Edwards Lifesciences
Fourth Quarter 2023 Earnings Conference Call
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Presenters
Mark Wilterding, Investor Relations and Treasurer
Bernard Zovighian, CEO
Scott Ullem, CFO
Daveen Chopra, Global Leader of TMTT
Larry Wood, Group President of TAVR and Surgical Structural Heart
Wayne Markowitz, Global Leader of Surgical Structural Heart

Q&A Participants
Larry Biegelsen - Wells Fargo
Robbie Marcus - JPMorgan
Travis Steed - Bank of America
Patrick Wood - Morgan Stanley
Vijay Kumar - Evercore
Matt Taylor - Jefferies
Matt Miksic - Barclays
Chris Pasquale - Nephron Research
Danielle Antalffy - UBS

Operator
Greetings, and welcome to the Edwards Lifesciences Fourth 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, Investor Relations and Treasurer. Thank you. You may begin.

Mark Wilterding
Thank you very much, Diego, and good afternoon, everyone. Thank you all for joining us. With me on today's call is our CEO, Bernard Zovighian, and our CFO, Scott Ullem.

Also joining us for the Q&A portion of the call will be Larry Wood, our Group President of TAVR and Surgical Structural Heart; Daveen Chopra, our Global Leader of TMTT, Wayne Markowitz, our Global Leader of Surgical Structural Heart and Katie Szyman, our global leader of Critical Care. Just after the close of regular trading, Edwards Lifesciences released fourth quarter 2023 financial results.

During today's call, management will discuss those results included in the press release and accompanying financial statements and then use the remaining time for Q&A.

Please note that management will be making forward-looking statements that are based on estimates, assumptions and projections. These statements include, but are not limited to: Financial guidance and expectations for longer-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 product 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 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.

Bernard Zovighian
Thank you, Mark, and welcome, everyone. At our recent investor conference, I introduced our exciting vision of a new era of structural heart innovation to address significant unmet patient needs. Today, I will build on that theme and share key highlights of our team's strong performance in 2023, as well as our confidence in 2024.

We are pleased with our strong 2023 financial performance with full year sales up 12% to 6 billion, including strong growth across each of our four product groups. We invested more than 1 billion in research and development, and we achieved key strategic milestones, including the introduction of new technologies and indication expansion to ensure sustainable healthy growth in the near, mid and long term.

We exited the year with strong momentum with Q4 growth of 13% and TAVR growth of 12%. These results were better than expected, driven by our broad portfolio of innovative therapies.

In 2024, we are well--positioned to enter a new era of structural heart innovation. In TAVR, we are strengthening our leadership. We are experiencing strong adoption of our flagship SAPIEN 3 Ultra RESILIA and continuing enrollment in our ALLIANCE pivotal trial for our next-gen TAVR technology, SAPIEN X4.

In January, we achieved a very important milestone with the completion of enrollment in PROGRESS, a pivotal trial studying the treatment of moderate aortic stenosis patients, a population estimated to be twice as large as severe aortic stenosis.

This randomized trial enrolled approximately 750 patients, two years ahead of schedule. At TCT, later this year, we plan to present data from EARLY TAVR, a pivotal trial studying the treatment of patients with severe aortic stenosis, but without symptoms. We believe that all these initiatives position us for healthy, sustainable TAVR growth, well into the future.

In TMTT, we achieved significant milestones with continued PASCAL global expansion and the introduction of EVOQUE in Europe. In Germany, EVOQUE was recently granted NUB reimbursement status 1, a very important step in therapy adoption. I am also pleased to announce that EVOQUE recently became the first transcatheter therapy to receive USFDA approval for the treatment of TR patients.

This is an exciting development for a wide range of U.S. patients. It will enable access to a groundbreaking treatment option that not only has the potential to significantly improve their quality of life, but also shows favorable clinical trends in all-cause mortality, reintervention and heart failure hospitalization. With the ongoing introduction of EVOQUE, we are now offering a unique and broad portfolio of trans-catheter repair and replacement solution for mitral and tricuspid patients.

In addition, the completion of enrollment in the pivotal trial studying SAPIEN M3 put us on track to further enhance our portfolio. I am confident that we are reaching an inflection point as the only company with a commercially approved portfolio of catheter-based technologies to treat the millions of patients suffering from mitral and tricuspid disease.

In addition to the meaningful progress of TAVR and TMTT, we are pleased with the company innovative RESILIA tissue, which was pioneered by our surgical business. We are on track to treat 0.5 million patients with RESILIA-based heart valve by the end of 2024, supported by seven years of clinical evidence.

The previously announced spinoff of Critical Care is progressing as planned and will enable our sharpened focus on structural heart. As a result, Edward's 2025 organic sales growth rate will be even more distinguished. In addition, this will give us more agility, increase our pace of innovation and provide an expanded opportunity to serve a large and growing patient population.

Because we are solely focused on structural heart disease, we are uniquely positioned to deliver sustainable growth and extraordinary leadership.

Now I will provide some additional detail by product group. In TAVR, our full year 2023 global sales of $3.9 billion increased 10.6%, year-over-year. Our U.S. and OUS sales growth rates were similar. In the fourth quarter, our global TAVR sales of 979 million increased 12%, year-over-year. Performance was driven by double-digit growth in the U.S., Europe and Japan.

The company competitive position was stable, globally, and local selling price were also stable. In the U.S., we remain pleased with the continued expansion and adoption of a SAPIEN free Ultra RESILIA platform. This technology builds on Edward's long-standing leadership in tissue technology and durability by combining advancements in tissue science with the industry-leading SAPIEN 3 Ultra valve.

