Edwards Lifesciences
Third Quarter 2024 Results Conference Call
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Presenters
Mark Wilterding, Senior Vice President of Investor Relations
Bernard Zovighian, CEO
Scott Ullem, CFO
Larry Wood, Group President of TAVR & Surgical Structural Heart
Daveen Chopra, Global Leader of TMTT
Wayne Markowitz, Global Leader of Surgical Structural Heart

Q&A Participants
Larry Biegelsen - Wells Fargo
Vijay Kumar - Evercore ISI
Robbie Marcus - JPMorgan
David Roman - Goldman Sachs
Travis Steed - Bank of America
Matt Taylor - Jefferies
Matt Miksic - Barclays
Joanne Wuensch - Citibank
Danielle Antalffy - UBS
Patrick Wood - Morgan Stanley
Adam Maeder - Piper Sandler

Operator
Greetings, and welcome to Edwards Lifesciences Third Quarter 2024 Results Conference Call.

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

Please note that this conference is being recorded.

I will now turn the conference over to your host, Mark Wilterding, Senior Vice President of Investor Relations. Thank you. You may begin.

Mark Wilterding
Thank you very much, Diego, and welcome, everyone. Thank you for joining us, this afternoon. With me on today's call is our CEO, Bernard Zovighian, and our CFO, Scott Ullem. Also joining us for the Q&A portion of the call will be Larry Wood, our Group President of TAVR and Surgical

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

Just after the close of regular trading, Edwards Lifesciences released third quarter 2024 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 growth opportunities, strategy, leverage and integration of our acquisitions, regulatory approvals, clinical trials, litigation, reimbursement, competitive matters and foreign currency fluctuations. These statements speak only as of the date on which they were made, and Edwards does not undertake any obligation to update them after today.

Additionally, the statements involve risks and uncertainties that could cause actual results to differ, materially. Information concerning factors that could cause these differences and important product safety information may be found in the press release, our 2023 annual report on Form 10-K, and Edwards' other SEC filings, all of which are available on the company's website at edwards.com.

Unless otherwise noted, our commentary on sales growth refers to constant currency sales growth, which is defined in the quarterly press release, issued earlier today. Reconciliations between GAAP and non-GAAP numbers mentioned during this call are also included in today's press release. Growth rates refer to continuing operations and do not include contributions from Critical Care, which was sold on September 3.

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

Bernard Zovighian
Of $1.4 billion increased 10% on a constant currency basis versus the year ago period, slightly ahead of our expectations. TAVR and TMTT both contributed significantly to growth in the third quarter as more patients, globally, benefited from our catheter-based structural heart therapies.

During the quarter, our team made important advancements in our clinical research and new product introduction to address the unmet needs of structural heart patients, around the world. Next week, at TCT, you will hear more about our commitment to generating important clinical evidence to help physicians and the health care ecosystem take care of the many patients in need.

At the conference, we will be discussing the pivotal clinical data presentation of early TAVR, TRISCEND II and Class IID, along with more than 20 other important updates. Edwards is leading the advancement of science in this large, diverse and rapidly growing field.

Our priority remains positioning TAVR for long-term growth. In addition to introducing differentiated next-gen technologies, we are leading several global initiatives, including reaching more patients through patient awareness, activation and access, and enhancing physician training and support programs.

For TMTT, we continue to scale our fast-growing business, and we are pleased with its trajectory over the last several quarters. Key initiatives include broadening the launch of PASCAL, advancing the introduction of EVOQUE in the U.S. and in Europe, and launching SAPIEN M3 in Europe, next year. Edwards' unique pipeline of innovation should drive strong multiyear growth.

We are also committed to bringing differentiated surgical innovation to patients supported by strong evidence generation, ensuring we remain at the forefront of surgical advancements.

Moreover, we are entering new therapeutic areas, such as aortic regurgitation, or AR, and implantable heart failure management, or IHFM. These initiatives align with our long-term vision of expanding into more therapies, driving sustainable growth for Edwards.

It was an especially busy quarter as our team around the world delivered on our strategy. We closed the sale of Critical Care in September, took important actions to sharpen our focus on structural heart, including integrating recent acquisition and rightsizing the company for long-term profitable growth.

As we look ahead, we see significant growth opportunities across our differentiated portfolio of leading structural heart therapies for TAVR AS, TAVR ER, TMTT, surgical and IHFM. This commitment will be discussed in detail at the upcoming investor conference where we will outline our strategies for differentiated value creation in the years ahead.

