Edwards Lifesciences Corporation
Third Quarter 2023 Earnings Conference Call
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Presenters
Mark Wilterding, Senior Vice President, Investor Relations and Treasurer
Bernard Zovighian, CEO
Scott Ullem, CFO
Larry Wood, Group President of TAVR
Daveen Chopra, Global Leader of TMTT

Q&A Participants
Robbie Marcus—JPMorgan
Larry Biegelsen —Wells Fargo
Vijay Kumar —Evercore ISI
Josh Jennings —TD Cowen
Travis Steed —Bank of America
Joanne Wuensch – Citibank
Matt Miksic – Barclays
Danielle Antalffy – UBS
Pito Chickering – Deutsche Bank

Operator
Greetings, and welcome to the Edwards Lifesciences Third Quarter 2023 Earnings Conference Call.

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 and Treasurer. Thank you. You may begin.

Mark Wilterding
Thank you very much, Diego, and good afternoon, and thank you all for joining us. We are coming to you live from San Francisco at the 35th Annual TCT Conference.

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 are Larry Wood, our Group President of TAVR and Surgical Structural Heart and Daveen Chopra, our global leader of TMTT.

Just after the close of regular trading, Edwards Lifesciences released third quarter 2023 financial results. During today's call, management will discuss those 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 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 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 safety information may be found in the press release, our 2022 annual report on Form 10-K and Edwards' other SEC filings, all of which are available on the company's website at edwards.com.

Unless otherwise noted, our commentary on sales growth refers to constant currency sales growth, which is defined in the quarterly results press release issued earlier today.
Reconciliations between GAAP and non-GAAP numbers mentioned during the call are also included in today's press release.

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

Bernard Zovighian
Good afternoon, everyone. As Mark said, we are hosting today's call from TCT in San Francisco. I am going to start by covering some of the exciting developments at the conference, share highlights of the significant progress our team has made advancing our strategy, review our strong third quarter results and finally, discuss our confidence in the outlook for Edwards.

There are a lot of data being presented this week about technologies Edwards has developed. Included among these are results from three late-breaking clinical trials, all of which reflects Edwards commitment to generating high-quality evidence to advance innovative therapies for patients suffering from structural heart disease.

Yesterday, physicians presented 5-year data from the PARTNER e low-risk pivotal trial. We believe these data demonstrate a TAVR with the SAPIEN platform should continue to be the preferred therapy for treating patients who have severe symptomatic aortic stenosis.

After more than 20 years of rigorous clinical experiences and trials, now eight New England Journal's Medicine publication, and over a million patient treated, SAPIEN technology offers patient unique benefits. SAPIEN 3 has demonstrated 99% freedom from death and disabling stroke at one year, 90% survival at five years and is the only valve with a THV and THV indication. This is true lifetime management benefit which expands option for patients.

Tomorrow at TCT, we are looking forward to the presentation of a 6-month analysis of our EVOQUE transcatheter tricuspid valve, the first of its kind therapy for the millions of patients suffering from tricuspid valve disease. In addition, tomorrow, you will see the 1-year full cohort result of a CLASP IID pivotal trial with PASCAL.

We continue to make meaningful progress to advance our vision of offering a portfolio of innovative transcatheter therapies to treat tricuspid and mitral valve disease.

In the last several weeks, we achieved four important milestones in support of our commitment to patient-focused innovation. First, CE Mark approval for the EVOQUE transfemoral replacement system; second, CE Mark approval for the MITRIS RESILIA surgical mitral valve; third, PASCAL PRECISION approval in Japan.

Finally, the completion of the enrollment in the first ever pivotal trial for any transfemoral mitral replacement therapy, the ENCIRCLE Trial for SAPIEN M3.

Turning now to Q3 financial performance. Third quarter global sales grew 11% to $1.5 billion, led by our differentiated portfolio of innovative therapies. We were pleased with the results, which were in line with our expectations and to have present another quarter of double-digit sales growth.

For the full year, we continue to expect total company sales growth to be in the 10% to 13% range. Now I will provide an overview of the third quarter sales performance by product group.

In TAVR, we continue to see strong demand for our leading SAPIEN platform with third quarter sales of $961 million, up 10%, year-over-year. Our U.S. and OUS sales growth rates were comparable. Our U.S. and OUS competitive positions were stable and globally, local selling prices were stable.

In the U.S., our third quarter TAVR sales were driven by the continued successful launch of SAPIEN 3 Ultra RESILIA. On the clinical side, we are pleased with the pace of enrollment in our pivotal trial ALLIANCE , designed to study SAPIEN X4, our groundbreaking next-generation TAVR technology.

In Europe, Edwards sales growth was driven by the broad-based adoption of our SAPIEN platform. We look forward to additional data supporting the Edwards benchmark program to be presented at the PCR London Valves conference in November.

Our sales in Japan grew year-over-year, reflecting a gradual recovery in market growth and strong adoption of SAPIEN 3 Ultra RESILIA, competitive trialing in the third quarter where it was less pronounced versus in the first half of this year. And as expected, we grew faster than overall procedure growth.