Developing safe, effective and durable heart valve requires significant long-term commitment, and we are proud to build on 65 years on valve innovation, while leveraging the expertise and know-how of more than 2,000 engineers and R&D specialists, across the company.

We are proud of uninterrupted leadership in structural heart and will continue to invest vigorously in these platforms. In addition, our scaling of patient activation initiatives, along with next-gen TAVR and additional evidence on asymptomatic and moderate AS patients position us for healthy, sustainable TAVR growth well into the future.

Outside of the U.S., in the fourth quarter, our double-digit growth was comparable with our global TAVR growth, driven by Europe and Japan. Long term, we continue to anticipate excellent opportunities for growth.

As the international adoption of TAVR therapy remained quite low in many regions. In Europe, Edwards sales growth was driven by the broad-based adoption of our SAPIEN platform. It is encouraging that the growth in Q4 was widespread across all major countries. Looking ahead, we are pleased with the recently announced CE Mark approval for SAPIEN 3 Ultra RESILIA, and we are planning for a disciplined launch.

We were pleased with our sales growth in Japan and as expected, we grew faster than overall procedural growth. After more than 20 years of rigorous clinical experience and over 1 million patients treated with SAPIEN around the world, our TAVR platform is positioned for continued global leadership and strong sustainable growth.

Given the undertreatment rates, we are confident in the future of TAVR, driven by greater awareness, patient activation, a platform that delivers lifetime management for AS patients, advances in new technologies such as RESILIA, as well as indication expansion and increased global adoption.

Turning to TMTT now. In 2023, we remain focused on our key value drivers to unlock the significant long-term opportunity for patients, a portfolio of differentiated therapies, positive clinical trial results to support approvals and adoption and favorable real-world clinical outcomes.

Based on the deep learnings we have achieved from our clinical trial and real-world experiences, we have carefully constructed a strategic portfolio of leading transcatheter technologies to provide both repair and replacement solutions for mitral and tricuspid patients.

PASCAL Precision, EVOQUE and SAPIEN 3 will provide best-in-class therapies to treat a broader range of patients. Full year global sales of 198 million increased 67% versus the prior year.

TMTT fourth quarter sales of 56 million increased 71% versus the prior year. Q4 sales were driven by the accelerating adoption of our differentiated PASCAL Precision platform and activation of more centers, across the U.S. and Europe.

We were encouraged by the ongoing double-digit growth of overall transcatheter edge-to-edge repair procedure, which highlights the large unmet patient need. We continue to expand global access of PASCAL Precision in new countries, including Japan, where we recently completed our first cases.

Since launch, we have proudly treated more than 20,000 patients around the globe with PASCAL repair system.

In mitral replacement, we have received FDA approval for SAPIEN 3 continued access program. Physicians are continuing to treat patients with this novel therapy. In tricuspid replacement, we initiated the launch of EVOQUE in Europe, with a focus on outstanding outcomes and the goal of eliminating tricuspid regurgitation in patients.

And in the U.S., following the recent early FDA approval, we are initiating the introduction of this novel therapy and building the foundation for long-term expansion. As we did for TAVR, we are focusing on best-in-class physician training, generating more evidence and achieving excellent patient outcomes.

We are grateful for the strong ongoing collaboration with clinicians all over the world to provide the treatment options to many patients suffering from tricuspid valve disease.

In tricuspid repair, the CLASP II TR pivotal trial with PASCAL continues to enroll well, and remains on track to complete enrollment by the end of this year.

As a summary for TMTT, we are reaching an inflection point with the only portfolio of approved catheter-based mitral and tricuspid technologies. We remain committed to bringing our

differentiated therapy to patients with this life-threatening disease and believe our strategy positions us well for leadership.

In our Surgical product group, full year global sales of 999 million increased 13% versus the prior year. Fourth quarter global sales of 248 million increased 10%. Growth was driven by strong global adoption of Edwards' premium RESILIA technology and overall procedural volumes. We are confident about the future of this tissue technology and its role in improving patient lifetime management.

We continue to see positive momentum in our innovation, globally, with continued adoption for patients best treated surgically, including those with complex and concomitant procedures. We continue to expand the overall body of RESILIA evidence, including ongoing patient enrollment of our momentous clinical study. We received CE Mark approval of our MITRIS RESILIA valve in the fourth quarter and have begun to launch in several European countries with favorable physician feedback.

Turning to Critical Care. Full year global sales of 928 million increased 10% versus the prior year. Fourth quarter Critical Care sales of 250 million increased 11%. Growth was driven by contribution from all product lines, led by HemoSphere, a smart recovery with strong adoption of our Acumen IQ sensor equipped with the hypotension prediction index algorithm.

Critical care strategy is to drive growth through smart recovery and smart expansion, which are designed to help clinicians make more informed decisions and get patients home to their family, faster.

And with that, I will turn the call over to Scott.

Scott Ullem
Okay. Thanks a lot, Bernard. So today, I'll provide a wrap-up of 2023, including detailed results of our fourth quarter, as well as provide guidance for the first quarter and full year 2024.

As Bernard mentioned, we were pleased with our better-than-expected Q4 sales performance with strength across all product groups.

We achieved total sales of $1.53 billion, which represents 13% year-over-year growth. We achieved adjusted earnings per share of $0.64. Our GAAP earnings per share of $0.61 included onetime expenses associated with our planned spin-off of Critical Care. A full reconciliation between our GAAP and adjusted EPS for this and other items is included with today's release.

