

Edwards Lifesciences
Second Quarter 2023 Results
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Presenters

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Bernard Zovighian, Chief Executive Officer
Scott Ullem, Chief Financial Officer
Larry Wood, Group President of TAVR
Daveen Chopra, Global Leader of TMTT

Q&A Participants

Robbie Marcus - JP Morgan
Adam Maeder - Piper Sandler
Pito Chickering - Deutsche Bank
Richard Newitter - Truist Securities
Danielle Antalffy - UBS
Matt Miksic - Barclays
Chris Pascuale - Nephron
Josh Jennings - Cowen
Travis Steed - Bank of America
Matt Taylor - Jefferies
Larry Biegelsen - Wells Fargo
Vijay Kumar - Evercore ISI

Operator

Greetings, and welcome to the Edwards Lifesciences second quarter 2023 results conference call. At this time, all participants are in a listen only mode. A question-and-answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press star zero on your telephone keypad. Please note that this conference is being recorded. I will now turn the conference over to our host Mark Wilterding, senior vice president, investor relations and treasurer. Thank you. You may begin.

Mark Wilterding

Thank you very much, Diego. Good afternoon and thank you all for joining us. With me on today's call is our chief executive officer Bernard Zovighian along with our chief financial officer Scott Ullem. Also joining us for the Q&A portion of the call are Larry Wood, our group president of TAVR and surgical structural heart, and Daveen Chopra, our global leader of TMTT. Katie Szymann, our global leader of critical care is out of town today, but she'll be with us on future earnings calls.

Just after the close of regular trading, Edwards Lifesciences released second quarter 2023 financial results. During today's call, management will discuss those results included in the press release and the company's 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 aren't limited to, financial guidance and expectations for longer term 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're 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 difference and important product safety information may be found in the press release, our 2022 annual report on Form 10-K, and Edwards's other SEC filings, all of which are available on the company's website at [Edwards.com](https://www.edwards.com).

Finally, a quick reminder that when using terms constant currency and adjusted, management is referring to non-GAAP financial measures. Otherwise, they are referring to GAAP results. Reconciliations between GAAP and non-GAAP numbers mentioned during this call are available on today's press release.

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

Bernard Zovighian

Thanks, Mark, and hello, everyone. I am pleased to share with you the work that our team did to help more patients than even before with our lifesaving therapy. Today, I'm going to talk about the strong second quarter performance across product groups, our progress in advancing our patient focused innovation strategy, and our confidence in the outlook for Edwards in the years ahead.

In the second quarter, we achieved double digit sales growth driven by increased adoption of our innovative therapies. Total sales of \$1.53 billion grew 12 percent on a constant currency basis, slightly higher than our expectation. We experienced broad based growth across Edwards portfolio. Given improving healthcare staffing and our first half performance, we continue to expect strong results in 2023. As a result, we have listed our full year 2023 sales and EPS guidance. Longer term, we are confident in our focus in differentiated strategy, given heart valve failure is largely underdiagnosed and undertreated. We remain committed to increasing our warnings and providing innovative lifesaving therapies so even more patients can benefit.

Now, I will provide another view of the second quarter sales performance by product group. In TAVR, we continue to see strong demand for our leading SAPIEN platform with sales of \$992 million, up 10 percent year over year on a constant currency basis. Our U.S. and O.U.S. sales growth rates were comparable. Local selling prices were stable. In the U.S. our second quarter TAVR sales were aided by improved hospital staffing levers and the continued successful launch of SAPIEN 3 (inaudible) that total procedure growth was in line with our sales growth.

Additionally, we will be (inaudible) to this quarter in our pivotal trial ALLIANCE, designed to study our next generation TAVR technology SAPIEN X4. Outside of the U.S., we have positive constant currency sales growth from all regions. In Europe, Edwards' sales growth were driven by the broad-based adoption of our SAPIEN platform. Our sales in Japan grew sequentially and year over year on a constant currency basis. Although, our results continue to be impacted by lower-than-expected market growth and competitive trialing in the first half of this year. As a result, we estimate overall O.U.S. TAVR (inaudible) of growth in Q2 was slightly higher than Edwards O.U.S. TAVR growth.

During the quarter, at the Europe PCR Medical Congress data on the benchmark study, we are presented on 2,400 patients treated with SAPIEN valves across 28 European centers. It was very encouraging to note that patients experienced a 33 percent reduction in the median hospital length of stay while maintaining strategic clinical outcomes. This study showed that, by implementing best practices, with the SAPIEN platform, centers can be more efficient without compromising patient outcome.

Turning to TNTT, we remain focused on three key value drivers to unlock this opportunity: a portfolio of differentiated therapies, positive clinical prior results to support approvals and adoption, and favorable real world clinical outcomes. TNTT second-quarter global sales of \$48 million increased nearly 70 percent on a constant currency basis versus the prior year. Growth, while driven by contributed strong overall procedure volumes, adoption of our differentiated Pascal precision platform, and activation of more centers across the U.S. and Europe. We continue to hire, train, and grow the field team to deliver on our high touch model as we expand.

In mitral, enrollment is ongoing in the Class II-F pivotal trial for function in mitral patients. We are also pleased with the enrollment in the second pivotal trial for the SAPIEN N3 mitral valve replacement and remain on track to complete enrollment around the end of this year.

