, last year.

We were happy with the ramp in Q1. So I think we do expect to see an increase in Q2 over Q1. But even with that, we expect the second half to have a higher growth rate than the first half. So I think that that's good.

And as it relates to the SMART trial, I mean, we talked a lot about it at ACC. I think it's just a reminder, and we've talked about this before, but the decision on what valve to use is multifactorial. It's never been about one criteria. It's never been about one data point.

And so, we continue to have confidence in our platform and the value proposition and with our Ultra RESILIA technology and all the other things that we're doing. But we always model in competition, but we feel very good about our platform and our leadership.

Bernard Zovighian
So let me, Larry, let me add something about it. I know that there were plenty of questions about that trial at ACC. I was not at ACC. But our strategy to bring, basically, groundbreaking science, the highest quality of evidence to help over 1 million of patients who are not being treated today and being able to unlock this large of a caveat market potential, this is what we are doing; this is our strategy.

So you know us very well. In the last 10 years, we studied 12,000 symptomatic severe aortic patients, across mainly FDA-approved studies. And today, again, we are the only company conducting a groundbreaking research into the treatment of AS, through early TAVR in progress. So again, I can tell you I'm very proud about who we are as a leader in circular heart disease. I think what happened at ACC with the SMART in my mind is, no, it was an interesting study, but more noise than anything else.

Larry Biegelsen
Thank you. And Scott, if I saw it correctly, you raised the revenue guidance, but you did not change the EPS guidance. Why is that? Thank you.

Scott Ullem
Yeah, that's right. We brought revenue guidance up nearly $150 million, and you're right, we kept our $2.70 to $2.80 range the same. There are a couple of reasons. One was we ended up with a lower tax rate in the first quarter than we expected. Not sure that we're going to be able to maintain that low of a tax rate the rest of this year.

The other one is, it’s just early in the year. And so, we'll talk more about how EPS is trending, three months from now. But we decided at this point early in the year, we just keep it the same. We think the top end of the range can accommodate multiple different scenarios that could play out in the rest of 2024.

Larry Biegelsen
Thank you.

Operator
Our next question comes from Matt Taylor with Jefferies. Please state your question.

Matt Taylor
Great. Thank you very much for taking the question. I did want to ask a more specific question about the TMTT performance, and you talked about this importance of the portfolio. And so, I guess, the first way I wanted to ask you was, is EVOQUE, I guess, helping to pull through or improve the performance of PASCAL? And do you expect that as you go through time was even more of a portfolio across mitral and tricuspid to be able to use that portfolio approach to gain even more share.

Daveen Chopra
I'll answer that. Yeah. This is Daveen. I'll answer that. No, honestly, if you look at quarter one, no, I don't really think there was any significant kind of direct pull-through from EVOQUE versus PASCAL. But if you pull back up, I think us having a portfolio products to treat the maximum number of patients by having repair and replacement technologies for both mitral and tricuspid help show our leadership and that physicians would then want to continue to work with us, as leaders in the space.

I think--so there's always going to be a continued kind of link in that way. But when we look at kind of growth opportunities and what's happening for growth overall, if I look at PASCAL, right, in Q1, we continue to open up new centers. We continue to grow in the centers that we work with and that we continue to gain--work with physicians more deeply in that way, which I think was fantastic. Additionally, and we think that will continue for quarters going into the future.

Additionally, we continue to grow, geographically. There are also countries in the world where we're just kind of bringing PASCAL for the first-time. We're in the new kind of the initial stages of where we'll be with PASCAL. So we think that's going to be an important opportunity. And then clearly, that's PASCAL, and number two, EVOQUE, EVOQUE is just starting. We see EVOQUE being a long runway for us of growth, across the board.

And then we've talked about in the future, we will also then bring our M3, SAPIEN M3 transcatheter mitral valve to the market, which will add another layer of growth for the future. And I think having all these technologies, together, really provides a leadership role that we can have.

Matt Taylor
Thank you very much.

Operator
Our next question comes from Joanne Wuensch with Citi. Please state your question

Joanne Wuensch
Good evening, and thank you for taking the question and very nice quarter. I want to spend some time on Critical Care. I can't remember the last time I saw over 14% revenue growth in

that segment and, particularly, as it's sort of preppings go out on its own, what drove that growth, how sustainable is it and wow? Thank you.

Bernard Zovighian
Katie, do you want to take another question?