Around the world, we remain focused on improving diagnosis and treatment of the many more patients who remain undertreated.

In summary, the combination of our global TAVR leadership, along with the data presented at TCT this week, gives the company further confidence in the future of TAVR and the company's expectation of a $10 billion opportunity, by 2028.

Now turning to TMTT. Our commitment to the unmet needs of mitral and tricuspid patients took a significant step forward with the achievement of several important milestones in this past quarter. TMTT third quarter global sales of $52 million increased 65% versus the prior year.

This performance was driven by accelerating adoption of our differentiated PASCAL PRECISION platform, the activation of more centers across the U.S. and Europe, as well as TEER procedure growth.

We continue to be pleased with our excellent clinical outcomes, reflecting the impressive performance of PASCAL PRECISION and the value brought by our comprehensive high-touch model. We are continuing the expansion of PASCAL PRECISION globally, with the expected launch in Japan, before the end of the year.

In our mitral clinical trials, we look forward to the 1-year CLASP IID randomized pivotal trial and CLASP IID registry outcomes with PASCAL to be presented as part of a late-breaking scientific sessions tomorrow at TCT. This will add to the body of evidence supporting TEER as an effective therapy for patients.

With the earlier-than-expected completion of enrollment in the ENCIRCLE pivotal trial for SAPIEN M3, we believe we are one step closer to offering an important value replacement option, beyond TEER, to serve even more patients suffering from mitral valve disease.

In tricuspid, earlier this month, we received CE Mark approval for EVOQUE. We look forward to bringing this new therapy to Europe, through a disciplined launch that will focus on ensuring excellent patient outcomes. Now, with this approval, physicians in Europe will have access to this groundbreaking option in addition to TEER.

As noted, tomorrow at TCT, lead breaking data from the TRISCEND II pivotal trial of the EVOQUE replacement technology, will be presented on the first 150 randomized patients based on EVOQUE's FDA breakthrough pathway designation. This landmark presentation on a novel therapy demonstrate our leadership and commitment to innovation and science, and our focus on helping large population of patients with unmet needs.

In summary, for TMTT, we are proud of the new therapy introductions, clinical trial achievements and geographic expansion we have achieved to advance our vision to build a portfolio of therapies to transform the lives of mitral and tricuspid patients.

In Surgical, third quarter sales of $247 million increased 11%, driven by a balanced combination of stronger global adoption of Edwards premium technology and overall procedure growth.

We continue to see strong momentum of our resilient portfolio globally, which has been widely adopted because of the excellent durability of this proven tissue technology supported by the recent 7-year aortic data and 5-year mitral data from our COMMENCE clinical trial.

We are confident about the future of this technology as we expand the overall body of resilient evidence, including ongoing patient enrollment of our Momentis clinical study. Finally, we received CE Mark approval for our MITRIS RESILIA mitral valves, earlier this month. We expect to introduce these valves in the fourth quarter, followed by full European launch in 2024.

In Critical Care, third quarter sales of $221 million increased 6%, driven by our smart recovery portfolio with strong adoption of our Acumen IQ sensors equipped with the high potential protection index algorithm.

We remain confident in our pipeline of Critical Care innovation as we continue to shift our focus to smart recovery technologies designed to help clinicians make better decisions and get patients home to their family, faster.

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

Scott Ullem
Thanks a lot, Bernard. We are pleased to report third quarter sales performance in line with our expectations, with strength across all product groups.

We achieved total sales of $1.48 billion, which represents 11% year-over-year growth. We achieved adjusted earnings per share of $0.59. Our GAAP earnings per share of $0.63 benefited from a change in U.S. tax regulations. A full reconciliation between our GAAP and adjusted earnings per share for this and other items is included with today's release.

I'll now cover some additional details of our third quarter sales results and full year 2023 outlook by product group. A continuation of double-digit global TAVR growth reflected a more balanced 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.

In Japan, improved growth in the third quarter was driven by the ongoing launch of our SAPIEN 3 Ultra RESILIA valve.

For global TAVR sales, we continue to expect full year 2023 sales of $3.85 billion to $4.0 billion, representing 10% to 13% growth. TMTT growth in Q3 was driven by adoption of our differentiated PASCAL PRECISION platform, activation of more centers across the U.S. and Europe and strong procedure volumes.

Overall, we are pleased with our continued progress towards establishing a portfolio of TMTT therapies, combined with temporary clinical data in order to achieve our vision of transforming the lives of patients with mitral and tricuspid valve disease. We continue to expect full year 2023 TMTT sales of $180 million to $200 million.

In Surgical Structural Heart, 11% sales growth in the quarter was driven by the adoption of Edwards RESILIA products. Based on positive year-to-date performance, we continue to expect that our full year sales will be in the range of $960 million to $1.02 billion, implying low double-digit growth in 2023.

And in Critical Care, we continue to expect full year 2023 sales of $870 million to $940 million.

For total Edwards, based upon the performance we have delivered year-to-date, we continue to expect full year 2023 sales to be in the range of $5.9 billion to $6.1 billion, and full year sales growth to be in the 10% to 13% range.