In tricuspid, the Class II-TR pivotal trial with Pascal continues enrolling well. With the completion of (inaudible) enrollment, continued access for Evoke allows U.S. centers to continue to offer this therapy for tricuspid patients. We remain on track for European approval by the end of 2023 and U.S. approval around the end of 2024.

In surgical, second-quarter sales of \$256 million increased 13 percent on a constant currency basis, driven by the adoption of a premium resilient products across all regions. Physicians and patients value the feature and benefit of this advanced tissue technology for both aortic and mitral surgical valve procedures. Patient enrollment continued in the second quarter for our momentous clinical study designed to demonstrate the durability of resilient tissue in the mitral position. We expect that confidence from the recently presented seven-year data of our clinical trial will continue to support adoption of our resilient family of products.

In critical care, second quarter sales of \$235 million increase, 13 percent on a constant currency basis, driven by contributions from all product lines. Growth was led by a smart recovery portfolio and healthy adoption of our Acumen IT sensor. Self-momentum for our Hemisphere monitoring platform was also positive in the second quarter with a health pipeline of future opportunities.

Before I turn it over to Scott, I also want to mention our expectation for the upcoming TCT conference in October. During the conference, we expect several important presentations regarding our transcatheter technologies. In TAVR, we are expecting a presentation of five-year clinical data with the TAVR low risk pivotal trial. In TMTT, we anticipate the presentation of a one-year full cohort of the CLASP 2D pivotal trial results. Additionally, we anticipate a presentation of the plan interim analysis of a place in two randomized cohorts. I look forward to seeing many of you at the investor event we plan to host at TCT. Our investor relation team will communicate details as we get closer to the event.

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

Scott Ullem

Great. Hey, thanks a lot, Bernard. We are pleased with our sales performance in the first half of the year, posting our second consecutive quarter of double-digit constant currency growth. All product groups grew double digits, and sales were balanced across regions, with the exception of Japan, which was impacted by the trialing of competitive TAVR products. We achieved total sales of the quarter of \$1.53 billion, which represents 12 percent year over year constant currency growth. We achieved adjusted earnings per share of \$00.66. Contribution of our better-than-expected sales performance was partially offset by higher performance-based compensation and investments in our transcatheter operations in support of our growth strategy.

Our GAAP earnings per share of \$00.50 was impacted by the intellectual property agreement I commented on last quarter. We previously had a long-term intellectual property agreement with Medtronic that expired last year. And in consideration for the new agreement, we paid \$300 million, approximately half of which has been expensed and the other half will be amortized over the next 15 years. Reconciliation between our GAAP and adjusted earnings per share for these and other items is included with today's release.

I'll now cover some additional details of our second quarter sales results and full year 2023 outlook by product group. A continuation of double digit global TAVR growth reflected a more stable hospital staffing environment as well as strong adoption of the SAPIEN family of valves. U.S. TAVR sales growth was driven by the launch of SAPIEN 3 Ultra Resilia, which remains on track to represent the majority of our U.S. TAVR sales before year end.

In Europe, Edwards sales growth was driven by the continued demand of our SAPIEN platform and was broad based by country. We still see some health system capacity challenges but are encouraged that centers are adapting to continue to treat their patients.

In Japan, although growth was below our expectation in Q2, we anticipate that growth rates will improve, driven by the ongoing launch of SAPIEN 3 Ultra Resilia. For global TAVR sales, we are adjusting the low end of our outlook slightly higher to \$3.85 billion to \$4.0 billion. And we now expect full year TAVR growth to be 10 to 15 percent on a constant currency basis versus previous guidance of 10 to 12 percent.

TMTT growth in the second quarter was driven by strong procedure volumes, adoption of our differentiated Pascale precision platform, and activation of more centers across the U.S. and Europe. Overall, we're pleased with our continued progress toward bringing a portfolio of TMTT therapies, combined with contemporary clinical data in order to achieve our vision of transforming the lives of patients with mitral and tricuspid valve disease. We now expect full year 2023 sales of \$180 million to \$200 million versus our previous expectation of \$170 million to \$200 million. In surgical structural heart, 13 percent constant currency sales growth in the quarter was driven by the adoption of Edwards premium products as well as strength in valve surgery procedures as hospital staffing levels have continued to improve.

Based on positive year to date performance, we now expect that our full year sales will now be in the range of \$960 million to \$1.02 billion versus previous guidance of \$870 million to \$970 million. This revised range implies low double digit constant currency growth in 2023.

Finally, turning to critical care, we continue to expect full year 2023 sales of \$870 million to \$940 million. For total Edwards, based on the strong first half of the year, we now forecast full year 2023 sales to be in the range of \$5.9 billion to \$6.1 billion versus prior guidance of the high end of \$5.6 billion to \$6.0 billion. We now expect full year total company sales growth to be in the 10 to 13 percent range on a constant currency basis versus previous guidance of 10 to 12 percent.

Lastly, we now expect our full year adjusted earnings per share to be between \$2.50 and \$2.60. We are projecting third-quarter sales to be between \$1.44 billion and \$1.52 billion. We are also projecting third quarter adjusted EPS of \$00.55 to \$00.61. I'll now cover additional details of our P&L. For the second quarter, our adjusted gross profit margin was 77.7 percent, as expected, compared to 80.5 percent in the same period last year. This reduction was driven by a less favorable impact from foreign exchange. We continue to expect our full year 2023 adjusted gross profit margin to be between 76 and 78 percent.