Katie Szyman
Yeah. Thanks, Joanne, for the question. So for Critical Care, as you know, we have capital sales as part of the mix. And so, we just see high variability of demand, really, every quarter across all our product lines. We also have distributor sales that kind of will come up and down. So, it was a great quarter for us, overall. It's still early in the year. So you saw us raise guidance to 8% to 10%, and we're very confident in that 8% to 10% range. But we don't want to bring it up too much more at this point just because of that variability in demand.

Joanne Wuensch
And for Critical Care, you can comment on profitability during the quarter or should we just hang tight from that one? Thank you.

Scott Ullem
Profitability for the company, Joanne.

Joanne Wuensch
No, Critical Care, if possible. Thanks.

Scott Ullem
Yeah. Well, let's hold off on product line profitability. Suffice it to say, it was a good top line quarter, and that's helping our bottom line, as well.

Operator
Thank you. And our next question comes from Shagun Singh with RBC. Please state your question. Shagun Singh, your line is open. Please go ahead. All right. We will move on to the next question. And our next question comes from Matt Miksic with Barclays. Please state your question.

Matt Miksic
Hey. Thanks so much for taking the questions. So just one question on sort of TAVR and transcatheter valve growth, and I'll just keep it to one. If you could maybe talk a little bit about the launch of EVOQUE and the activity that that drives in some of your major centers. And I guess how you're--you and the team in the field is kind of managing those activity levels or the bandwidth of those centers versus the continuing volumes that they perform in TAVR.

Just maybe any color or thoughts on how that might play into the total transcatheter business?

And then, Scott, I don't know if you'd be willing to do this, but if you can possibly quantify the impact on SG&A that you've mentioned about the field resources and sort of patient activation resources that you've planned and are executing on, this year? Thanks.

Larry Wood
Yeah, so I'll start, Matt, and then I'll hand it over to Daveen. This is kind of like what Daveen and I do, every day. We partner very closely on these sorts of things. And clearly, as we roll out these new therapies, we want to make sure that people do it with the right volume. And so it's a key part of when we start centers, making sure that they have a whole program that encompasses their entire structural heart patient population.

And so, our teams work closely together. We have this unique environment where we have very dedicated teams because we want to bring that detailed procedural knowledge and the knowledge of all things related to it. But it still requires a lot of coordination between Daveen and I, and we've been doing this for a while. This is true with PASCAL and the launch is there, and it remains true of EVOQUE. Daveen.

Daveen Chopra
Yeah. I mean, I'll just add maybe some comments about the--maybe the capacity question that you kind of asked. The reality is, in mitral repair, in cure technology that's been around for several years and continues to grow with more and more patients being treated. The number of patients being treated and kind of reminds you of EVOQUE is relatively small in quarter one and for the future just based on these very large, more established numbers of procedures.

So for us, overall, I don't necessarily believe that the EVOQUE procedures, for any time in the near future, are going to affect overall capacity. But I do also, and to put--carry out to Larry's point, we collaborate very well together to ensure that when we're opening up a center or working with center for the first time, we're working with that center to ensure that they do have the capacity to then add in these incremental procedures.

Bernard Zovighian
What it is fair to say is that, so far, we have not faced a big challenge in terms of centers having a lack of capacity to be able to treat the patients, whether TAVR patients or EVOQUE patients.

Daveen Chopra
Or TEER patients.

Bernard Zovighian
And TEER patients, yes.

Scott Ullem
And Matt, it's Scott, your question about SG&A. You heard us say in the opening remarks that we're expecting SG&A as a percentage of sales to be around the top end of our original range of

29% to 30%. And that move up a little bit was largely based upon the increased investments that we're making in field resources and patient access initiatives. And it also kind of gets to Larry Biegelsen's earlier question about why we didn't move EPS guidance range up yet.

We've been waiting to see how sales trended here at the beginning of the year before deciding how aggressively we wanted to go after some of these investment initiatives. And based upon first quarter sales, we're going to move forward with some of those, and that's the reason we're moving up our spending outlook.

Matt Miksic
Thanks so much.

Operator
And our next question comes from Shagun Singh with RBC Capital Markets. Please state your question.

Shagun Singh
Great. Thank you so much and sorry about earlier. It just sounds like U.S. TAVR growth was high-single digits. Is that fair? Was it about 10%? And other drivers that can get you to consistent double-digit growth in the foreseeable future, just what's your confidence there?