Now, I will provide detail on Q3 results by product group. In TAVR, third quarter global sales of $1 billion increased 6%, when adjusted for currency and billing days. Edwards' strong competitive position and pricing remained stable globally, although we experienced a few instances of regional pressure. We are confident in our differentiated technology, high-quality evidence and the value we continue to demonstrate to patients, clinicians and health care leaders.

We remain deeply committed to advancing evidence for AS patients. In August, 1-year data for the RHEIA trial, a first-of-its-kind trial focused exclusively on outcomes for women receiving TAVR were presented at the ESC meeting held in London. Investigators reported superior outcome for women receiving the Edwards' SAPIEN 3 or SAPIEN 3 Ultra Valve, as compared to

those receiving surgical aortic valve replacement for the primary endpoints of death, stroke, rehospitalization, at one year.

We are proud of this high-quality clinical research. The outstanding success of TAVR points to the importance of valve selection for women undergoing aortic valve replacement, especially valves with small annuli, to preserve their option for future valve-in-valve procedures, ensuring the lifetime management of their disease.

Next week at TCT, the clinical community will hear results from the early TAVR trial. The trial is the first and largest randomized controlled trial to date studying asymptomatic severe AS patients and the impact of early integration with TAVR.

Turning to the U.S. Our year-over-year third quarter TAVR sales growth rate was in line with our global TAVR constant currency growth rate. We believe our U.S. competitive position was largely unchanged.

In the U.S., although hospitals and physicians continue to acknowledge heart team capacity constraints nationally, it is encouraging that many hospitals are exploring additional investments to address future workflow needs to manage these patients. We know from experience that hospitals have, historically, demonstrated the ability to scale to support transcatheter procedure growth, over time.

Outside of the U.S. in the third quarter, our constant currency TAVR sales growth was in line with our global TAVR growth. In Europe, our market position improved sequentially, supported by the continued launch of SAPIEN 3 Ultra RESILIA. We are pleased with the exceptional patient outcome delivered with this platform. And we expect this momentum to continue as more centers adopt our best-in-class TAVR platform.

Additionally, we received CE Mark approval for our Alterra system for congenital heart patients. Alterra should result in quality of life improvement and a reduction in the number of procedures that these younger patients will require, over the lifetime. We have initiated the introduction of its novel therapy in Europe, and initial feedback from clinicians has been positive.

In Japan, slower market growth pressured our results. We remain dedicated to expanding this therapy to address significant undertreatment of AS among the substantial AR population in Japan.

In closing, we are pleased with our Q3 TAVR results, which were slightly above our expectation. Our 5% to 7% growth guidance for the full year remains unchanged. However, we expect the Q4 year-over-year sales growth rate to be lower due to some onetime items that Scott will describe later.

We remain confident that Edwards is positioned for healthy and sustainable TAVR growth, driven by our differentiated TAVR technology, our deep commitment to advancing patient care through high-quality clinical evidence, new indication, and our investment in patient activation initiatives.

Last quarter, we announced the acquisition of JC Medical and J-Valve, early innovators in the treatment of AR. These acquisitions provide an opportunity in a new therapeutic area to address the unmet needs of AR patients around the world, a deadly disease that impacts more than 100,000 patients in the U.S. alone, and is largely untreated today.

As the pioneer in valve innovation, we believe Edwards is best positioned to develop, study and deliver novel technologies.

I am pleased to report that we performed our first implant in the JOURNEY pivotal trial with the Edwards J-Valve AR system, recently acquired from JC Medical. As noted in our announcement of the JenaValve transaction, the acquisition is subject to regulatory review and other customary closing conditions. We are responding to a second request from the FTC in connection with their review and anticipate closing the acquisition, mid-2025.

Now turning to TMTT. Our unique innovations, including the PASCAL repair system, the EVOQUE tricuspid replacement system and the upcoming SAPIEN 3 mitral replacement system, provide a broad set of treatment options to serve the many diverse and complex patients in need.

We are pleased with the Q3 results, achieving $91 million in sales, representing 74% growth over the prior year. Sales were led by PASCAL growth globally. We continued the initial commercial expansion of EVOQUE in the U.S. and Europe.