Selling, general, and administrative expenses in the quarter were \$469 million, or 30.6 percent of sales, compared to \$409 million in the prior year. This increase was driven by performance-based compensation and investments in transcatheter field-based personnel in support of our growth strategy. We continue to expect full year 2023 SG&A as a percentage of sales to be 29

to 30 percent as we invest in field-based personnel and our therapy adoption initiatives. Research and development expenses in the second quarter grew eight percent over the prior year to \$270 million or 17.7 percent 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 2023, we continue to expect R&D to be 17 to 18 percent of sales as we invest in developing new technologies and generating evidence to support TAVR and TMTT. During the second quarter, we recorded at \$27 million, reducing in the fair value of our contingent consideration liabilities, which benefited earnings per share by \$00.04. This benefit was excluded from our adjusted earnings per share of \$00.66. This reflects an adjustment of assumptions regarding potential milestone payments for a previous acquisition.

Turning to taxes, our reported tax rate this quarter was 9.7 percent or 13.1 percent, excluding the impact of special items. Our rate benefited from higher R&D tax credits and a 200-basis point excess tax benefit from stock-based compensation. We continue to expect our full year tax rate, excluding special items, to be 13 to 17 percent.

Foreign exchange rates decreased second quarter reported sales growth by 70 basis points, or \$8 million, compared to 2022. At current rates, we continue to expect an approximately flat year over year impact to full year 2023 sales, compared to 2022. Foreign exchange rates negatively impacted our second quarter gross profit margin by 220 basis points compared to the prior year. Relative to our April guidance, FX rates had a minimal impact on second quarter earnings per share.

Adjusted free cash flow for the second quarter was \$286 million, defined as cash flow from operating activities of \$34 million, less capital spending of \$48 million and excluding a \$300 million payment related to the Medtronic intellectual property agreement I mentioned earlier. We continue to expect full year 2023 adjusted free cash flow will be between \$1.0 billion and \$1.4 billion.

Before turning the call back over to Bernard, I'll finish with an update on our balance sheet and share repurchase activities. We continue to maintain a solid and flexible balance sheet with approximately \$1.5 billion in cash, cash equivalents, and short-term investments as of June 30th. We continue to expect average diluted shares outstanding for 2023 to be between \$610 million and \$615 million. We have approximately \$650 million remaining under our current share repurchase authorization.

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

Bernard Zovighian

Thank you, Scott. So, based on our strong first half results, we have increased confidence that 2023 will be an important year for Edwards. And we expect to deliver 10 to 13 percent sales

growth while making meaningful progress on our innovations to improve care for many more patients. Longer term, I have great confidence in our team to further extend our leadership position by bringing our differentiated technologies to patients globally.

In closing, we are well positioned for success. With that, I pass it back to Mark to open up Q&A.

Mark Wilterding

Thanks a lot, Bernard. With that, 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' questions during the remainder of the call.

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

Operator

Thank you. And if you'd like to ask a question, please press star one on your telephone keypad. A confirmation tone will indicate that your line is in the question queue. You may press star two if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. And once again, please limit yourself to one question and one follow up.

Our first question comes from Robbie Marcus with JP Morgan. Please state your question.

Robbie Marcus

Thanks for taking the questions, and congrats on a nice quarter. Maybe to start, global TAVR growth around 10 percent, a little weak in Japan. Where do you think we are in the recovery process in terms of stabilizing the system, stabilizing timelines and staffing in the system? And when do you think we'll get to a new normal in TAVR procedures and diagnosis and treatment?

Bernard Zovighian

Robbie, this is Bernard here. Thanks for the question. We are pleased with our global TAVR result in Q2. Ten percent constant currency growth comparable U.S., O.U.S., basically -- and it has been driven by continual strong demand for our leading SAPIEN platform. Also, what we have experienced is an improvement in the hospital staffing lever in the U.S. and globally. But I'm going to let Larry add some comments here.

Larry Wood

Hey, Robbie. Deciding what the new normal is probably a little bit tricky. But I feel like the system has continued to get better. I think when we track staffing, we're not where we should be, and we're not where we would have projected to be in absence of the pandemic. But I think patients are certainly coming in, and they're getting their visits. And I think when we look at some of the leading indicators, diagnoses are up, and patients are moving through the system. We still feel constrained somewhat at the Cath lab level. That's the whole place that we still

struggle. And I think centers have made tremendous strides. But it's still an adjustment coming out of COVID, and we're not back to what I'd call pre-COVID normal levels. And so, I think we still have a little ways to go. And I think we see that a little bit globally. It varies a lot across Europe. And we see it a little bit in Japan depending on -- I think they're still dealing with a little bit more COVID here and there. But I think the encouraging thing is we're at 10 percent globally, and we know we haven't fully recovered yet. So, I think there's still some opportunity for us to continue to do better. And we know the other treatment remains huge, and we still think there's a lot of opportunities to continue to grow this over the long term.

Robbie Marcus

Great. Thanks for that. And maybe just kind of a similar question. TMTT you beat in the quarter. That seems like it was even a bit more impaired over the past few years than the whole TAVR complex. Maybe just talk about mitral and tricuspid, particularly the launch of Pascale in the U.S., how you think adoption is going versus planned, how you're seeing the competitive situation play out and just your thoughts on TMTT in general, relative to TAVR normalization. Thanks a lot.