We are maintaining all of our previous sales guidance ranges for 2024 with the exception of TMTT. Absent big moves in foreign exchange, we expect total company sales of $6.3 billion to $6.6 billion, TAVR sales of $4.0 billion to $4.3 billion Surgical Structural Heart sales of $1.0 billion to $1.1 billion and Critical Care sales of $900 million to $1 billion.

Given the early FDA approval for EVOQUE, we now expect full year TMTT sales to be at the higher end of our previous $280 million to $320 million guidance range.

For the first quarter, we're projecting sales of $1.53 billion to $1.61 billion and adjusted earnings per share of $0.62 to $0.66.

And now I'll cover the additional details from our P&L. For the fourth quarter, our adjusted gross profit margin was 76.8%, compared to 81% in the same period, last year. This expected year-over-year reduction was driven by impacts from foreign exchange. Last year, Edwards' gross profit margin was lifted by a significant impact from FX.

We continue to expect our full year 2024 adjusted gross profit margin to be between 76% and 78%, driven by high-value technologies that yield strong gross profit margins.

Selling, general and administrative expenses in the quarter were $480 million, or 31.3% of sales, compared to $411 million in the prior year. This increase was driven by investments in transcatheter field-based personnel in support of our growth strategy and patient activation initiatives.

We continue to expect full year 2024 SG&A as a percent of sales to be 29% to 30%, as we invest in field-based personnel and patient activation initiatives and increase our focus on efficient G&A leverage. Research and development expenses in the fourth quarter grew 16% over the prior year to $270 million, or 17.6% 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 2024, we continue to expect research and development to be 17% to 18% of sales, as we invest in developing new technologies and generating evidence to support TAVR and TMTT growth with the goal of treating even more patients. During the fourth quarter, we incurred approximately $17 million of onetime costs associated with our previously announced spin-off of Critical Care.

Additional onetime costs will be incurred throughout 2024 ,prior to the expected separation at year-end.

Turning to taxes. Our reported tax rate this quarter was 12.3%, or 13.4% excluding the impact of special items. For the full year 2023, our reported tax rate was 12.4%, or 15.0% excluding the impact of special items. Our lower-than-expected non-GAAP rate in the fourth quarter benefited primarily from U.S. tax credits on foreign remittances and income tax.

We continue to expect our 2024 tax rate, excluding special items, to be between 14% and 17%. Foreign exchange rates decreased fourth quarter reported sales growth by 80 basis points, or $9 million, compared to the prior year.

FX rates negatively impacted our fourth quarter gross profit margin by 320 basis points, compared to the prior year. Relative to our October guidance, FX rates had a nominal impact on fourth quarter earnings, per share.

Free cash flow for the fourth quarter was $48 million, defined as cash flow from operating activities of $136 million less capital spending of $88 million. Adjusted free cash flow for the full year 2023 was $943 million, defined as cash flow from operating activities of $896 million, less capital spending of $253 million.

Adjusted free cash flow excludes the $300 million payment related to the Medtronic intellectual property agreement.

We continue to expect full year 2024 adjusted free cash flow will grow to be between $1.1 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 strong and flexible balance sheet with approximately $1.6 billion in cash, cash equivalents and short-term investments, as of December 31, 2023.

During the fourth quarter, we repurchased 6.0 million shares through an accelerated repurchase agreement and a pre-established 10b5-1 plan. As a result, average diluted shares outstanding during the quarter declined to $607 million.

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

And with that, back to you, Bernard.

Bernard Zovighian
Thank you, Scott. In conclusion, we are proud of the significant progress we made in 2023, advancing new breakthrough therapies for patients and delivering solid financial performance and healthy profitability. We are even more excited about 2024. This year, we anticipate launching groundbreaking technologies and advancing multiple important clinical trials.

These breakthroughs, along with significant unmet patient needs, give us confidence in our ability to accelerate growth in 2025 and beyond. In TAVR, we will continue to drive global adoption of SAPIEN 3 Ultra RESILIA, present pivotal trial data from early TAVR studying asymptomatic AS patients and enrolling--and a pivotal trial studying the next-generation SAPIEN X4.

We also look forward to a number of key developments in TMTT, including the U.S. and European introduction of EVOQUE, the expanded global adoption of PASCAL Precision, Class 2 Tier enrollment completion and SAPIEN M3 approval in Europe, by the end of 2025.

And in Surgical and Critical Care, we remain committed to healthy growth and expanded leadership.

In closing, longer term for Edwards, we are confident in our plan to expand the structural heart opportunity, which reflects our sharpened focus on valvular and non-valvular patients and our commitment to innovation. We believe that executing our strategy will create value for all of our stakeholders.

With that, back to you, Mark.

Mark Wilterding
Thank you very much, Bernard. With that, we're ready to take everyone's questions. As a reminder, please limit the number of questions to one plus one follow-up to allow for broad participation. If you have additional questions, please re-enter the queue and management will answer as many participants as possible during the remainder of the call. Diego.

Operator
Thank you. And if you would like to ask a question at this time, press "*", "1" on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press "*", "2" if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset, before pressing the star keys.

And once again, please try to limit yourself to one question and one follow up.

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

Larry Biegelsen
Good afternoon, thanks for taking the question. And congratulations on the early approval of EVOQUE in the U.S. I feel like I need to start there. So, I'd love to hear you guys talk about your commercialization plan for EVOQUE. Are you ready to launch now? Should we expect the price premium? And talk about the reimbursement pathway should we expect you to file an NCD? And I had one follow-up.

Bernard Zovighian
Thank you, Larry. I hope you are doing well. Let me start and then I will ask Daveen to add some color here. So first, the way we are thinking about this one is like we did in TAVR. We are--we want to make sure that we are going to introduce this very novel therapy, having in mind you're building foundation for long-term expansion.