Globally, we continue to see more patients diagnosed and treated as long as strong therapy adoption, resulting in mitral procedures experiencing ongoing double-digit growth and even stronger tricuspid therapy growth. Adoption of a differentiated PASCAL technology is expanding in both new and existing sites, around the world. We look forward to presenting the 2-year outcomes of a Class IID pivotal trial studying DMR patients at TCT, next week.

We are also pleased to announce the earlier-than-expected completion of enrollment for the CLASP II TR trial studying TR patients with PASCAL randomized against optimal medical therapy, alone. This achievement is great news for patients suffering from tricuspid regurgitation given the differentiated characteristic of PASCAL.

The EVOQUE launch continues to progress well, as we successfully activated new sites in both the U.S. and Europe, beyond our initial trial centers. We are also increasing our field teams to deliver on our high-touch model to support new sites as they bring EVOQUE into their clinical practice in order to achieve excellent patient outcome.

The strong interest in this therapy continues to highlight the large unmet need. The full 400-patient cohort of a TRISCEND-2 pivotal study at one year will also be presented at TCT, next week.

In our continued efforts to reach more patients, a fourth and larger size EVOQUE valve, the 56-millimeter, was recently approved in the U.S. The addition of this larger valve size will expand the addressable patient population.

On October 1, EVOQUE became eligible for Medicare's new technology add-on payment. This additional payments above standard reimbursement is in effect for three years and will support increased access to this breakthrough therapy for the many U.S. patients in need.

Based on the ongoing global adoption of our two therapies, PASCAL and EVOQUE, we remain confident in our full year TMTT sales guidance at the high end of $320 million to $340 million.

In surgical, third quarter sales from continuing operation of $240 million increased 5%, over the prior year. Growth was driven by strong global adoption of Edwards premium surgical technologies INSPIRIS, MITRIS and KONECT. We continue to see positive procedure growth, globally, for the many patients best treated surgically, including those undergoing complex procedures.

We continue to expand the overall body of RESILIA evidence and enrollment in Europe for our momentous clinical trial studying MITRIS is ahead of schedule.

In addition, the comments AR Manuscript has been published in the Journal of Thoracic and Cardiovascular Surgery, which shows positive outcome for patients with AR treated with RESILIA tissue valves after five years.

Finally, two investigator-initiated registries out of Europe, Endure and Impact, have shown a favorable outcome in younger and more complex patients who were implanted with the RESILIA INSPIRIS valve.

In summary, we continue to believe that our full year 2024 surgical sales growth will be 6% to 8%.

Turning to structural heart failure. In Q3, we closed the acquisition of Endotronix, making--marking our entry into implantable heart failure management, or IHFM. Our vision for IHFM is consistent with our other structural heart technologies, to establish a platform that ensures best-in-class outcome for patients in need, resulting in multiyears of growth.

We released a strong 12-month results from the proactive HF pivotal trial at the HFSA Conference, which demonstrated significant benefit to patients managed with the Cordella

system, an implantable pulmonary artery pressure sensor, allowing early targeted heart failure intervention. In addition, the proactive HF II trial has also been initiated, which will extend the evidence base for implantable heart failure management and further demonstrate the value of data-driven heart failure management.

With the recent approval of Cordella in the U.S. and the completion of our first cases, our focus is on building our commercial team, deploying physician training, case support to ensure high quality of outcomes. Revenue will ramp over time, as we focus on disciplined commercialization, outcome, system usage and patient engagement.

And now I will turn the call over to Scott.

Scott Ullem
Thanks a lot, Bernard. We were pleased with our financial results in the third quarter, starting with third quarter sales from continuing operations of $1.35 billion. Our continuing operations underlying sales growth was 9.6%, and Edwards adjusted earnings per share was $0.67, both slightly ahead of what we modeled for Q3 guidance provided in July. A full reconciliation between our GAAP and adjusted earnings per share for continuing operations is included with today's press release.

The sale of Critical Care, as well as the acquisitions we announced last month, resulted in some new features in the presentation of our financial results, this quarter.

First, it's important to note that our original sales guidance for Q3 assumed we would own Critical Care for all of Q3. We were pleased to close the sale of Critical Care in early September, so we did not have Critical Care sales in the last month of Q3.

Second, the discontinued operations in today's release and the 10-Q that we will file in early November are comprised of the two components that represent our plan to exit product groups that are not focused on implantable medical innovations for structural heart disease. The discontinued operations includes Critical Care, as well as a small noncore product group that reduces the reported sales of surgical structural heart.