Lastly, we continue to expect our full year adjusted earnings per share to be between $2.50 and $2.60. We're projecting fourth quarter sales to be between $1.45 billion and $1.53 billion. We are also projecting fourth quarter adjusted earnings per share to be between $0.60 and $0.66.

Now I'll cover additional details of our P&L. For the third quarter, our adjusted gross profit margin was 76.4% as expected, compared to 81% in the same period, last year. This year-over-year reduction was driven by impacts from foreign exchange. Remember last year, Edwards' gross profit margin was lifted by an unusually positive impact from foreign exchange.

We continue to expect our full year 2023 adjusted gross profit margin to be between 76% and 78%.

Selling, general and administrative expenses in the quarter were $440 million, or 29.7% of sales, compared to $377 million in the prior year. This increase was driven by investments in transcatheter field-based personnel in support of our growth strategy and performance-based compensation.

We continue to expect full year 2023 SG&A as a percent of sales to be 29% to 30%, as we invest in field-based personnel and our therapy adoption initiatives.

Research and development expenses in the third quarter grew 16% over the prior year to $270 million, or 18.3% of sales. This increase was primarily the result of continued investments in our transcatheter valve innovations, including increased clinical trial activity.

For the full year 2023, we continue to expect R&D to be 17% to 18% of sales as we invest in developing new technologies and generating evidence to support TAVR and TMTT.

Turning to taxes. Our reported tax rate this quarter was 12.7% ,or 18.8%, excluding the impact of special items. Our reported rate benefited from the suspension of certain U.S. tax regulations surrounding foreign tax credits. Our slightly higher-than-expected non-GAAP rate resulted primarily from income mix and a lower excess tax benefit from stock-based compensation. We continue to expect our full year tax rate, excluding special items, to be between 13% and 17%.

Foreign exchange rates decreased third quarter reported sales growth by 140 basis points or $16 million, compared to the prior year. At current rates, we now expect an approximately $40 million year-over-year negative impact to full year 2023 sales, compared to 2022. FX rates negatively impacted our third quarter gross profit margin by 410 basis points, compared to the prior year.

Relative to our July guidance, FX rates had a $0.01 negative impact on third quarter earnings per share.

Free cash flow for the third quarter was $356 million, defined as cash flow from operating activities of $411 million, less capital spending of $55 million. We continue to expect full year 2023 adjusted free cash flow will be between $1.0 billion and $1.4 billion.

And 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 $1.9 billion in cash, cash equivalents and short-term investments, as of September 30.

During the third quarter, we repurchased 2.2 million shares under our 10b-5 plan. We continue to expect average diluted shares outstanding for 2023 to be between $610 million and $615 million. We have approximately $500 million remaining under our current share repurchase authorization.

And with that, back over to you, Bernard.

Bernard Zovighian
Thank you, Scott. In closing, after more than 20 years of rigorous clinical experience, over 1 million patients treated and this week's 5-year PARTNER III results, Edwards TAVR is positioned for strong, sustainable growth as many patients remain undiagnosed and untreated.

In addition, we have two strong global businesses, Critical Care and Surgical, which are positioned for durable long-term growth, driven by portfolios of differentiated technology. Moreover, we are achieving many significant milestones in TMTT that gives us the confidence about progressing our vision to treat the many mitral and tricuspid patients in need.

Altogether, we are convinced of a tremendous opportunity to drive success in the future through our patient focus, breakthrough technologies and leadership.

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

Mark Wilterding
Thank you very much, Bernard. Before we open it up for questions, I'd like to remind you about our 2023 investor conference, which we will host at our headquarters in Irvine, California, on Thursday, December 7. This event will include updates on our latest technologies, views on longer-term market potential, as well as our outlook for 2024.

More information and a registration form are available on our website. 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 question, please re-enter 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'd like to ask 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. One moment, please, while we poll for questions.

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

Robbie Marcus
Great. Thanks for taking the questions. Maybe to start, you guys did 11% TAVR growth in the quarter, roughly similar U.S., OUS. How do we think about what's holding it back here from being faster? Pre-COVID it was growing at much higher rates. It's been one of the slower to recover subsectors in med tech.

Data you presented this weekend should be supportive of growth. But what gives you confidence this can remain a double-digit growth market for the foreseeable future?

Bernard Zovighian
Thank you, Robbie. Let me start, and then I will ask Larry to continue here. First, we are pleased to this quarter. Again, it is the third quarter in a row of double-digit sales growth. We are very pleased about it. Very balanced between U.S. and OUS. Ultra RESILIA adoption is going very well, according to plan, in U.S. and in Japan.

And we look at the opportunity with so many patients are undiagnosed and then treated. So we feel good about what's ahead of us. We feel that we are well positioned. All of the data presented this week give us even greater confidence. But Larry, you want to add anything?

Larry Wood
Yeah, I don't have a lot to add. This is our third straight quarter of double-digit growth which, coming out of COVID and all the rockiness that we saw during that period of time, it's actually been really good to see the stability that we've seen in the continued growth even as our business gets larger. So, I actually feel really good about our growth rate.