So we're going to be focusing on physician training, generating more evidence, excellent patient outcome, making sure we have coverage, payment, reimbursement established in the U.S. and in Europe. So we are having here a long-term view, the same way we did it in TAVR in last 20 years. But again, Daveen, I'm sure you want to share some of your plan.

Daveen Chopra
No, definitely. Thanks, Bernard. I'll start by saying, of course, we are very excited by this approval coming through the FDA breakthrough pathway. This innovation is obviously the first transcatheter technology in the U.S. to change the life of the many patients suffering from tricuspid regurgitation. As we look at kind of our rollout model, as Bernard said, we are really planning a controlled rollout this technology, focused on great clinical outcomes.

And we're really going to start with those centers, that--who are in a clinical trial and then over time, we'll grow to new centers. We're going to have a dedicated team of clinical case support who has been training on the over 1,000 EVOQUE cases that now have been done to date. And this team will continue to scale, as we move forward.

Specifically on your question on--I think I heard a question about NCD in there and the kind of timing. Obviously, with EVOQUE, it's a parallel review technology. So CMS is working on the national coverage kind of on their own process, and we are continuing to work with them to kind of provide information to help support their process. So as we all hear more about that, we'll--you guys will definitely in the loop on that.

Bernard Zovighian
So what you can see, Larry, here. We have a long-term view on this one. We want to shape this space as we like and in a way that everybody is going to be very proud of, like we did for TAVR.

Larry Biegelsen
That's helpful. And Daveen, just one follow-up for you. What are your thoughts on the likelihood of seeing a statistically significant mortality benefit at one year or 18 months when the full TRISCEND II data is presented at TCT? And how important is that for adoption and reimbursement? Thanks.

Daveen Chopra
Well, I think right now, as we've talked about, we've obviously shown very favorable trends in all-cause mortality, heart failure hospitalizations and tricuspid regurgitation. And those were some of the key trends that help us lead to our approval. Obviously, our full data set will come out of TCT in the fall with one year follow-up, and it's hard to speculate on what that data will show.

Larry Biegelsen
Alright, thanks so much.

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

Robbie Marcus
Great. Thanks for taking the questions, and congrats on very nice data. Maybe just to follow up on that. We've seen just TMTT in general, whether it's mitral tricuspid maybe ramp over the past few years a little slower than expected. Obviously, COVID really disrupted that upward trajectory.

Maybe just speak to some of the bottlenecks that you see in the system, especially with tricuspid replacement, it's a totally new therapy. There will be some education, I imagine. But maybe just speak to what you see as the bottlenecks and what Edwards can do to help ramp adoption in a pretty sick patient population.

Bernard Zovighian
Thank you, Robbie. So let me start on your earlier comment about a little slower than expected in the past years. And then Daveen can talk about a bottleneck in the system. So if you think about it, since the beginning, since six years ago, when we put together this vision, we did study this patient population, mitral and tricuspid.

And we knew that they were very complex diverse. And we knew from the beginning that one device, one therapy, a repair technology only will not be sufficient. Repair technology, and we are very pleased about PASCAL but can only treat some, a small proportion of patients. So it is why we have this vision of having a portfolio.

So right now, what we have is this portfolio on the tricuspid side, we are on track to get also a mitral replacement. And what we are--what we are going to see, what we are going to see altogether is an acceleration. Clinicians will be able to treat more patients. So the dynamic in the next 10 years is going to be very different than the dynamic in the last 10 years. But again, Daveen.

Daveen Chopra
Yeah, I'll make a couple of quick comments. First, we're really excited because we see that the replacement technology really has the potential to treat a large number of patients. Because especially in tricuspid regurgitation, note one patient is alike.

There's really a huge heterogeneity and replacement, we really see as the core of treating the largest number of patients, and then we see other technologies like TEER, as well as other modalities that are still in trials potentially to add new patient groups on top of that.

We've seen in Europe where tricuspid as a therapy has been approved longer, that centers are starting to continue to build up and grow the tricuspid practice.

As you bring in technology to market, you start seeing the awareness of the disease to grow and you see more referrals and you see more patients getting to the heart team. And some of that becomes from how we're imaging people correctly and we're referring them correctly at centers.

And we can see that that's exactly what we see, potentially, that will happen out with the new therapy of tricuspid in the U.S. We'll be able to start building up diagnosis, referral to heart teams.

And also, we see that there's an opportunity, as Larry talked about in the investor conference, in the TAVR group, reading so much with patient activation. And we see that all those learnings from patient activations in the future will be able to be leveraged over to the TMTT space, both for mitral and tricuspid to continue to grow the market.

Robbie Marcus
Great. I appreciate that. Maybe one on the TAVR market. We have the exciting data from early TAVR coming later this year at TCT. How do you think about what that does to the TAVR market growth, going forward? Do you put up double-digit growth in the fourth quarter.? That's what guidance includes the next few years for the most part. How do you think about what's coming from low, intermediate and high risk and severe? And then how do you think about what asymptomatic adds? Is that just what helps keep you with double digit, or can that help accelerate growth? Thanks.

Larry Wood
Yeah, thanks, this is Larry. That's a great question. I think the first thing is we're just going to learn a lot from this trial. There's a lot of unknown questions out there in terms of what percentage of patients are truly asymptomatic when subjected to a stress test. I think how fast do people progress and what happens to people while they're waiting.