Third, as it relates to previously announced acquisitions, we do not expect meaningful contribution to Edwards sales in 2024 and 2025. The additional operating expense from three of the four acquisitions announced is included in our fourth quarter earnings per share guidance.

Additionally, there is a new line of the profit and loss statement above operating income, called “Other Operating Expense and Income,” reflecting an impact related to critical care transition service agreements. So now I'll cover additional details of our continuing operations P&L.

For the third quarter, our adjusted gross profit margin was elevated at 80.7%, slightly higher year-over-year and sequentially, due to variable expense timing. We expect fourth quarter gross margin to be in line with the high end of our 76% to 78% full-year guidance range, which is also a reasonable preliminary modeling assumption for 2025.

Selling, general and administrative expenses in the quarter were $421 million, or 31.1% of sales, compared to $382 million in the prior year. This increase was driven by an expansion of field-based personnel to support growth of our transcatheter therapies, including the launch and rollout of PASCAL and EVOQUE.

Research and development expenses in the third quarter grew 4% over the prior year to $253 million, or 18.7% of sales. This increase was primarily the result of continued investments in our transcatheter valve innovations, including increased clinical trial activity.

Adjusted operating profit margin in Q3 was elevated at 31.4%, reflecting unusual benefits of variable expense timing. We expect Q4 adjusted operating margin to decline to the mid-20s, resulting in full year 2024 average adjusted operating profit margin of approximately 27% to 28%, which is also a reasonable preliminary modeling assumption for 2025, with forecast for expanding margin, thereafter.

Turning to taxes. Our reported tax rate this quarter was 10.1%, or adjusted, 12.4%. We expect a similar adjusted tax rate in Q4. As a reminder, our original 2024 adjusted tax rate guidance range was 14% to 17%, and we are benefiting this year from several onetime tax events, resulting in a lower than originally expected rate.

Foreign exchange rates decreased third quarter adjusted sales growth by 70 basis points, or $7.9 million compared to the prior year.

GAAP earnings per share of $5.13 reflects the onetime gain on the sale of Critical Care. Also unique to this quarter were several special items, including a restructuring charge, a gain on our original investment in Endotronix, and a $30 million charitable donation to support the work of the Edwards Lifesciences Foundation.

Turning to the balance sheet. Following the Critical Care sale, we had approximately $3.5 billion of cash and cash equivalents, as of September 30. You'll see a balance sheet in our 10-Q filing in early November.

During the third quarter, the company repurchased $1 billion of stock through a combination of preestablished trading plans and accelerated share repurchase programs. Edwards currently has approximately $1.4 billion remaining under its share repurchase authorization. Based on our year-to-date share repurchase activity, we expect average diluted shares outstanding for Q4, 2024, to be between 590 million and 595 million.

I'll finish with comments related to guidance. Our full year guidance for Edwards sales growth of 8% to 10% remains unchanged, as does our guidance for our 3 product groups. Our guidance assumes fourth quarter year-over-year TAVR growth below the full year TAVR range of 5% to 7%. Recall, Q4 of 2023 was an especially strong quarter for TAVR.

In Q4 of this year, we have seen impact from the hurricanes in the Southeast, as well as a onetime impact from a China distributor rebate adjustment and fewer selling days versus Q3. It's important to note that our daily TAVR procedure volume is still forecasted to be sequentially higher in Q4 versus Q3.

We expect Q4 sales of $1.33 billion to $1.39 billion and Q4 earnings per share of $0.53 to $0.57. We look forward to providing detailed 2025 financial guidance at our investor conference in New York on December 4.

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

Bernard Zovighian
Thank you, Scott. We are confident that our innovative therapy will allow Edwards to treat more patients around the world and continue to drive strong organic growth in the years to come. As patients and clinicians increasingly recognize the significant benefit of breakthrough technologies, we remain as optimistic as ever about the long-term growth opportunity.

With that, I'll turn it back to Mark.

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

Please refrain from asking questions related to our early TAVR or TRISCEND-2 pivotal trials. We will present data on those trials next week at TCT and host investor briefings on both Monday and on Wednesday, after the presentation, to discuss the results in more detail. We really hope to see you there.

Diego, please go ahead with additional details on how participants can access the Q&A portion of the call.