I think we're continuing to work to get patients off the sidelines and our patient activation. I think the data--hopefully, the data here is reassuring for patients. People were worried about a durability signal with TAVR.

And now we have really high-quality data published with the *New England Journal of Medicine* that shows absolutely no durability signal at five years using BART 3 definitions. So we think all of those are positive and those continue to help us have double-digit and sustainable growth, over a long period of time. So I feel great about where we are.

Robbie Marcus
Great. Maybe one more product question here for me. You just got EVOQUE approved in Europe with CE Mark. We'll see the data for six months tomorrow in tricuspid replacement. This is a market we hear from doctors a lot. It may not be terribly excited about repair, but replacement could be a really exciting option.

What do you think Edwards needs to do as a company to take this market and accelerate adoption and drive uptake here in an area that's been pretty slow with tricuspid repair? Thanks.

Bernard Zovighian
Thank you, Robbie. So, we are going to do what we have done in TAVR for the last 15 years, basically focusing on--number one, on the patient outcome. So it is why we are going to be focusing on making sure our team is well trained, well equipped to support their physicians. We are going to have a disciplined launch in Europe, and we are going to produce evidence like the TRISCEND II cohort you are going to see, tomorrow. And we are going to continue to produce more evidence. But maybe, Daveen, you want to add anything here?

Daveen Chopra
Yeah-no. Thanks, Bernard. I appreciate it. No, I think as Bernard has said, we really do believe that it's the comprehensive high-touch model and outstanding outcomes is a key step. But it's much more than that. And us having the ability to take the TAVR playbook from long ago and help apply to this news area is really important.

And for us, that includes not only technology, innovation, evidence but also continuing to then, over time, work on helping improve diagnosis, referral and eventually treatment of patients. But for us, this is a comprehensive kind of play a long-term play for us to really build a new therapy that we're really excited about to help patients with.

Bernard Zovighian
And if I may add, Robbie, here, we are also at the beginning of better understanding of this tricuspid disease. We believe that we still add a replacement option. Physicians will have more options to treat even more patients. So we are going to learn a lot here about what therapy for what patient but having two therapy in Europe. And us leading that space, we are going to learn a lot in the past few years, and I'm sure patient will benefit from that.

Robbie Marcus
Thank you.

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

Larry Biegelsen
Good afternoon. Thanks for taking the question. Scott, year-to-date, the TAVR growth is a little over 10%, I believe, and the midpoint of the guidance is about 11.5%. So, should we be thinking about the low end of the TAVR range of 10% to 13% for the year? And if not, what drives the acceleration implied in Q4 for TAVR? Then I had one follow-up.

Scott Ullem

Well, I'd take you back to the beginning of the year when our guidance for the full year for both TAVR and Edwards was 9% to 12%. We increased it to, ultimately, 10% to 13% because of the first quarter and the second quarter results.

So, we're coming in about where we thought we would for Q3 and Q4. The 10% to 13% guidance reflects the stronger-than-expected Q1 and Q2. In the fourth quarter, our guidance for the full company is about $10 million higher at the midpoint than our results in Q3. So we haven't broken out guidance by business unit, but you can expect that, overall, we expect a fourth quarter that looks pretty similar to the third quarter.

You're right. I think for the full year, we're probably going to end up about in the middle of the range that we said 10% to 13%, but that doesn't mean that it's 10% to 13% for Q4 because, again, that higher range reflects the increase from the first quarter.

Larry Biegelsen
Thank you for that. And obviously, people are starting to think about '24, right now. So Bernard, at our conference, you talked about targeting double-digit annual revenue growth. Does that apply to 2024?

And Scott, '23 guidance implies margins are down year-over-year because of investments in currency. What are some of the puts and takes on the P&L that we should be thinking about? And any help on FX would be appreciated. Thank you.

Bernard Zovighian
Thank you, Larry. Let me take it on the first part of your question here. So for 2024 guidance, you will get all of the details in December at our investor event.

And the question is about my confidence and our confidence as a company, yes, we are confident. As I said during the script, I think like we have an amazing opportunity in front of us with so many patients. All of our businesses are in solid position in global leadership position. So I am confident for the years to come for 2024, more to come in December, Larry.

Scott Ullem
And Larry, it's Scott. For the second part of your question about FX. We'll talk about more of the specifics at the investor conference. But if you take our exchange rate environment right now and apply it to 2024, it would be a headwind to sales and also a headwind to EPS. So we'll be able to quantify that more specifically. And we'll see what happens to FX rates between now and then, as well.

Larry Biegelsen
Got it. Thank you, guys.

Operator

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 a first one for you on the TAVR 5-year data that was presented. A lot of noise in the Street on the lines crossing for Edwards and your peer, the lines widening between TAVR and Control. Does that worry you at all just from Edwards' perspective when you look at the data?

And I think you also mentioned MARK CE definition for durability. Is that something that your peer also used the same definition, or are there some differences here in how durability was defined in these two trials?