And then I wanted to get your take on AHA's aortic stenosis initiatives. It seems like they're expanding that to additional centers. And some of our checks have suggested that that has a positive impact on TAVR volumes. So just anything you can share on that program, the scope of expansion and potential volume impact to TAVR. Thank you for taking the questions.

Scott Ullem
Yeah. I'll take the first part of that about U.S. TAVR growth. We try not to be too specific about breaking down every region. But what we can say is that TAVR in the U.S. grew faster than our global underlying growth rate for TAVR in the first quarter. Larry, do you want to talk about the other pieces?

Larry Wood
Sure. So the AHA program, we're very excited to partner with the AHA on this. And you're looking for an analog, years and years ago, the whole door-to-balloon drive where they created a quality metric that was based on time. And because we know the faster when a patient is having an MI, they get a balloon across that lesion, the survival rate rises dramatically, and it's critical that they do that.

But for AS, we really don't have any quality initiatives around the time from diagnosis to treatment. And I will say most centers sort of start the clock when the patient ends up with the heart team, and they think they do it pretty quickly. But the part of the story that they miss is the upstream component. From the time that patient got that first echo that they have severe

disease, sometimes there's a long journey before the patient actually gets referred to the heart team. And we're trying to do is work on a time metric like door-to-balloon, where every patient has to get treated within 90 days of diagnosis.

And one of the first things that it does is centers have to go back and look at what their own data say. And most centers think they're doing a good job and when they actually dig deep and find their own data, they find out they're not gearing near as well as they thought they were.

But if we can get this quality metric implemented, then it would completely change the urgency around patients' move through the system. It would be a quality metric they would have to report on. So we continue to expand this initiative, but the real goal is to make a guideline or quality metric be part of the system where centers would have to report on it.

And we think we do that, it could dramatically improve patient care because we know these AS patients do not wait, well. They have very high mortality rates. If you go all the way back to PARTNER 1, which was the higher risk patients, they had a 50% mortality rated a year when left untreated, and that mortality rate starts very quickly in the process. So, we're very excited to partner with AHA, and they're a great partner for us because they have demonstrated expertise in getting these sorts of things put in place.

Shagun Singh
Thank you so much.

Operator
Our next question comes from Chris Pasquale with Nephron Research. Please state your question.

Chris Pasquale
Thanks. First on EVOQUE, you're launching a pretty meaningful price premium to the other technology out there. Do you see the implementation of the NTAP in October is a gating factor for commercialization or do you think you can make significant progress over the next six months prior to that incremental reimbursement kicking in?

Daveen Chopra
Yeah, thanks for the question, Chris. Appreciate it. Yeah. So first, just a couple of comments. We really believe that EVOQUE offers exceptional clinical and economic benefit to both patients and health care systems. We think that's a key factor. And we've seen a great increasing interest and demand from physicians to help have this technology treat their patients. So the results I think we're going to see continued centers opening up and continued kind of patient grow, each quarter.

If you think about the NTAP, what you mentioned with NTAP, that we're psyched that CMS is actually proposing to move forward with NTAP. And then we hope that expects, as you said, to

start October 1. And that helps make up any incremental cost between the cost of EVOQUE procedure versus the existing DRG, which is that DRG for TAVR and TEER. So we think that will continue to add to it. But between now and that we continue to see a lot of interest from physicians, as well transcatheter system because we think this technology does so much for patients.

Bernard Zovighian
Probably fair to say that NTAP will have a big impact next year and the year after, but not necessarily this year. Thank you.

Chris Pasquale
Okay. And then it sounded like there was a purposeful mention of the commitment to fielding both replacement and repair technologies for both, tricuspid and mitral. In tricuspid, the early consensus from physicians seems to be the replacement is going to lead the way. How are you thinking about which patients might be best served by each technology and what that means for EVOQUE today and then longer term, how PASCAL could deal in tricuspid as Class TR gets closer to completing enrollment?

Daveen Chopra
Yeah. This is Daveen, again. I'll make a couple of comments on this one. Generally, yes, we are believers that both repair and replacement technology for each valve really helps treat the maximum number of patients. These patients and these disease states are really heterogeneous. There's no one magic bullet. There are a lot of patients that continue to need different types of technologies.

I think all of us, the physician community, the medical community, ourselves, we're all continuing to work and figure out which product repair replacement is right for what patient. Do we have a clean answer, today? No, but are we continuing to work on it and have some ideas? Definitely so.