Bernard Zovighian

So, let me start, Robbie. And then I will ask Daveen to add some comments here. So, we are pleased about the Q2, obviously, gravity. What we are seeing is that the mitral market has done well in Q2. It's back to growing and (inaudible) double digit, something like that. The adoption of Pascale precision is going very well. It's going very well in U.S. It's going very well in Europe. And we are activating more centers across U.S. and Europe. So, we see a way to think about it. We have some great momentum from the market, from Pascale precision, and from us activating more centers. But Daveen, you want to add anything here?

Daveen Chopra

Yeah, thanks, Bernard. I think, as Larry and Bernard talked about, the market -- we continue to see recovery from the staffing portion of it. And I think you're right that maybe we got hit a little bit more on the staffing side during COVID. But coming out, we're also still seeing recovery. But I still think there's opportunity to keep getting better on that component. But that being said, with such a large number of patients looking for new therapies, we continue to see relatively strong market growth.

That being said, as we dive into it, we continue to open up new centers in both the U.S. and Europe. Specifically in the U.S., I think we're continuing to hear great feedback from physicians about the differentiated features and benefits of the Pascale system. We're ramping up the teams. We're opening up new centers each week. We're going through kind of the value add, value analysis committees in the contracting processes with each new center in the U.S. week in and week out. And we're really focusing, as you can imagine, on the largest accounts in the U.S. who do the most here so far. And so, I'm pretty excited with where we're going in U.S.

Maybe just to comment both on Europe -- I think as Bernard said, we've been, again, opening up new centers in Europe. And I want to make a comment that tricuspid, especially in Europe, continues to see very strong growth. It's a newer therapy, smaller obviously, in market size, but continue to see very strong growth where we're seeing that the market is growing and people are really seeing that Pascale actually in this situation, the tricuspid space, has really got these differentiated features for automatic and tailored treatment really for tricuspid care. So, overall, we continue to be excited about where Pascale is going in its launch.

Scott Ullem

And then, about the financial implications of everything that Bernard and Daveen just talked about which is we're feeling good about how TMTT is developing in 2023. You saw original guidance for sales was \$160 million to \$200 million. We bumped up the bottom end of the range by \$10 million last quarter, bumping it another \$10 million this quarter and it's an indication of how positive we feel about our progress this year.

Operator

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

Matt Taylor

Hey, guys. Thanks for taking my questions. So, I just wanted to ask, one, about the margins basically. So, you had nice gross margins here in Q2. I know you're making a lot of ongoing investments. And so, two things, I guess. What are kind of the key points to take to think about -- in terms of gross margins and opex spending through the second half of the year in terms of phasing or anything discrete to call out. And then, just conceptually at a higher level, how should we think about operating margin progression over the course of the next couple of years, especially as you might have some of your bigger clinical studies starting to wind down.

Scott Ullem

Thanks for the questions. I'll start with gross margin. Gross margin -- we're seeing some benefit of mix in 2023, but it's more than offset by the impact of foreign exchange that actually hit us last year in 2022 and it is flowing through our income statement in 2023.

You asked about phasing. It's going to get more impactful negatively in Q3 and Q4 based upon current exchange rates. Now, if exchange rates change, that may change a little bit as well. But we're expecting gross margins to come down a little bit in Q3 and Q4, relative to the first half. All that said, we expect to end up right where we thought we would in the range of gross margin guidance for 2023, so really nothing changed.

In terms of operating expenses, you're right. We've been putting more investment into especially field-based personnel, in Europe, in U.S., and even outside. And that's weighing on operating expenses. But that's okay. It's part of a deliberate plan to really drive topline growth by making sure that we've got the right people in the right places supporting our clinical

partners and making sure that patients are getting the right kind of care, especially are we're introducing these new products in places like TMTT and what Daveen talked about earlier.

As it relates to operating margin progression over the next couple of years, we continue to see opportunities to expand our operating margin, and we're looking for ways that we can do that. We've identified areas where we can make changes and gradually, incrementally expand our operating margin. But really, it's a secondary focus. The primary focus is investing for long term top line growth. Yes, some clinical trials wind down over the next couple years. But we've got other ones spooling up. You know about what trials Larry is running in TAVR and Daveen has going in TMTT. And this is a super important area of investment for us, again, to drive topline sales by contributing to this really robust body of clinical evidence that we have supporting the growth in those two transcatheter businesses.

Matthew Taylor

Great. Thank you, Scott.

Operator

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

Vijay Kumar

Hey, guys. Thanks for taking my question. Bernard, maybe my first one on just TAVR guidance here. I think the underline was raised at the high end to 13 percent. The first half TAVR underline has been 10 to 11. I'm curious why the high end was raised. Was there something within the quarter that you saw, some phasing, or is there something coming in the back half, which gives you the confidence perhaps that 13 percent is even possible?

Bernard Zovighian

Great, you know, Scott --.

Scott Ullem

Yeah, Vijay, maybe I'll jump in here and give you a sense of how we see it. The change in guidance, the expansion on the top end of the range, largely reflects better than expected performance in the second quarter and the first half results compared to what we originally expected back at the time of the investor conference. And so, because we overachieved in the first half, we are introducing this higher top end of the range to accommodate a potential faster growth scenario the way we saw earlier in the year. We're still modeling and planning around midpoint of that 10 to 13 percent range. But that's the reason why we expanded the top end.

Vijay Kumar

Understood. And maybe one sort of related question here. First half, we've seen SAVR grow mid-teens. How much of that is volume versus price? Why are we still seeing SAVR outgrow TAVR? I think I heard Larry mention the macro environment staffing is improving. But I'm just --

so, it's hard for us to see SAVR outgrow TAVR. Is this a fundamental change in the market, or perhaps new product introductions that's driving SAVR? Some color on SAVR versus TAVR would be helpful.