Bernard Zovighian
Thank you, Vijay. Let me start at a high level. I believe last night's investor event was very insightful with Dr. Leon and Dr. Mark. They went very deep into the data. They went very deep into the meaning of the data and the trial design. At the end of the day, for me, it is--I like to keep it very simple; 90% survival at five years. That's amazing for patients. That's, in my mind, what we should remember, but I'm going to ask Larry to comment with greater detail here.

Larry Wood
Yeah, thanks, Bernard. Yeah, this whole thing about the curves continuing to diverge just isn't really accurate. I think we had a little bit of a catch-up. But if you notice from the New England Journal Medicine manuscript, we are impacted somewhat by the patients that withdrew on the surgical side, disproportionately.

And when we did the phone sweep, the absolute difference that we're showing at five years is about 1%. When you go into the causes of death, you look at cardiovascular and mortality, they're about the same.

We had, I think, double the rate of cancer. We had 3x as much COVID death in the TAVR group, as we had in the surgical group. And I think higher rates of sepsis, which were all adjudicated to be not TAVR related. And I don't think anybody is suggesting that TAVR causes cancer or COVID.

So, when you get into the depths of the data, I mean, we feel great about the data. What's amazing about this data set is that both groups performed incredibly well. And given the prominence of Edward surgical valves and then obviously, our TAVR cohort, we're looking at both groups that have over 90% survival at five years.

And the other thing that people have been worried about with TAVR was durability. And you're right, we did use the BART definitions for durability which, remember, isn't what surgery has historically used. Surgery, historically, has used, freedom from X plant due to structural valve deterioration, not echo derived criteria.

And so, part of what drives the *New England Journal of Medicine* publication is we used all the contemporary standards, all the contemporary things. So I don't want to comment on other people's data. You can ask them about their data and what methodologies they use. But I'm very comfortable we applied the highest academic standard STAAR study. And again, we feel great about the data.

And I think there's just a little bit of an oddity here that people are discussing that somehow TAVR has to be better than surgery. If we have two procedures, TAVR and surgery, and we can go to patients and say, your results are identical at five years, then that's going to automatically default people to the less invasive therapy. And now we need to continue to follow these patients. We need to follow them all the way out to 10 years. But for a pretty significant interim look at the data at five years, I don't think we could be any happier about the data than we are.

Bernard Zovighian
And in addition, Vijay, if you think about what we have been saying all along about the underdiagnosis and undertreatment of this patient. Now you look at this PARTNER III, five years, we hope--we certainly hope that the referring of a network of cardiologists will send more patients because they have options, safe options, effective options. So, we feel good about all of this.

Larry Wood
Yeah, I mean I'll just add, I think this was a great day, a great meeting for the field, in general. If you have patients on the sidelines who say, I'm just--I just don't want to have open heart surgery, I'm too scared of open heart surgery, but they're being told, TAVR doesn't really have any data behind it. It's still early.

If you look at both data sets that were presented, there's absolutely no durability signal at five years or four years depending on which study you're looking at. And I think that should just give the referral community tremendous confidence that they can send patients for this procedure and they're going to get a durable outcome.

Vijay Kumar
That's helpful. And Bernard, just one more for you. There were some headlines on investigation in Europe. Any financial implications here? It's just the headlines looked a little odd, and I know it's a silly question, but I have to ask, is there any GLP-1 exposure to TAVR, are TAVR patients related to obesity and not GLP-1s? Thank you.

Bernard Zovighian
No, thanks. In Europe, there is no financial exposure. We had a brief statement on that. So no expectation here.

With regards to GLP-1 exposure to TAVR, we don't think so. We have not seen any evidence that losing weight has any impact to aortic stenosis disease. We don't know that. We don't see

that. We don't--we have not seen any evidence. So we don't see any possible implication here. Larry, anything to add?

Larry Wood
No, I totally agree. I think as it relates to just general things, obviously, people losing weight is a good thing, but we've never seen anything related to even coronary disease. A lot of these things are genetically derived and genetically driven, and I don't think your weight is going to be the determinant of those things. So, I don't really see any impact of this.

Vijay Kumar
Thanks, Guys.

Operator
Our next question comes from Josh Jennings with TD Cowen. Please state your question.

Josh Jennings
Good afternoon. Thanks for taking the questions. I wanted to just ask first on the tricuspid repair and replacement segment, and just get your views on patient-reported outcomes driving approvals and then, potentially, reimbursement decision--positive reimbursement decisions. Are patient reported outcomes or quality of life improvements enough to clear those two hurdles?

Bernard Zovighian
So let me start, and then I'm sure Daveen can add his thoughts. It is a good start. We have seen it at TRILUMINATE so far, correctly, and we believe TRILUMINATE was a good study, good outcome for patients, safe with great quality of life improvement for this patient who have a miserable life. We need to remember that.

With EVOQUE, we are going to talk about it, tomorrow. So it is tough for me to talk about it today. We might talk about it more at the end of the day tomorrow, at our investor conference. But at the end of the day, quality of life improvements are important. Solid safety profile also is important. And all of that, we see that as a great start for this patient who has no other options, today.

Daveen, you want to add anything?