With technologies like EVOQUE, we see like this unique elimination of TR, big quality of life improvement. And we see these favorable trends that all-cause mortality and heart failure hospitalizations, along with a very predictable procedure, very clean kind of times. In Europe now, we're starting to have a little--we already have PASCAL for now a couple of years in Europe, PASCAL tricuspid, where people really love PASCAL where it has some really great features for the tricuspid valve, really a atraumatic clasping, etc.

But physicians there are starting to see how EVOQUE makes a lot of sense for certain segments of their patients. So no, we haven't quite figured out the exact mix of these patients, but we know both are really important for treating the most patients.

Bernard Zovighian

That’s great, Daveen. Maybe I will add something. About six, seven years ago, we believe that having repair and replacement for both mitral and tricuspid was going to be important. Today, we are confident that, indeed, it is the case. And this will provide a physician options to treat many patients and to best select what therapy for what patient.

So if you're asking what exactly technology for what patient, I think it is still early. We still--we need probably more time, more research to do that. But for sure, I think this portfolio put basically, a physician in a driver seat to make the best decision for their patient, which is what we wanted, initially. And as a result, this is going to unlock this very large opportunity, and we are going to see a sustainable growth from TMTT in the years to come.

Daveen Chopra
And I'll leave it up on your comment about kind of the clinical data. And that's why it's so important that we continue to enroll in trials like Class II TR. So that's our tricuspid trial. It's a randomized study where getting more data in understanding how these different technologies can really help patients. It's super important for ourselves. So not only post-market studies for EVOQUE, but also these other randomized studies, pre-market studies that are so important to collect this data to continue to understand where these technologies can work best for patients.

Chris Pasquale
Great. Thanks.

Operator
Our next question comes from Pito Chickering with Deutsche Bank. Please state your question.

Philip Chickering
Hey there. A follow-up to Chris' question. I just want to make sure that I heard that you expect limited EVOQUE sales until the NTAP kicks in October 1. And with G&A, at the high end of your previous guidance to 3%, how many centers do you think will be ready to perform the procedure by that date?

Daveen Chopra
So this is Daveen. On the NTAP comment, we believe right now, each quarter, we continue to open up new centers. We continue to train physicians on it, and it's a steady state, nice growth in providing the technology to more patients. And we've seen a lot of demand from physicians for this technology for those patients. I think to Bernard's point, NTAP adds a continued allowance of growth, as it gets to more scale, that’ll really help support 2025 and 2026 growth. And then the second question was--I missed the second part of your question.

Scott Ullem
I mean, I think the question was how many centers do you think we'll be ready to do procedures, once the NTAP is active. And I think what we can say is, certainly, the sites that

have been involved in clinical trialing are going to be ready to activate. Beyond that, we're just going to be strategic and deliberate about where we activate.

Daveen Chopra
And we're going to focus on centers that are already the higher volume tricuspid centers that have their infrastructure set up, have their right side imaging set up. So it's going to be just a steady kind of growth, TRISCEND II centers and moving to other high-volume tricuspid centers.

Philip Chickering
Okay. And on the asymptomatic in the indication, if that trial is positive to get FDA approval, is that going to be exclusive to SAPIEN? And any color on how much creep you've seen, if any, for docs treating asymptomatic patients, today.

Larry Wood
Yeah. Thanks. Well, none of us know the trial results as yet; that won't happen until later this year. So if the trial is positive and, obviously, the more positive the trial is, the more benefit that you get from it. But I think it's really about how patients get referred for therapy. And I think that that's going to be the key thing.

So I think it speaks to the treatment in referral for aortic stenosis and the time point we should do that, more than a specific therapy. Now that being said, it is a randomized trial against the SAPIEN platform. And so, if you're going to think about treating patients earlier, you're going to have to have a platform that delivers outstanding clinical outcomes, right, you're going to have to have those low mortality rates.

And this is where we think our platform really shines because if you look at, again, our PARTNER III low risk data, we had 99% survival at a year. We had 90% survival rate at five years and very low complication rates. And that's probably more in line with the patient population that would be asymptomatic, is probably more towards a lower-risk patient population. And we're the only ones who made the investments in that trial ,at this point. So--but I do think it speaks to the deadliness of the disease, broadly.

Philip Chickering
Great. Thanks so much.

Operator
Our next question comes from Richard Newitter with Truth Securities. Please state your question.