Operator
Thank you. And at this time, we will conduct our question-and-answer session. If you would 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 can press “*”, “2”, if you would like to remove your question from the queue. Once again, to ask a question at this time, press “*”, “1”

on your telephone keypad. For participants using speaker equipment, it may be necessary to pick up your handset, before pressing the star keys.

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

Larry Biegelsen
Good afternoon. Thanks for taking the question. Scott, I guess, maybe help us bridge, the Q4 guidance implies about $2.20 on an annual basis, just using the midpoint, times four. Can you bridge from the prior guidance to $2.75 at the midpoint? Did it only change for Critical Care, which we thought was always going to be $0.40 dilutive? It seems like something else changed. And I had one follow-up.

Scott Ullem
Yeah, thanks for the question, Larry. There are a couple of things that changed. One was the elimination of critical care which, on a full year basis, would have impacted earnings per share to the tune of about $0.35. We're also picking up in the fourth quarter some additional expense related to three of the four acquisitions that we announced earlier, which hit us in Q4. Q4 does not reflect some of the benefits of the rightsizing that we conducted earlier and that we will see in 2025.

Larry Biegelsen
That's helpful, Scott. And then just a follow-up on that--sorry.

Bernard Zovighian
Just on what Scott said, Larry, obviously, we are also expecting growth from our continued operation in 2025, together with the EPS leverage. And we will provide you a full guidance during investor conference in December.

Larry Biegelsen
Okay. I mean, that was my follow-up, Scott. I mean, I know you anticipated the question. Just using that kind of Q4 EPS of $0.55 at the midpoint, people are going to multiply and get to $2.20. How should we think about that in the context of 2025 EPS? You gave some helpful color on the operating margin. Is there anything else we should consider when we're trying to kind of model 2025 here?

Scott Ullem
Yeah. Obviously, the big driver is top line growth, and we'll be prepared to talk about that for Edwards and for different product lines on December 4. And you're right, we tried to give you some building blocks for margins, both operating margin--we talked about the special tax rate benefits we achieved in 2024, which we're not going to model achieving in 2025. And as Bernard just mentioned, we're going to see benefits from some of the actions that we've taken this year when we hit the full year 2025.

So those are the different moving pieces that we can give you for now, and we'll take you through the top line impact in December.

Larry Biegelsen
Alright, thanks so much, guys.

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

Vijay Kumar
Hi, guys. Thank you for taking my question. Scott, maybe if I could go back to this Q4 guidance assumptions. I think you called out a few line items on TAVR. Between the hurricane and China, could you parse out what the impact of--hurricane, I'm assuming we've already seen some impact. And what was China? Is this just one-timer on China? Could there be some lingering impact as we think about next year?

In days, I know you said lesser days versus third quarter, but on a year-on-year basis, any change in the number of days in Q4?

Scott Ullem
Sure. Thanks for the question, Vijay. First on China. No, this is a onetime adjustment to a rebate for a distributor in China. It does not have anything to do with our operations or our sales growth in China, at this point.

As it relates to selling days, yes, there are three fewer selling days in Q4 than there were in Q3, and that impacts us when we start talking about sales dollars. But what's important to note and remember is the procedure volume on an average daily basis is growing, sequentially, in Q4 over Q3.

Vijay Kumar
Understood. And then maybe one more related to the guidance here. What is the implied operating margins here for Q4, when you look at the EPS and the revenue sales dollars? Is that something like mid-25s? And I'm just trying to think what is the right run rate here on operating margins as you get the benefit from rightsizing expense line item. And sorry, back on the days, on a year-on-year basis, was it consistent, or did the year-on-year basis change?

Scott Ullem
Well, I understood the first part of your question. Let me answer it and then maybe you can help me on the second part of the question. So yes, for Q4, the guidance assumes mid-20s or implies mid-20s percentage operating margin. For next year, we expect that to grow to the range of 27% to 28%, which is also the same as our full year 2024 operating margin.
And help me with the other piece of your question, Vijay.

Vijay Kumar
Sorry, on the days--fourth quarter days versus fourth quarter '23, I was looking on a year-on-year basis on the days comment.

Scott Ullem
I believe the selling days were comparable or the same in Q4 of 2023 as in 2024. We'll check that and I'll come back on if that's not right.

Vijay Kumar
Understood. Thank you, guys.

Operator
Thanks you. And our next question comes from Robbie Marcus with JPMorgan. Please state your question.