Daveen Chopra
Yeah, I mean, I think we continue to see out of our European experience where we do have PASCAL tricuspid approved, that we could see these great outcomes where the technology is really making a difference in patients' lives. It's taking patients that, ultimately, can't do the things they want to do in their day to day. They feel really down. They have trouble breathing, and it really just helps them live the life that they want to lead.

And so for us to see now in this randomized trial that's been presented with TRILUMINATE, to see high-quality data where that you can treat tricuspid regurgitation in a randomized trial, get safe results and have significant TR reduction with meaningful quality of life. Wow, I mean that's just fantastic for patients. It's something we love.

And ultimately down to the community and the regulators are going to keep looking at the benefit and risk trade-off to make the decisions that they need to make. But we continue to be super excited by what these therapies are doing for tricuspid patients.

Bernard Zovighian
What we--in addition of what Daveen said, what do we like about where we are today is, in the past few years, it was only about TEER. It was only about repair. So physicians didn't have a lot of options.

And what we are doing is now progressing with our vision. To being able to offer to physician a toolbox, so they can decide what therapy, for what patient, for what anatomy. And so that's big progress to where we were a few years ago, even in a few months ago. So great progress here, and I see more to come.

Josh Jennings
Thanks for that. Just one follow-up on just the U.S. sales strategy and having two separate teams for TAVR and for the TMTT franchise. Just wanted to hear about how that's going. And I guess the concern is just are you missing any cross-selling synergies that you could, potentially, garner from the TAVR sales reps and their deep relationships with some of these interventional cardiologists. Thanks for taking the question.

Bernard Zovighian
So what about--I ask Larry, who's leading that every day to comment on this.

Larry Wood
Yeah. It's funny, when we launched TAVR in the U.S., if you remember, half of our procedures were transapical. And people were like, "Hey, you already have a selling organization that's selling to surgeons, why are you developing this whole new sales organization, you can get a lot of synergy."

But it's really all about providing that high-touch model and that level of expertise, and we built out a completely separate sales force for THV, and I don't think there's a day we look back on that and think that, that was a bad decision. I think we feel that that was the right decision for the therapy.

Mitral patients are different than aortic patients. And if you ask your clinical specialists and your salespeople to try to be experts in 10 therapies, they're going to be generalists in all of them,

and not experts. And I think one of the reasons we've had the success we've had in TAVR is, I think our average field clinical specialist supports about 1,200 cases a year.

And so, you bring that level of expertise to every case and we really drive differentiated outcomes for patients, which I think what's driven the therapy and what's driven our leadership.

And we like that model a lot. We think it's been hugely successful. Just because our teams sit in different organizations doesn't mean they don't talk. And Daveen and I talk a lot. I have surgical structural heart now, but I talk to Wayne, our General Manager of that, all the time. We look for where there are opportunities for us to work together.

But at the same time, we want to make sure we have focus on these new therapies, and we bring the highest level of expertise possible so we drive the best outcomes for patients possible because we believe that is what's going to drive long term, the success of our franchises.

Daveen Chopra
I'll add one thing on that. This is Daveen. Even here at TCT, as I talk to physicians, the one thing I consistently hear from physicians is they so appreciate our comprehensive high-touch model.

They love that their Edwards person who is so deep in the mitral tricuspid space, and that's all they breathe, live and really think about. And so, they can offer the best possible advice to the physician, the best possible collaboration to ensure the best possible patient result. And I just love seeing that this week as I talk to physicians.

Josh Jennings
That's helpful. Thanks so much.

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

Travis Steed
Hey, thanks for taking the question. Maybe just to clarify, one clarification. When I add your Q4 guide of $0.60 to $0.66, I'm getting to a full year of $247 million to $253 million, which is different than your full year guidance. So I don't know if there was a restatement or just wondering--maybe my math is off. I just wanted to clarify that, if you don't mind.

Scott Ullem
No, your math is spot on. At the midpoint of the range, that's exactly what it implies. And so, take the midpoint, it ends up at the lower end of that $2.50 to $2.60 range, but still within the range.

Travis Steed

Okay. Got it. And then the comment on U.S. and OUS growth rates being comparable. Is that referring to constant currency reported? It looks like OUS is a little bit lighter this quarter, and just wanted to make sure I understood everything going on OUS and some of the Japan comments and what's going on in Japan.

Scott Ullem
All the growth rates we talked about were underlying constant currency growth rates.

Travis Steed
Okay. That's fair. And then my last question was on 2024. I know you're not going to talk a lot about 2024. But curious if you think you can still hold share stable with new competition coming in, or if you think it's fair to assume something less than the market growth rates in 2024?

Scott Ullem
Yeah, it's Scott. Let's hold off on that question about share and the environment, new product introductions and all kind of stuff. There's a lot that we expect to happen in 2024. And we'll look forward to getting into all of those details and forecasts when we get together at our investor conference in December.

Travis Steed
Alright, great. Thanks a lot.

Operator
Next question comes from Joanne Wuensch with Citibank. Please state your question.