Richard Newitter
Hi. Thanks for taking the question. Going back to the trend in Europe and your confidence and visibility to a recovery there for your business, I guess, is it more that you just--you think the price discounting is going to ease? And because you have RESILIA coming in that region, it will

offset and that's the acceleration or is there--what else can you tell us that gives you comments there?

Larry Wood
Yeah. We had a good Q4 in Europe. And so, this does feel like it's probably more temporary, and it's something that we're going to put a little bit more focus on. We do sell at a premium in Europe, and some people were pretty aggressive with discounting. And I think we have to beat that beat with our value proposition and with new technology. And we're super excited. While S3UR feels old to the U.S. at this point in Japan, it's a brand-new product for Europe. They have no experience with it.

So we're excited because it's the only platform in anywhere that has the dry RESILIA technology. And again, this is something that's been on our market-leading surgical valves for--we're probably approaching a decade, now. So it's a huge milestone for us to be able to get this technology into Europe. And we do think that physicians still are going to make their long-term product decision based on what's best for their patients.

Richard Newitter
Okay. Thanks. And following up here on just the selling days. I think you said, Scott, in 3Q, the billing days go the other way, positive for you. Is order of magnitude similar to 1Q and then same geographic impact or anything you want to add there?

Scott Ullem
Sure. In the third quarter, order of magnitude, same thing. It's about a day, globally, and geographically, very similar. Europe or Eastern Europe a day or two days, everybody else is a day. So it's really a day across the board in the third quarter.

Richard Newitter
Okay. So more evenly split by region.

Scott Ullem
Yeah, it's more--it's--most of the regions are one day in the third quarter, whereas in the first quarter, we had Europe and Japan at two days, but I'm not sure that level of precision is that important. Suffice it to say, in aggregate, in total, it's a day in the first quarter, and a day in the third quarter.

Richard Newitter
Okay. Thank you.

Operator
Our next question comes from Danielle Antalffy with UBS. Please state your question.

Danielle Antalffy

Hey. Good afternoon, everyone. Thanks so much for taking the question. Congrats on a good start to the year. Larry, I was hoping--I appreciate this whole initiative, the patient acquisition initiative and working to get patients treated. You guys talked about at your Analyst Day and on the Q4 call, the AI, the utilization of AI at some piloting this at some centers.

And I was wondering if you could give any color on how much faster you're seeing growth at those centers, if at all yet, if you can quantify that. Just to get a sense of like if this does get implemented more broadly what it could--what we could see from a growth perspective.

Larry Wood
Yeah, I appreciate the question, Danielle. It's a little hard to quantify. We're still putting some of these systems in place. And remember, it's not just identifying the patients. People have to start rewiring the way patients get referred and the way they come in. And so, I think we're really, really pleased with the pilots that we've run in the places that we've gone. We barely clearly identify that there's an upstream population that many of the centers didn't even know existed.

And now how we tap into those, how we move those patients through the system, how they add capacity to address these patients, that's where the pilot centers are kind of in that phase now.

But we--when I spoke of this in the investor conference, we have, in our minds, 100% validated the undertreatment of aortic stenosis. We've done it in enough centers with enough different people. It's been backed by enough publications, really even leading academic programs.

Now it's a matter of going through all of the steps to get these patients off the sidelines and get the proper therapy. And--but this is going to be something--it's not a day--and one day, there's going to be this massive step function. It's going to be this continued effort, over time. But again, it's going to be the thing that drives our growth over, I think, a very extended period of time.

Danielle Antalffy
Sure. And I guess just one quick follow-up on that, plus asymptomatic. I mean, you talked a little bit about this at the Analyst Day, but asymptomatic almost more about easing workflow and decision-making processes. I mean, asymptomatic assuming the trial's good and you get the guidelines, plus this initiative, I mean, should we see both acceleration specifically in TAVR in 2025? I know you're not going to give '25 guidance, but I thought I'd try.

Larry Wood
Yeah, I'm not going to get into guidance, and I really want to be cautious not to speculate on trials that are in flight. We'll see the data at TCT. And after we see that data, then I'll be happy to talk about what I think the repercussions are and how I think it plays out. What I can tell you is the patient journey, right now, is a complicated one. Patients get diagnosed with severe

aortic stenosis, and then they had this holder layer on top of it, which is, do you have symptoms, are the symptoms attributable to our aortic stenosis, are the symptoms enough to refer you for care?