I think the biggest thing about it is, as we've talked about, and I spent a lot of time at the investor conference, the time from a patient to get diagnosed to treated is just really long. And a lot of that is the interpretation of the guidelines and this overlay of symptoms. And it's all really sand in the gears preventing the patients from moving through.

And unfortunately, given the deadliness of the disease, a lot of people never actually make it to therapy. I think with the early TAVR trial, assuming that it's successful, it will just streamline that process where we can just apply guideline criteria to aortic stenosis, and it won't require this additional evaluation of symptoms and people can just move through.

But remember, only about 13% of patients right now with severe aortic stenosis actually get treated. So there's a huge under treatment right now. We think asymptomatic just adds to that.

Bernard Zovighian
In addition, Robbie, what I like is our commitment to--after 20 years of TAVR, we are still super committed to bring big evidence. Look at these two trials, PROGRESS and EARLY TAVR. This is a potential for sure to learn more, but also to expand indication, to change in the guidelines. So as a leader in the space, for sure, we like it, we are committed. But I believe that in the next 10 years, even TAVR, we are going to see some very exciting things happening.

Larry Wood
Yeah, I think that's right. And I think it's sort of returned to a little bit of the earlier days in TAVR, where I think we're planning on having a steady cadence of new trials and new data and new evidence that continues to not only raise awareness about the therapy but also open up new opportunities for patients to get treated that don't currently get treated, today.

Robbie Marcus
Appreciate it. Thank you.

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 talking about EVOQUE over a multiyear period. Just curious how you think that market develops compared to the mitral market, if you think that goes faster or slower. And when you think about the data that we have so far, it seems like replacement is doing better than clipping. So I don't know if you think about the mechanism of action, why replacement would be better than clipping and kind of where you see a place for clipping in the market in tricuspid?

Bernard Zovighian
Go ahead.

Daveen Chopra
Yeah, so I guess I'll start off with the latter part of your question about the technology. As I kind of mentioned, we see that in replacement where you're able to really eliminate tricuspid regurgitation. We see an awesome opportunity to help patients and really improve their quality of life.

And we see kind of replacement with its broad applicability really being able to treat a large chunk of those tricuspid regurgitation, the vast majority of tricuspid regurgitation patients. But there's still--but again, based on the disease state and the heterogeneity of tricuspid regurgitation, there's still going to be many patients where replacement may not make sense for anatomical or other considerations, where whether it's a clasping technology or other modality may make sense.

Back to your first question about how the market develops related to mitral. I think we see continued strength in this. We think the mitral market had some early strength in kind of slowdown during COVID. We think that the bicuspid market, as referrals and awareness of the disease continues, will continue to kind of grow at a very strong rate, at rates that we think, think can kind of probably exceed kind of mitral, especially with the two modalities entering the market in a very similar time, you now have an opportunity to treat a larger proportion of patients.

Travis Steed
Helpful. And a follow-up, curious on the SMART trial. If the data there is good, if you think there's an impact on the market? And then also, there was news last week, when last competitor comes to the market in 2024. Does that change your view on 2025? I'm just curious what kind of competition you had kind of baked into your long-term guidance? Thanks a lot.

Larry Wood
With regard to the SMART trial, I think we'll just have to wait and see the trial, and we don't know what it's going to show. But I think the key thing is thinking about how physicians select TAVR valves for their patients. And that's really a multi-factorial decision. I think you have to look at mortality rates, stroke, future interventions, all those things. And hemodynamics is certainly one consideration.

But I don't think it's even the driving consideration, compared to some of the other factors that are probably higher on the hierarchy for patients.

In terms of the competitive space, we didn't have a lot in 2024 because the--it was expected the approval was going to come late. And we know a time to ramp a new therapy. We'll have to see what the impact on 2025 is and what the revised approval timing is. And there's no real value in me speculating on that.

Bernard Zovighian
Yes. And in addition, as me being in my first year as CEO, I'd like to reflect a little bit about where we are as a company. And when I think about valve, making a heart valve, it is not easy. Given the nature of patient needs, this is not luck. We are committed and focused for more than 60 years and we bring experience, a very deep knowledge.

What we have seen, even in the past few years, many platform, many companies coming in and leaving the market after a year, two years or three years. So we are leading the space with a very significant long-term commitment, more than 2,000 engineers, R&D, R&D specialists. We are proud of our uninterrupted leadership in the space. And we are going to continue investing.

So for sure, we take all the competitors very seriously, but we are very confident about our leadership, about our technologies and about our evidence.

Travis Steed
Great, and congrats again on the EVOQUE approval.

Operator
Thank you. Our next question comes from Patrick Wood with Morgan Stanley. Please state your question.

Patrick Wood
Amazing. Thanks for taking the questions. I guess maybe for the first one on TAVR and Japan in general. Do you think you've been taking back some share, post trialing. It sounded like you feel very good about the market, and you were taking back some share on that side. Just any color you could give there would be great.

Larry Wood
Sure. I think what happens when new technology comes into Japan just because of the way the certification process works and people having to move through that process, that certainly had an impact for us. I think in Q4, we grew faster than the market. And I think that really relates to some of the trialing ending and people kind of moving back to our platform.

But this is sort of something that goes on, but we're very pleased with how we grew in Japan in Q4 and continue to look forward to that market growing because it's a very--it's a much lower penetrated market than places like the U.S. and Europe. So we continue to see that as a long-term growth driver for us.

Patrick Wood
That's very helpful. And then just quickly as a follow-up, I get this might be difficult to comment on, but the faster-than-expected approval of EVOQUE, what in your discussions with the FDA? And what do you think they placed a great weight on in getting it comfortable with it into market faster than expected. Do you think there was like one area of data or sense of the products because that's obviously not been the experience for everyone. So just curious to get any thoughts there.