Bernard Zovighian

So, Vijay, let me start, and then, I will ask Larry to add his comments here. So, both SAVR and TAVR business are growing nicely. And the SAVR sales growth has exceeded TAVR because of a combination of things. Market growth -- SAVR market growth, but not only. Premium pricing over innovative price premium technologies. And because of all of that (inaudible) better competitive position. So, again, in SAVR, what you have is a number of things happening, where in TAVR is it mainly procedural growth. Larry, you want to add anything here?

Larry Wood

Yeah, I think that's right. We sort of have the three components that help contribute. So, you can't look at the growth rate and turn it all into procedures because, for the TAVR side, it is overwhelmingly majority procedures. But it's more of a combination of things on surgery. I will say as we move through the COVID recovery though we probably saw hospitals prioritize their surgical programs, probably most. And I think that deals a little bit with patient acuity and just the need to get those patients treated probably a little bit sooner. So, I think Cath lab recoveries maybe lagged a little bit behind the surgical recovery. But again, we're very happy with where we saw TAVR procedure growth this last quarter.

Operator

Thank you. Our next question comes from Larry Biegelsen with Wells Fargo. Please state your question.

Larry Biegelson

Good afternoon. Thanks for taking the question. Two on the pipeline and the TCT updates on this call. Let me start with the TRISCEND II comments. That's big news here. Arguably EVOKE is your most important pipeline product. So, I guess my questions, Bernard -- just a couple here. One, has the trial stopped yet? Second, what would success look like to you given the Triluminate (sp) results showed only a quality-of-life benefit but no positive trends on heart outcomes. And lastly, on TRISCEND II, if positive, I would think approval could come in mid '24, not late '24.

Bernard Zovighian

Thank you, Larry. I see that you are aggressive. That's good. Look, we completed the enrollment of a full cohort of TRISCEND II. I think we have been sharing that in the past. We need to wait one year follow up and then putting together all of the data, presenting that with the FDA. So, this is going to take some time. So, it is why we still believe that around 2024 approval in the U.S. is reasonable. Are we going to go faster? For sure. But I think end of 2024 is reasonable.

Now, I'm sure your question about how do we feel about study results is in light of what we have seen with Triluminate. It is tough to comment because Triluminate was using one technology. TRISCEND II is using a different technology, different devices. We don't know -- you know, very little about tricuspid disease. So, it's very tough to comment on that. But I have to say that quality of life is very important for patients. Again, we will have to see what the result of this study. And we are confident. Daveen, you want to add anything here?

Daveen Chopra

Yeah, I'll just add two small points. Thanks for the question. This interim analysis was a part of a statistical plan. So, it's already been planned out and was also a part to kind of show these results. So, we're excited to share these results with the clinical community. And I'll make the other comment that, for us, I'm actually pretty excited about what we've seen actually previously with Triluminate. This helps really confirm outcomes that have come out of other studies with tier technologies that we have on the Pascale device that tier and tricuspid delivers great tricuspid reduction with meaningful quality of life improvements. And we are excited to see randomized data. So, to me, these are all great positive tailwinds in tricuspid, and we're excited to see what the TRISCEND II interim planned analysis will show.

Larry Biegelsen

That's helpful. Just for my follow up, the other one on the PARTNER III five year data, what do you think physicians will be focused on here. There's been some concern among investors and clinicians given the curves converging between TAVR and SAVR between year one and two in the two-year data. Is there anything you can say that could allay concerns? Thank you.

Scott Ullem

I can't speak to the data or what's going to be presented. I think what people are going to be looking at is what the trial was powered for and what it was designed to do. We have a composite end point of death, all stroke, and rehospitalization, and those are the three components. So, I think first and foremost, you look at the primary. And then, I think people are going to look at the subcomponents of that and say what do they see happening in the trends in the trial. I think that's what people are going to be looking for. But we're excited to -- the data is coming forward, and it seems it's going to continue pulling it in. And once it's all adjudicated the clinicians will obviously take the steering wheel, and they'll present the data. But I think overall, every time we have one of these data reports, it just adds to our body of knowledge and adds to the body of evidence. And I think that's what we do for the clinical community. So, again, I think primarily we focus on the primary endpoint just like we did in the trial, and we'll see where we are.

Operator

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

Travis Steed

Thanks for taking the question. I was wondering -- a follow up on U.S. TAVR growth. I wanted to understand a little bit better. I think you said price was stable. But it sounds like RESILIENT has gone faster than expected. So, I don't know if there's any way to kind of parse out the U.S. -- it sounds like 10 percent TAVR growth in the U.S. How much of that was actually price versus RESILIENT in the quarter?

Scott Ullem

Thanks for your question. The price is a pretty small factor in the U.S. growth number. It's overwhelmingly driven by the procedure growth. When you look at what we're going for with RESILIENT for S3-UR, we're still in the -- I wouldn't call it necessarily the early part. But we haven't even reached halfway in the launch of RESILIENT yet. And while we did go for a list price increase of \$1,500, if you look at that a percent of the total device cost, it's a lot smaller than what we did on the surgical side of things. So, it's certainly a contributor and it's a long-term contributor for us. But it's pretty small in comparison to the procedure growth. And remember too, as people's volumes go up, they continue to hit rebate tiers and they get discounted accordingly. So, you've got to factor all that in as well.