Robbie Marcus
Great. Thanks for taking the questions. I'll switch it over to some of the products. TMTT, again, came in better than expected. We've seen from your competitor a nice quarter on the repair side. I was wondering if you could talk about, on tricuspid repair specifically, I was wondering if you could talk about your tricuspid replacement and how you're seeing doctors choose in the market which patients are appropriate for which, and the decision-making process.

Daveen Chopra
No. Thanks, Robbie. This is Daveen. I appreciate the question. Maybe I'll just start off with a couple of overall comments on EVOQUE. Obviously, we've been very pleased ,so far, with the introduction of EVOQUE in both the U.S. and in Europe. And we've really seen strong physician and patient demand, which really enforces that there's a lot of unmet needs for these patients.

And we've loved to have seen so far with EVOQUE that we've got very predictable times that are very similar to the clinical trial, that are very similar from both clinical trial sites as well as new sites, and clinical outcomes are very much similar to TRISCEND-2.

And we also have seen in the U.S. where we just have EVOQUE, that from our experience in Europe where we've had both repair and replacement, we see that it's important to have a portfolio of both repair and replacement technologies to really treat the diversity of these complex patients that are tricuspid patients.

And so right now, we're continuing to open up new centers, activating new sites, focusing on other big tricuspid centers, really with robust training and high clinical support. And we're continuing to add to our clinical kind of support training team.

Specifically to your question about repair and replacement, I think we're all still figuring that out, about who's the right patient for each. We see that there may be some anatomical considerations where one may be better for--than another. But I think as a world, we're still all trying to figure this out, but we really do believe that you need both technologies to really see--to treat the most number of patients.

Two other quick comments are, obviously, over time, we believe that EVOQUE in our portfolio, now if you pull back up and look at TMTT, EVOQUE's going to become a larger and larger percent of our portfolio. But right now, PASCAL is still our largest growth driver on a year-on-year basis just because it's a more established base and a larger base, overall. But we look exciting to treating more and more patients with both EVOQUE and PASCAL.

Robbie Marcus
Great. Maybe just as a quick follow-up. On TAVR, you've now had three more months to kind of evaluate the market and really dig into the capacity issue. And I'm asking this more from a market perspective because none of your competitors kind of validated a capacity issue. And so when you see it, I imagine--you're one of the biggest in the structural heart labs, so I imagine you probably have the best view. But how are you thinking about capacity here? Is it more of a TAVR volume issue versus capacity?

I know the market is still substantial from a top-down basis. Just because we don't hear anybody else kind of validating the capacity. So would love to get your thoughts there on what you're seeing on the ground. Thanks a lot.

Larry Wood
Sure. Thanks, Robbie. This is Larry. Yeah, it's something we spent a lot of time on in the quarter. We spent a lot of time with hospital administrators and with our physicians in the field. And I think one of the things to just think about is, given our market position overall, we're more dependent on market growth than any of our competitors are.

For people that are coming off small bases, if they pick up a little bit of share, a few patients here and there, they don't really necessarily see the capacity constraints in the same way.

I also think you just have to look at all of the new technology in the last couple of years that's coming to the Cath lab space. And frankly, we're part of the problem. As Daveen is growing and bringing in new products like EVOQUE and we see continued adoption of PASCAL and you see adoption of other technologies, it's just putting tremendous pressure on the structural heart teams to be able to prioritize patients and to move patients around.

Now, we've been very encouraged in our discussions with administrators that they see this as being a long-term growth part of their hospital systems, which means they now, I think, are starting to realize just not that they're going to have to add some capacity, but they're just not going to be able to move resources around to be able to address the patient needs. So we have

heard of hospitals that are now specifically investing in the structural heart space so that you can meet these needs.

But it's a little bit different by hospital. There are some places that maybe the constraints are a little bit more physical constraints with rooms and other places, it's more just a staffing issue and they can prioritize it. But one of the reasons we brought together a lot of administrators is so that they could share best practices for how they're trying to manage all of the challenges that they have and try to move that forward. And we'll continue to do that, until this gets resolved. But that's kind of an update on where we are.

The one thing I will stress is it's not a shortage of patients. I think we do see backlogs growing, we say time to treat is increasing for our TAVR patients. And that's just the other issue that we have to address because we know these patients don't wait, well. I don't know, Bernard, do you have anything to add just as a broader company?