Daveen Chopra
Yeah, no, sure. This is Daveen, again. I'll kind of jump in this one. Obviously, we received an approval through this FDA breakthrough pathway. And this was a really innovative pathway where the basis of approval was the breakthrough cohort of the 150 patients we presented at TCT.

And--but at the same time, as we were working with the FDA and answering their questions, we presented and gave them other data from our larger cohort, other descriptive statistics. And as we mentioned, it's that larger cohort where the results really showed those favorable trends in all-cause mortality, heart failure hospitalizations, tricuspid reinterventions. It was those kinds of

trends that I think that we believe probably have the FDA come back to us and say, oh, yeah, this kind of makes sense, we probably don't need an advisory panel, that led to our approval.

And so, we're very excited that the full cohort of data, the full 1-year cohort on the 400 patients will be presented at TCT, so we can kind of see all the data, not just kind of the breakthrough cohort plus the initial kind of look at the other data. And that going forward, right, for us, as we launch out this therapy, we continue to have a great deal of evidence.

We're going to continue to have trials and more data that help show how great this therapy really could be for patients. We're planning to build this therapy with really careful physician training, great clinical outcomes. And supporting this therapy just like we as an organization did for TAVR not that long ago. And so, I'm excited really for that long-term opportunity and what this means for helping patients.

Patrick Wood
Looking forward to it. Thanks again for taking the questions.

Operator
Our next question comes from Vijay Kumar with Evercore. Please state your questions.

Vijay Kumar
Hi, guys. Thanks for taking my question, and congratulations on a nice sprint here. Maybe on the last question on EVOQUE, Daveen, you made some comments here about the totality of data. But I'm curious on when you think about the market development, is there like a bar, like do we need to see a stat significance in mortality? Like, there's a reason this valve was called forgotten valve. So, I'm curious what wakes up physicians to take the valve seriously, maybe compare in contrast on how this adoption curve could look like versus, I don't know if TAVR is a good example, but I would love your comments.

Daveen Chopra
Yeah, no, I'll start off a little bit first on the totality of data. Now with EVOQUE, we've implanted and tracked data in clinical trials on over 1,000 patients in various studies. And what we've consistently seen is that these patients are patients who don't have an option.

There are patients who are looking for options out there and don't feel great and can't do the things that they want to do every day in their life. And that the EVOQUE technology really makes a huge difference in their life. This concept of quality of life really does matter for patients to be able to pick up--play with your grandkids, walk up the stairs. It really does matter.

And I'm not trying to discount that these other statistics matter, right, mortality, heart failure hospitalization. Those all matter, as well. But we've, I think, shown in the breakthrough cohort

that we, at the starting point, have this amazing quality of life improvement. And that's why our indications about improvement in health status.

We've got the favorable trend in the other data points, all cohorts mortality, heart failure hospitalization, tricuspid reintervention. And those favorable trends, we'll continue to see more data as we go in the future. But as I mentioned before, we're going to continue beyond just this study, the TRISCEND II trial. We're going to continue to gather data on patients.

We're going to continue to gather large data on large numbers of patients to help show how EVOQUE can really help patients. And I think it's that kind of data, along with kind of all the other key things we talked about, careful physician training, controlled rollout, excellent outcomes that will really help create this market and really do the market development.

And so, it's hard for me to speculate how will this compare maybe the technologies like TAVR, same question about mitral, but I'm excited for what it can do. I think there's so much opportunity to grow this market.

Bernard Zovighian
Thank you, Daveen, well said. And we are very excited. Think about TAVR. Twenty years later, we are still generating evidence. We are still innovating with Ultra RESILIA X4. We still believe that there is a way for TAVR to grow healthy double digit in the many years to come, globally. So here, for TMTT EVOQUE, it's probably thinking the same. It is not the next five years, it's like 10 or 20 years here that we are thinking of.

Larry Wood
Yeah. Just to pile on that, having spent so much time in the TAVR space. When we deal with regulators and with payers and stuff, there's a lot of focus on mortality and people get really almost singularly focused on it. But spending the time with the patient groups that I spend, living longer, but living poorly is not a feature to them. If you told them they had this exact same life expectancy, but their quality of life would dramatically improve, that's far more valuable to them.

And I think when you can get that quality of life improvement and you can get the mortality benefit, that's where you really have the home run therapy like what we've seen with TAVR. And so that's really what we're trying to build on. But I wouldn't discount the quality of life benefits; they're really significant for patients.

Vijay Kumar
Understood. That's helpful. And maybe, Scott, one quick one for you on this Q1 EPS guide. I think at the midpoint, it's slightly below sheet. I'm curious on what's driving that? Is that a step up in OpEx, or is that a gross margin or below the line sort of issue that's impacting Q1 EPS?

Scott Ullem

Yeah, it's a couple of things but, largely, it relates to just the lumpiness of SG&A and R&D and in what period we record those expenses. Q1, the increase in OpEx will outpace revenue, according to our current forecast. And that's the reason why we end up with the midpoint of the range of $0.64 level with the EPS from the fourth quarter. But overall, it's important to remember that for the full year, we're expecting bottom line growth to exceed top line growth once you get through the different quarter-to-quarter cadence.

Vijay Kumar
Thanks, guys.

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

Matthew Taylor
Hi, thanks for taking the question. I wanted to ask you if you thought that the delays that your competitor's having in the U.S. would have any impact on international markets? Does it provide you an opportunity to gain any share? Does it change anything?