Joanne Wuensch
Good afternoon. Thank you for taking the questions. Two of them, I know you don't want to talk about 2024 but last year, you did a great job with helping us understand the impact of FX on gross margins. And it sounds like you're going to have a FX headwind, next year. Can you sort of level set us for how to think about gross margins, next year?

Scott Ullem
I hate to do this to you, Joanne but again, we're going to have to hold off until we get to December. Really, all we can say right now is that we think we're going to see some pressure on the top line reported sales dollars, won't impact our underlying growth rates. And the reported sales dollars headwind is going to flow right down to earnings per share. Now again, that's not current foreign exchange rate.

So when we get to December and we lay out our full year guidance for 2024, and we'll go through all the lines of the P&L and take you through all the details. But at this point, we really can't tell you more.

Joanne Wuensch
Okay. My follow-up question, which is completely unrelated, you did have another quarter of double-digit surgical valve revenue. And I'm curious what's helping to drive that and how much of it is maybe an upcharge from RESILIA versus underlying demand. Thank you.

Bernard Zovighian
Yeah, so let me start here. So 11%, obviously, we are very pleased. I don't know if you remember, but a few years ago, nobody here believed in Surgical and we believe in Surgical because we have been a pioneer here, we have been a great innovator. And our innovation is paying off.

What we see in Q3, again, like in 2023, we see a balanced combination between adoption of our RESILIA platform, premium pricing and also the procedural growth. So altogether, but it is very balanced between procedure growth and our premium technology.

Larry Wood
Yeah, I'll just add. It's--we'll try to bring this to life a little bit at the investor conference is, I almost feel like when we have a good surgical quarter that you guys get mad at us because you think it comes at the expense of TAVR. And I'll tell you as the guy that runs both those business units, that gets really frustrating after a while, and my new GM is really mad about it.

So--but what you have to understand is our surgical business isn't 100% aortic stenosis. Our surgical business treats aortic, we treat mitral. And even in the aortic space, we don't just treat aortic stenosis, we treat aortic regurgitation. We have products like KONECT, where we're treating aortic aneurysm disease. We have repair products, replacement products. So there's just a lot more that goes into that business than aortic stenosis. So thinking that the zero-sum game between the two businesses just isn't the right way to think about it.

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

Matthew Miksic
Hey, thanks for taking the questions. So one, if I could on--sometimes Scott and Bernard, you're able to offer some color as to what--how the different types of centers in the U.S. have been performing. You mentioned staffing is stable. Any color as to which large, small or size centers were additive to growth in what ways? And then I have one follow-up.

Bernard Zovighian
Yeah, maybe I'm going to ask Larry to comment on that.

Larry Wood

Yeah, we look at this every quarter, and I will just tell you just even internally amongst us, we sort of see the growth rates by segment, and then we sort of make up the reasons for why we think they're different a little bit.

I will tell you, during COVID, we saw trends that said when COVID spiked, people tended to stay a little bit closer to home, and we saw maybe some of our smaller centers grow more and larger centers would grow less. And then as COVID waned, we'd see larger centers kind of return to higher growth.

I think this quarter, we probably saw a little bit more growth in the higher--in the bigger centers than the smaller centers. But really, I think it's getting a little bit negligible over kind of returning to a little bit of a sense of normalcy as it relates to growth across center size.

Matthew Miksic
That's helpful. Thank you for that. And then just one follow-up on just--maybe a segment of the market that's got to be getting bigger, I guess, by this point. But looking forward being the only valve on the market with a valve-in-valve indication.

How big is that now? And how important is that? We talk a little bit about the expanding indications into not asymptomatic and moderate AS patients over the intermediate and long term. But does valve-in-valve become a factor that you can talk more about? Or maybe help us understand how that factors into your growth or the general growth in the market at this point.

Larry Wood
Yeah, I think--it's a good question. I think valve-in-valve isn't a huge part of our offering, right now. It's not a big driver for us. We do do TAV-in-SAV, so TAV in failed bioprological surgical valves. And as TAVR came online, we saw more and more biological valve usage in younger patients because they knew they would have this TAVR option down the road.

So we think that that's going to be, as these patients live longer, obviously, our surgical valves are very durable, but that was a whole basis for INSPIRIS, was creating a valve that would be a great platform for their TAVR procedure down the road, and that's the whole basis for it, and we think that will pay dividends, later.

As--we just got the low-risk approval, it's still fairly new for us. It's not something that's been around forever. But the more and more patients that are younger that are getting TAVR, eventually, those patients will come back and need a second procedure.

And so for us, having a TAV-in-TAV option, it just feeds directly into our lifetime management strategy, which is putting in a first valve and ensuring that you have a strategy for that next intervention. And that's true, whether it's INSPIRIS as your first valve or whether it's a SAPIEN 3 as your first valve, we want to make sure we have an option for that patient when they come back.

And that's what's great about both of our Surgical and TAVR platforms is they're both really a great host for that future valve. And we do think, as you advance down the road, the TAV-in-TAV will become a bigger contributor to our growth, over time.

Matthew Miksic
Thanks so much.