Travis Steed

Great. That's helpful. And then, I did have a follow up on the raised TAVR guide for the full year. Is there anything you're seeing in July? Just curious -- what's giving you the confidence to raise the full year guide. And when you think about Q3, should we think about this being down sequentially versus Q2 and dollars like it has been historically?

Scott Ullem

Yeah, it's Scott. A couple things. The increase in the guide was largely reflective of our stronger than expected first half performance and the prospect of potentially overachieving what we had modeled for the second half. Although we're still modeling the midpoint of that range that we provided. As far as the July expectation, I guess we'll just leave it as the range that we put out for total company sales in the third quarter incorporates what we see so far months to date. But we're not going to get into the month-to-month report. In terms of what the later in the year trend may look like, a lot of it depends on seasonality. We get hit by the summer vacation season, not just in Europe, but also in the U.S. So, we'll be able to talk more about that impact when we get to our third quarter call, both for looking back on the third quarter and what the run rate looks like going into Q4.

Operator

And your next question comes from Josh Jennings with Cowen. Please state your question.

Josh Jennings

Two TAVR questions. One, first, just on the Japan recovery, can you just talk about or share any insights into the (inaudible)?

Operator

Excuse me, Josh. You're cutting out. Could you pick up your handset?

Josh Jennings

Oh, sure. Can you hear me now?

Operator

Yeah, much better. Thank you.

Josh Jennings

Sorry about that. Two TAVR questions. First one, Japan recovery trajectory. Maybe just help us better understand any factors that are limiting the recovery in Japan and how you see that market shaping up in the back half of the year. And then, the second question -- it's just on the progress trial. Any updates on the enrollment pace? I believe the first patient was enrolled in the end of 2021, so it's been about a year and a half of enrollment. Could that trial complete enrollment in 2023 or 2024? Thanks for taking the questions.

Bernard Zovighian

Thank you, Josh. So, in Japan, what we are seeing is a positive, like I said, sequential. And also, year over year growth in the quarter. It was (inaudible) expectation. But we believe it is transient for a couple of reasons. One the market -- as you know, the market is still impacted from COVID and is still recovering from COVID. And also, we believe it is transient because we are very pleased with the early feedback with the launch of SAPIEN III in Japan. So, we feel like we grew year over year sequentially below our expectations. But we are confident that we are going to improve this in Japan. Maybe Larry -- you want to add anything here?

Larry Wood

I think that's right. I think Japan certainly got more impacted during COVID waves, I think, even than some other regions in the last year probably. And so, as that stabilizes, we think that that helps. And as Bernard said, we did see growth year over year and sequential. We just probably had higher expectations and I think that's what's reflected in our comments. But we're optimistic in the back half of the year that we're going to continue to see recovery in Japan, and that's all factored into our guidance.

On progress, we don't have any updates on enrollment right now. I will say, overall, we've been pleased with how that trial has gone. But probably investor conference is when we'll probably provide a more fulsome update on that and probably give some more projections. We'll have a lot more information than that we can probably be a little bit more fulsome and probably a little bit more accurate about our projections.

Operator

Thank you. Our next question comes from Chris Pascuale with Nephron. Please state your question.

Chris Pascuale

Thanks. Scott, the 3Q EPS guidance -- a little bit lower than the Street was modeling. It looks like operating margins expected to contract by a couple hundred basis points versus where you were in the first half and then bounced back in 4Q. Is there anything in particular about the third quarter that drives that margin dip?

Scott Ullem

Well, the only thing in particular about Q3 is we pick up the summer seasonality which hits us on the topline. And generally, the expenses continue to go through and are not as seasonal. That's what it really reflects.

Chris Pascuale

And then, I know, Katherine is not on the call today. But just looking at the critical care guidance, that business has been running hot here, double digit growth first half of the year. Looks like guidance assumes a pretty meaningful decel in the back half. Is that just tougher comps, or is there something in particular you're looking at there?

Bernard Zovighian

Exactly. You got it. We had a great Q2 after a great Q1, very balanced across all product lines. And we didn't change the guidance. We changed the guidance in the last quarter. But it is more about the year-over-year comparison in the second part of the year. Thanks for the question.

Operator

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

Matt Miksic

Thanks so much for taking the question. So, I wanted to follow up on this very strong performance in SAVR and good but not as strong performance in TAVR as it pertains to staffing. And I know you talked about price a little and volumes. But can you talk a little about, given that TAVR interventional TAVR resources that sort of grew up during the clinical trial of TAVR across the clinical community in U.S., Europe kind of lost many of those folks who are maybe more proficient and good news, replacing them with other folks, but bad news, maybe some of those folks are still coming up the curve. If you could talk about -- is that more of an issue on the TAVR side because SAVR surgical interventions are bit more mature? Is that less of an issue on -- we've heard that from some centers that are sort of -- we're more productive, more skilled, more mature on one side versus the other, which is kind of one of the factors. But it'd be great to get some color. And I have one quick follow up.

Scott Ullem

Sure. Let me take a shot at that. So, probably the biggest place we saw turnover on the TAVR side of things were our (inaudible) coordinators. And I think we talked before about the number of clinical coordinators we train. And I think part of that -- it's just a really demanding job.