Larry Wood
We'll have to see what the impact is. We--certainly, we've seen cases where U.S. data has impacted international share in international markets. I think it just depends on what the data is. But I think the reality is there's been no data released. All there's been is just simply a signal that they're delaying their approval and waiting for additional data. So, I don't know how much people are going to react to that.

The other thing is there's more that goes into to the purchasing decision oftentimes, especially in Europe, than clinical data. And for the people that are purchasing on price because there's favorable pricing and it's a significant discount, I don't know how much that will get impacted.

Matthew Taylor
Got you. And can I ask one follow-up on--you mentioned the activation of patients a few times. I know you're doing a lot, there. Are you doing anything new and different there, or is it kind of more of the same? I just was noticing the call-outs on this call.

Larry Wood
I think we continue to do a lot of new things. We're running a number of programs. I think one of the things that I talked about at the investor conference is, I know there's a lot of speculation on and skepticism, frankly, on the undertreatment rates and are all those patients really there.

I can tell you we've done enough work in major health systems where we've applied things like AI to the Echo reports, and we can absolutely definitively say the patients are there, they're just not moving through the system for a variety of reasons. So, the first thing you have to do is validate, the second thing you have to do is get people to understand what to do about it, and

then you have to move them through the process and get treated. And we have multiple things that we're working on to drive those patients through, but we are literally continually evolving these programs to try to optimize them to activate patients off the sidelines and move them through the system in a streamlined fashion.

Matt Taylor
Thanks a lot, Larry.

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

Matt Miksic
Hi, thanks so much for taking the question. I had one on EVOQUE and one follow-up on margins, if I could. So not to put too fine a point on it, but moving from the middle of your TMTT range to the high end is like $10 million to $20 million.

And so, if we think about EVOQUE came about five, six months early. Does that tell us what we need to know about your sort of expectations for the run rate this year, knowing what we know now, I guess, and EVOQUE, as we just get started in the U.S.? And then I have one follow-up.

Daveen Chopra
No, Matt. Thanks so much for the question, Daveen again. Yeah, if you first look at the timing of it, right, we kind of said midyear was kind of our initial estimation, and midyear has got a couple of months kind of window. So this definitely was up by a couple of months earlier than we kind of expected.

And so, based on what we know now, we continue to be confident in what we think EVOQUE can do. And obviously, we'll see as we get through adoption and we start moving through centers, training, how fast the rate is, but that help us bring this up just a little bit.

I think the only other comment I'll make is things like new technology add-on payments, right, which are helpful for hospitals, to help ensure that they're adequately kind of profitable and doing a good job comes online October 1, and that date doesn't really change whether you get earlier approval or late approval. So there are some factors like that. But we'll continue to look at as we adapt over the course of the year and how it grows and give updates as--if needed.

Matt Miksic
That's great. And then the follow-up on the margins and Matt's question just now on the activities that you're getting after in the field. So you hired these folks in, I guess, in the fourth quarter, which is part of the step up in spending there. Just wondering, first, does that have an impact in Q4? Can you talk a little bit about the benefits that you're seeing so far from those investments? And then second, are you continuing those investments? Or to your point earlier,

Scott, about like leverage against those investments, are you kind of done and now it's about achieving leverage against sort of a set additional spend that you put into the field? Thanks.

Scott Ullem
Yeah, thanks for the question, Matt. Yeah, we're just getting started with building out our field force, both for EVOQUE but as well as we continue to expand the presence of our overall TMTT portfolio. And so, this is the beginning of an investment in building a foundation of a team in the field, not the end. You should expect that we're going to continue to grow our resources, invest in the field team.

And by the way, that's not limited just to TMTT. TAVR continues to grow aggressively, and we're investing more resources to support that growth, as well. One of the things we're doing, though, is looking carefully at general and administrative expenses, globally. And as Edwards has put down a broader global footprint, it gives us an opportunity to get some leverage from scale. And so, we're going to be continuing to look closely at that and making sure that we're being as efficient as we can be on the P&L.

Matt Miksic
Okay. And then the TAVR side, did you see any results, you feel ,from these field activations and patient activation efforts in Q4? Or is that something that's still to come? Thanks.

Scott Ullem
Yeah, Matt, I think we saw some benefit from the patient activation initiatives that we have in place. It's tough to isolate those from the other efforts that we have underway to continue to support the growth of TAVR. But no, that's certainly helping drive growth in the fourth quarter, and beyond.

Larry Wood
Just to add on to this, I mean, I think it'd be being correct to say our patient activation efforts are just starting to pay dividends now. We've been doing patient activation for the last, I don't know, five or six years through our digital campaigns through some of our website stuff, some of our patient resources, some of the general cardiology awareness events we do and a number of other things that have been driving this.

So I think patient activation has been contributing all the way along the way. I think what we're talking about now, though, is a much more sophisticated approach and program to really tapping into these untreated patients that are in the system, but hospitals don't really realize that they're there, and how do we bridge those gaps. And that's really where our activation now is because we know the patients are there.

We know they're diagnosed with an echo, but they're not moving. And so it's just a matter of tapping into those patients in the right way and getting them accelerated through the system.

Bernard Zovighian
What's fair to say, though, is in the past few years, we have done many pilots, many initiatives. We have extracted so many learnings. What we are doing right now is scaling. We are scaling and spending. We are spending resources in Q4 last year, this year and the next few years. So, you are going to see more and more because we believe there are so many patients in need not receiving a treatment.

Matt Miksic
Super helpful. Thank you.

Operator
Thank you. And our next question comes from Chris Pasquale with Nephron Research. Please state your question.