And there's a number of patients, even though the guidelines say any symptoms are cause for referral, there's a large number of patients that are being held upstream because somebody has decided the symptoms aren't significant enough. So, instead of this being a mathematical equation, it sort of turns into almost Olympic figure skating with all this judgment.

And when you end up with older people that have more comorbidities, that gets even more confusing and more challenging. If asymptomatic is successful and we have a powerful trial there, then it should simply move to track and field. It should just be a matter of if your aortic stenosis goes below 1.0, you should immediately be referred to a heart team for care. And I think that streamlining of care is going to be what makes the difference and takes a lot of the noise out of the system.

Danielle Antalffy
Thanks so much. Love those analogies.

Operator
And our next question comes from Josh Jennings with TD Cowen & Company. Please state your question.

Joshua Jennings
Hi. Good evening. Thanks for taking the questions. I was hoping to ask about SAPIEN X4 and just thinking about the design and the ability to provide, I think, 16 different deployment diameters. I mean, should investors be optimistic and clinicians that we could see lower gradients and a lower prostatic basis mismatch rate with the SAPIEN X4, relative to the SAPIEN 3 Ultra or SAPIEN 3 system? And--or is it really just the benefit for a future TAVR and TAVR that that sizing action will provide?

Larry Wood
Yeah. That's a great question, Josh. And clearly, you're deep on our platform and the details. I think the concept of this variable sizing is really being able to tailor our valve to the patient. Rather than driving the patient to a nominal, we can adjust our valve and make it different. As it relates to hemodynamics, we presented data at CRT that showed the improvements that we made with S3UR with the RESILIA tissue, we saw a pretty significant reduction in gradient.

And so, if you need a copy of that presentation, I'm sure Mark can get it to you. So we've already made a lot of those enhancements to our UR platform and X4 is a RESILIA platform, as well, so we would expect those benefits to be there, as well.

Joshua Jennings

Great. And then just to follow up on just the TAVR and TAVR replacement cycle. I think when that really fully kicks in, is TBD based on durability? But I would love to just hear your thoughts on TAVR and TAVR as the, I guess, more prominent choice for a second procedure and this lifetime management of aortic stenosis patients.

Larry Wood
Sure. I think you're right on this, Josh. Our platform with its frame design and its coronary access really the ideal platform for that second procedure, but it's also the ideal platform to use in that second procedure. I think a valve needs to be a good host but it needs to be a good guest and that's, I think, going to be critically important. We--if you go all the way back to the PARTNER I trials that are older now, those patients were 83 years old at the time of implantation. We're just sort of probably getting into that range now where TAV and TAV is just kind of probably starting hitting a little bit of an inflection point in the next couple of years.

And I think as time goes by, that is going to be a bigger part of the story. But again, we think our platform is very well suited for that, and it's good for patients. The idea that if you have a valve that had, make up a number, 10 years of durability, but they can get a second procedure and get another 10 or 15 years of durability out of it, you have equivalent of 25-year durability, without a patient having to have an open heart procedure. And I think that's incredibly powerful for patients.

Joshua Jennings
And just to finish the piece, Larry, just on--if surgery becomes kind of, I guess, the more prominent second procedure option of using TAVR first segment, I mean, your positioning on the surgical side is very strong, too, with KONECT RESILIA, but maybe just your thoughts there. Thanks.

Larry Wood
For sure. I think our surgical platform plays well into that, as well.

Operator
Thank you. And ladies and gentlemen, we've run out of time for questions. I'll now hand it back to Bernard Zovighian for closing remarks.

Bernard Zovighian
Thank you so much. Thanks, everyone. I want to close with offering some big picture comment about the quarter. Obviously, we are very pleased about the strong performance for the company growing 10%. And when you think about it, this is the result of the strategy we put in place, years ago. What we have today is a diversified portfolio with TAVR, mitral, tricuspid and surgical, all of them contributing to the performance of the company.

TAVR for sure, it is the largest business for us. It's still our number one focus. TAVR has a lot of growth potential. But mitral and tricuspid are now contributing in a very meaningful manner, a

lot of the performance of the company. So it is why we are so confident, longer term, that we are going to deliver a sustainable growth, quarter-after-quarter, year-after-year, with all of the catalysts we are having.

Again, thanks for your interest. If you have any additional questions, please do not hesitate to reach out to Scott and Mark or myself, and have a great day. Thank you.

Operator
Thank you. That concludes today's call. All parties may disconnect. Have a good day.