There's a lot that goes into that in terms of screening and moving people through the system. And so, I think there's a lot. So, we see a little bit more turnover in that than certainly -- and we don't really have the same level of work on the surgical side because on the TAVR side, remember, patients have to get a CT. They have to have a lot more workup. And not every patient gets -- most surgical patients, in fact, don't get a CT. And so, it's just easier to move surgical patients through the process because literally if a patient comes in and they're deemed a candidate for surgery, they can move right to surgery within a matter of a few days or a week where for TAVR, they're going to have to be scheduled for a CT. You've got to rule out coronary disease. And there's just other things that you have to do. So, there is pressure in staffing in the system, that would have impacted across the whole system. But there's just more systems back on the TAVR side. We didn't lose our operators. Those aren't the people we lost. We didn't lose our operators. We still have a lot of residents and a lot of people coming up through the system. So, it's not so much the impacting physicians as much as it is just general support staff.

Matt Miksic

Got it. That's helpful. And then, just on -- it's a question about some of the investments you've made. And maybe for Bernard and the rest of the team -- the investments that we see coming through the clinical programs now like REVOKE and Pascale, investments in innovations that you made some time ago. And I'm just wondering -- are you at a stage where you've got what you need to address the TMTT markets and sort of more advanced other valvular disorders, or are you still out there hunting for sort of better mousetraps or additional technology and IP that we should expect to kind of further flesh out those programs going forward? Thanks.

Bernard Zovighian

Thanks, Matt. This is a very good question. So, think about our vision in TMTT. Our vision is -- there are so many patients in need, you know, mitral and tricuspid. And we believe that to be able to unlock this very large market opportunity, we need a comprehensive portfolio. And we are building this comprehensive portfolio. So, what you can expect is us investing in innovation, next gen innovation. So, Pascale Gen II, Gen III, Gen IV, the same with Evoke, the same with mitral replacement. So, this is on the technology side. We know from experience in TAVR, you need technology with evidence. In TAVR, we don't have any randomized clinical study. We (inaudible) three, four, five, or even more potentially, in the space probably close to 10 between us and our competition. So, here we will have to think about it the same way. So, in my mind, we are not done at all in the TMTT clinical evidence, and we are not done in terms of further innovating to be able to treat all of the patients, mitral and tricuspid patients. We like definitely our technology. We like so far, our clinical evidence that we are providing and more to come.

Operator

Thank you. And our next question comes from Danielle Antalffy with UBS. Please state your question.

Danielle Antalffy

Good afternoon, everyone. Thanks so much for taking the questions. Bernard or maybe Larry, just on TAVR -- two questions there. Number one -- one of the things everyone is sort of trying to figure out as we move through Q2 is impacted backlog. I know the high acuity nature of the TAVR procedure, likely not much backlog. And I know you did benefit marginally in Q1. Just curious if you think you saw any of that work down in Q2.

That's the first question. Second question is -- over the last three quarters, you gave some color on high volume versus low volume centers driving a lot of the growth. Just curious if you could give some color there whether this is really broad based across low and high-volume centers. Thanks so much.

Larry Wood

Thanks, Danielle. We think as the front end of the funnel starts to fill back up again with referrals and that, I think there is a possibility that we are seeing a little bit of a backlog grow as we talk about the last mile still being probably the part that we see the most pressure on, staffing. I wouldn't be able to quantify that, and it's probably just sort of more of a directional thing. But the fact that we've seen the growth in TAVR for the first couple quarters of this year and we've back into double digits and it's not like our centers are out beating the bushes for patients. We're pretty pleased with our patient flow right now. So, I think that that's obviously really positive. I think in terms of large centers, small centers, we saw a dynamic throughout COVID that when COVID would sort of -- the way it would come through, that people -- we'd sort of see the smaller centers growing faster, indicating people may be stayed a little bit more local. When COVID tends to go away, then people tend to go back to the centers, the large centers of excellence, and they're willing to travel a little bit more. So, I think we saw a little bit more growth in the large centers in this past quarter than we saw in the small centers. But that's something that has varied a lot quarter by quarter. But this last quarter would have been more in the large centers than the small ones.

Operator

Thank you. And our next question comes from Richard Newitter from Truist Securities. Please state your question.

Richard Newitter

Thanks for taking my questions. Two here. The first one -- just on reconciling the raise to the high end of the TAVR range and your Japan commentary relative to expectations, do you need Japan and the dynamic there to approve in the second half to hit the midpoint of your guidance, or is that kind of what's embedded to get to the upper end? I'm just trying to reconcile those two pieces.

Larry Wood

We're expecting Japan to perform better in Q3 and Q4, and that's a contributor to our assumption about the midpoint of the range. Now, Japan does better than we're expected -- that could get us into the higher end of the range. And if it does worse, the lower end of the

range. All of that said, Japan is still a pretty small percentage of our overall sales in TAVR. But it's an important one, and it's an important growth driver longer term.

Richard Newitter

And then, just secondly -- thanks for that. Secondly, as we think about, especially in the U.S. TAVR -- you're at about 10 percent now. You've got RESILIA pricing, contributing some amount. So, I guess if you're 10 percent with RESILIA, as we just think out, whether it's '24 or it's just on a normalized basis, should we be thinking of your view that the TAVR market has approached a high single digit volume growth sustainably as we think back to normalized levels? Is that the right way to think about it?