Chris Pasquale
Thanks. I think I heard you mention patient activation, not just with regard to TAVR, but also as an important part of the EVOQUE rollout. I was encouraged to hear from a lot of physicians back at TCT, they're actually seeing many more of these tricuspid patients in their practice. So as you think about the initial launch here, do you expect to have to do a lot of work establishing referral channels? Or do you think there are already a large number of these patients identified and waiting for treatment?

Daveen Chopra
Yeah, hey, Chris, this is Daveen. No, I appreciate it. I think at least my reference toward in patient activation and how we think about in TMTT is more over the longer term, right. And we think about there's so much learning that TAVR is happening where, yes, we're doing some things right now.

We're testing small things, but it's really about over the midterm, how do we kind of help scale patient activation in a way that kind of TAVR has been doing and really helps drive kind of organic growth and a number of patients being diagnosed and being referred to heart teams.

Well, the other point I'll kind of make is that, right now, I think that most of our time or a lot of our energy is really about building capabilities for getting centers up and running.

So there are a lot of patients in the center. If you look at how our trials enrolled, especially the TRISCEND II trial. It enrolled really fast; it enrolled very quickly. So we know there's definitely groups of patients who now are looking for options. They've been diagnosed and looking for options. But as we grow over time, we're going to continue to try to build off that and leverage a lot of those kind of TAVR kind of patient activation efforts.

Chris Pasquale

That's helpful, thanks. And then a lot of focus, I think rightly so, on the new U.S. products. But you've got a couple in Europe, SAPIEN 3, Ultra RESILIA and MITRIS RESILIA both rolling out there. Are the price premiums for those products in Europe the same as what we see in the U.S.? And do you think you can get similar adoption in what is a more price-sensitive market? Thanks.

Larry Wood
Yeah, I'll start and then if Wayne has anything to add, he can. The price premiums are different in the different markets because it all depends on kind of where the starting price was. So we went for larger premiums in Europe than what we did in the U.S.

And so a more price-sensitive market, obviously, that's more of an issue. So we've seen more rapid adoption of our RESILIA-based therapies in the U.S. But we continue to see this growing in Europe. And I think we're really gaining momentum on our RESILIA platforms, in total. I don't know, Wayne, did you have anything to add?

Wayne Markowitz
Maybe just a couple of things I'd add was just if you think about our global adoption of the RESILIA premium technologies, we're also seeing tremendous growth out of the emerging markets. And a lot of those emerging markets are finding and identifying patients that can be best treated surgically with the RESILIA portfolio. So, it's been certainly a global effort but strong growth out of the emerging markets even with premium technology, which is encouraging to see, too.

Chris Pasquale
Great, thanks.

Operator
Thank you. And our final question for today comes from Danielle Antalffy with UBS. Please state your question

Danielle Antalffy
Great, thanks so much, guys. Thanks for taking the question. Larry, just a quick question for you on the progress trial in moderate aortic stenosis. I mean, I know this isn't the first time we're hearing about the speed of enrollment in that trial, but it's certainly a positive signal.

And I guess my question for you is, is there anything to read into the potential opportunity there based on the speed of enrollment? Was there anything unique about the trial that allowed us to enroll so much faster than you guys expected? And what could this mean for potential approval, number one. But number two, just more broadly, once we see this data uplift across the market.

Larry Wood

Yeah, thanks, Danielle. I think clinical trial enrollment, I think, is always an important marker for the opportunity. And I think having rapid clinical trial enrollment, I think, does certainly speak to that opportunity. I think it also speaks to the fact that everything we've done in the PARTNER Series trial has still been just isolated to severe aortic stenosis. And most of that work, it is better to do surgeries or better to do TAVR.

What--I think there's a lot of enthusiasm and excitement about now is actually attacking the disease in a different way and saying, should we be waiting until patients are literally at the end stage before we even consider doing anything, or should we be evaluating those patients, sooner? And as--and I think that could have two benefits.

The first is, if we showed that treating moderate patients is important and has real advantages for those patients, then I think it could provide a real accelerant for those severe patients that aren't moving, today. And I think we've seen that when we went from high risk to intermediate risk, we have the intermediate risk approvals, one of the biggest accelerations we saw was in the high-risk space.

Because people are like, for having to debate in the intermediate, then high risk are automatic at this point. But I think the other thing about it is if we can show a benefit in these moderate patients, there's literally twice as many moderate patients as there are severe patients.

And so, when we think about long term and just continual opportunities to drive the market, I think that steady cadence of data with early TAVR coming later this year at TCT. And then we're talking about a couple of years, two and a half years later, we get the PROGRESS trial. That steady cadence of data, we think, is going to be important for informing patients and improving treatment rates.

Danielle Antalffy
That makes sense. I'll leave it at that. Hanks so much, guys.

Bernard Zovighian
So in closing, I am very proud about what we did last year; 2023 was a great year. Strong performance across our four product groups, globally. When I think about this year, 2024, I'm super excited. We are going to have multiple breakthrough technologies, clinical trial in TAVR, TMTT and surgical. Here, we have a chance.

The same way we did it in TAVR 20 years ago to shape the TMTT space with EVOQUE and providing basically a toolbox to physician to treat so many patients. So, that's a very unique opportunity that we are taking very seriously.

The speed of critical care, we are executing on this one ,also in 2024. So I'm super confident that this year is going to be a super exciting year, and we are going to be very well positioned to accelerate growth in 2025, and beyond.

So with that, thanks for your continued interest in Edwards. Scott, Mark and I welcome any additional questions by telephone. Thank you, everyone.

Operator
Thank you. This concludes today's conference. All parties may now disconnect.