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

Danielle Antalffy
Hey, good afternoon, guys. Thanks so much for taking the questions. I was just wondering if I could follow up actually on the data, the 5-year data we saw, yesterday. And Larry, if there's any read that we can make or something that could, that we saw on the data that could give us more confidence in the upcoming asymptomatic data readout, or is that just too difficult to take anything from yesterday and apply it to that trial?

Larry Wood
Yeah, I appreciate everybody's trying to get an early read on early TAVR. And I don't think there's--I don't think there's anything that's really from this data that I--and I haven't even--we haven't even broken apart the early TAVR data. So I don't even know anything about the data set yet to even talk about and even if I did, I couldn't tell you.

I think just broadly speaking, the fact that we show excellent durability out at five years with no durability signal whatsoever, SVA symptomatic trial is successful, which we obviously hope it is. But if that trial is successful, it just takes one more burden away from people saying, do I want to treat people earlier in the disease state. And I think the more durability data we can put on the board will help make that if that trial is successful and we do get the indication, that that will be one barrier that's removed.

So, I think the long-term data continuing to build on the durability and safety and long-term results of the platform just continue to be important, and it's going to be important long term for the progress trial. If you're going to treat people with moderate disease down the road, you need to make sure you have a durable platform and that it has options down the road for these patients. So, I think it all is complementary, but I don't think anything about this trial informs the early TAVR results.

Danielle Antalffy
Okay. Got it. And then just a quick question on--Bernard, you mentioned there's still a lot of these patients untreated out there. I mean, as far as Edwards' progress on getting those patients off the couch into their physician's office diagnosed and referred for TAVR.

I mean, where are we in that process? You guys spent a lot of time at the Analyst Day last December. I imagine we'll get an update too in December in a few weeks here. But just curious what you can say about are you seeing any real traction in some of the direct-to-consumer campaigns, things like that? Thanks so much.

Bernard Zovighian
Thanks for the question. We see this initiative as super important to us. We have the right platform, we have the right science, so how can we get more patients. And we have done in the last, I want to say, years, maybe three to four years, a lot of initiatives, a lot of pilots. We learned a lot. This year, we scale some of the initiatives.

And so, we are going to talk more about it in December. Larry and his team are going to talk about it. But we feel like--we have some interesting learning, and we believe that we are starting to see some impact, also. So we feel excited about the potential of that. It is why when we say we believe the future is even more exciting, it is because of this reason. In addition, obviously, asymptomatic and moderate indication will add to all of this.

But Larry, do you want to add anything?

Larry Wood
Sure. I think one thing that I think people are missing a little bit is it's not like we just started doing patient activation stuff last year or in the last two years. I mean, we go all the way back to starting a website with a lot of educational information for patients, even things like how to find a TAVR center and questionnaires and patient information kits.

So we've been doing a lot of things over the last several years that I think is one of the reasons the market has grown and developed the way it has. So, I think a lot of our digital and patient activation efforts are still--are paying dividends, right now.

Now, the deeper you go into the prevalence pool, the harder it gets and the more activation you have to do. So it's sort of a--it's not a light switch. It's a never-ending journey that you're going to do to continue to build on the last program with additional programs to try to get people activated.

And I'll tell you, we have a lot of work streams, and we're looking forward to maybe getting into a little bit more detail at the investor conference and trying to show you a little bit about other things that we're working on. But we have a number of pilots and we have a lot of very mature programs at the same time that we think help us a lot.

Operator
Thank you. And our next question comes from Pito Chickering with Deutsche Bank. Please state your question.

Pito Chickering
Hey, good afternoon, guys. Per your script, you mentioned that the TAVR market share is stable. You look at competitive accounts with hospitals or doctors that use both SAPIEN and CoreValve, are you seeing any market changes in those accounts where RESILIA is competing against FX?

Larry Wood
Yeah, I think market share has been pretty stable. I don't think we've seen big shifts or big changes. We're very excited about RESILIA. And I think I think it does give people increased confidence in going into younger, lower-risk patients.

So we feel good about that. But maybe we can try to update that a little bit more at the investor conference. But again, I think, overall, I think share has been generally pretty stable.

Pito Chickering
Okay. Great. And then a quick follow-up for TAVR. I think you said procedure growth was the same as revenue growth. But was there any benefit from positive pricing from RESILIA? I thought that would help to drive revenue growth above volume growth. Thanks so much.

Larry Wood
There was a little benefit, but it wasn't the big driver of our growth.

Pito Chickering
Great, thank you.

Operator
Thank you. And ladies and gentlemen, that's all the time we have for questions, today. I'll hand the floor back to management for closing remarks.

Bernard Zovighian
Thank you. So let me close this meeting by saying I am pleased with our performance in 2023. Beyond the numbers, I am excited with the progress we have made, reinforcing our TAVR leadership position with new clinical evidence and expanding our mitral and tricuspid patient reach with new approved technologies.

As a result, we are confident in our long-term strategy to help even more patients around the world. Thanks for your continuing trust in Edwards. The IR team, Scott and I welcome any additional questions by phone. Thank you.

Operator
Thank you. And with that, we conclude today's conference call. All parties may disconnect. Have a good day.