Larry Wood

I'll try to answer that, and Bernard or Scott can certainly jump in as well. No, we don't think we're seeing an overall slowing of growth in the TAVR space. We think we actually have a pretty long runway here. We think there's still a lot of untreated patients in the system, and we continue to try to get through that. And as I said earlier, I still feel like we're somewhat constrained within the system for staffing, and we still put double digit growth on the board the first two quarters. So, I feel like there's still a long-term opportunity, and we haven't even begun to talk about the long-term impact of things like early TAVR and things like progress trials that obviously go much further. I think to try to think that this is going to go the way of population growth any time soon -- that's just not how we see it.

Scott Ullem

Yeah, I would just add to that Larry -- just to reinforce that. Our confidence in \$10 billion total addressable market hasn't changed one bit in 2028. And so, while COVID interrupted our trajectory to that (inaudible), we still feel a lot of confidence that we've got big growth ahead of us, not just with current indications or current product portfolio, but added to that our new technologies and broader indications in the U.S., Europe, and beyond.

Operator

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

Pito Chickering

Hey, good afternoon. Two quick question here. For the U.S. markets, is there any geographical spread for these large centers that are growing in markets that were still coming out of COVID versus ones in the South that were faster coming out of COVID, or is it broad based geographically?

Larry Wood

When we were in the middle of COVID, we saw a lot of variation in the country based on where COVID was at any given point and because there was a lot of variation in healthcare policy for various different states in terms of how they reacted. So, we saw a lot of different variations. I

would say most of those restrictions have sort of dissipated now, and I don't -- we're not seeing anywhere near that high variability from state to state or region to region that we used to see and that's certainly true in the U.S.

In Europe, we do see a little bit of regional impact, a little bit more where one region will grow faster than another region. But it's not anywhere near the extremes that we saw during COVID where we saw huge swings now. They're much more muted now. And I would say we -- if I look back through history, we've always seen a little variation in Europe from country to country. So, it feels like it's maybe not normal but it's getting pretty close to normal, I guess I'd say.

Pito Chickering

Okay, fair enough. And then, with the competitor talking about U.S. growth in mitral and the need to restart the referral network, can you talk about what you think the overall mitral market grew in the high market share is looking and any changes to your long-term market growth of that market?

Bernard Zovighian

So, let me start here, and then, Daveen, you can add some comments. What we have seen is a nice recovery in Q1 and in Q2 in the mitral market in the U.S. and even in Europe. I'm sure you know, Daveen, you have more precise commentary here to add.

Daveen Chopra

Yeah, sure. No, definitely. I think (inaudible) the overall TMTT market with both tricuspid and mitral continues to grow very well on the global basis, in that -- close to that 20 percent kind of mark globally. In the U.S. (inaudible) we do see strong growth. I think, Bernard, you were saying something like almost double-digit growth which is about the ballpark we're kind of seeing for U.S. mitral. So, we think it's there, but not as strong as it is on a global nature. As you remember in many countries of the world, these technologies are just coming for the first time in there. We're still launching this technology into many, many countries. We're in very few countries. There are countries in Europe, countries outside of Europe that we haven't even launched into yet. So, we continue to see, as we launch in new countries, that'll help the market grow as well as the continued adoption of mitral in the U.S.

Operator

Thank you. Our next question comes from Adam Maeder with Piper Sandler. Please state your question.

Adam Maeder

Hi, good afternoon, guys. Thank you for squeezing me in here. Two TAVR related questions. I'll ask them both up front. First, the ALLIANCE study -- it sounds like that's going to restart enrollment this quarter. Can you just talk about the fix or improvements to get safety and (inaudible) back in the clinic and remind us where we are in terms of enrollment with that study?

And then, the second question is just a clarification on S3 ultra RESILIA. I know you're launching that obviously here in the states. I think that's approved in Japan and launching. What is the status that -- of that technology in Europe? Thanks for taking the questions.

Larry Wood

Sure, thanks. Well, in terms of the changes we made to X4, they were all delivery system related. So, there weren't any changes made to the valve or anything along those lines, which is why we were able to make the changes pretty quickly and get back in the clinic. And so, we're really pleased with where we are. And we're all approved to begin enrollment. All of the centers have to go back in and go back through the RBs (sp) and whatnot. But we have a number of centers that are already greenlighted and ready to go. So, we expect to begin enrollment again very, very shortly. I'm not ready to give an update on enrollment, much probably like progress, we'll probably do that at the investor conference once we have a little bit more of a run because it's not really about where we are. It's projecting where we think we're going to finish. So, I'd rather give you a more fulsome answer on that a little bit later.

S3UR -- we're working with European regulators on that. But remember, there's been a huge change in the regulations in Europe to the MDR process, and there's also just a huge bottleneck in terms of the number of devices that are working their way through the system there. So, we don't have any timing on that. Frankly, all the notified bodies are sort of learning about how the new regulations play as are all the sponsors. So, we don't have any timing on that yet. But we do have it approved in Japan, and that launch is well underway. We do have it approved in the U.S., and that's underway. And in both of those markets, we expect that to be the majority platform as we exit the year.

Operator

Thank you. And ladies and gentlemen, we have now reached the end of the question and answer session. I will now turn the call over to Bernard Zovighian for closing remarks.

Bernard Zovighian

Thanks Diego. So, let me close this meeting by saying I am excited about our performance so far in 2023 and confident in our outlook for the rest of the year. In addition, beyond the numbers, I am pleased with our progress and pipeline development and clinical trial and confident in our long-term strategy to help even more patients. Thank you for your continued interest in Edwards. Mark, Oliver (sp), Scott, and I welcome any additional questions by phone.

Operator

Thank you. And that concludes today's conference. All parties may disconnect. Have a good evening.