Bernard Zovighian
No, I think you said it all and well, Larry. We are part of the issue here. We are such an innovator in the space with PASCAL, with EVOQUE, with TAVR. We have a market-leading position in TAVR. And you need to realize, also, that when we bring EVOQUE in one of the larger TAVR centers, it is taking--it is needing a lot of resource.

We want to make it--TR is a new disease. So the health, so basically this heart team is learning about the new disease, is training about the new device. We are--then they are screening patients. So it's not like one day kind of adjusting their workflow. It is taking multiple days, weeks.

But we are very confident that they are patients, tricuspid patients, mitral patients, AS patients, we are bringing innovative technologies. The health care systems have proven to us in the past they know how to scale. And all of these procedures are profitable.

So we are confident that, yes, it is an issue right now. We don't believe that it is a long-term issue. It is not going to take a few weeks to solve, but it is not going to take a few years to solve, also.

Robbie Marcus
Appreciate it. Thanks a lot.

Operator
Thank you. And our next question comes from David Roman with Goldman Sachs. Please state your question.

David Roman

Thank you and good evening, everybody. I wanted to start on just laying out some of the pieces here, post TCT. And I appreciate that we won't see the data until next week. But as you think about the subsequent activities that would take place either on the asymptomatic patient population as it relates to label expansion or additional patient activation efforts, what happens next there?

And maybe you can kind of talk through some of the dynamics on the tricuspid side as well, appreciating here that the FDA has already approved EVOQUE, and NCD is already underway, and you have the NTAP to support adoption. But maybe help us think about the activities that happen subsequent to TCT, and then when we should realistically expect to see a benefit of that flow through the business assuming positive outcomes in these studies.

Bernard Zovighian
Thanks, David, for the question. Anything related to TCT, I suggest we wait until next week, what we did in the next week to make sure we can go very deep with you. We have an event on Monday and we have an event on Wednesday, after the two presentations. So we will go deep then, and we are also going deep at investor conference.

Now with regards to the NCD for EVOQUE, maybe you want to touch on that, Daveen?

Daveen Chopra
Yeah, no problem at all. Yes. Right now, we are obviously in a national coverage analysis position where CMS is working along their pathway and through their work where we expect to see a draft NCD hopefully come out by year-end, and we hope to have an NCD in place by the end of Q1. And we're fully supportive of CMS's efforts to get this out as quickly as possible to support patients.

David Roman
Okay. And then maybe just a follow-up on the P&L here, and understanding that we'll get the guidance in December. But the 27% to 28% operating margin as a starting point implies kind of flattish, year-over-year. So is conceptually the right way to think about that, Scott, that the actions you've taken here to right size the company effectively help you fund the incremental investments associated with the acquired assets, and that that forms a new base of operating margin off of which we can see expansion, longer term? And then maybe just, Daveen, to clarify, can you just describe the interplay between the NCD and the NTAP, post Q1 of next year?

Scott Ullem
Well, I'll start. And you said it perfectly, David, yes, 27% to 28% implies the impact of the acquisitions and the rightsizing moves that we made, this year. And it is a base off of which we will grow. And our plan is that we're going to continue to expand operating margins after we get through 2025. Daveen.

Daveen Chopra
Yeah, sure. So the NTAP, which started October 1, is about incremental payment above the existing DRG. So a hospital center, depending on their cost structure and how--it's very center-dependent, can get incremental payment when they do an EVOQUE case for Medicare for that case.

The NCD is about coverage, meaning, which patients are covered or not to get the payment. So the NCD and what is written in the NCD will help determine which patients and which centers do EVOQUE and which patients would get reimbursed. The NTAP helps increase the amount of payment for each patient when they do a case.

David Roman
Very helpful. Thanks for taking the questions.

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

Travis Steed
Hey, thanks for taking the question. I just wanted to clarify the 27% to 28% op margin. Does that include the JenaValve, the deal that hasn't closed and includes kind of everything, the cost savings? And it seems like that's like $240 million, $250 million in earnings range. I don't know if there's a floor or you'd like to comment on that for the EPS side.

Scott Ullem
So the 27% to 28% includes three of the four acquisitions. We're not being very specific about what the implications would be for Jena. As we mentioned, we're responding to questions that we've received, and we're expecting that we'll get that closed, next year.

As it relates to earnings per share, yeah, let's not go there. I don't really want to get overly specific about what that looks like, again, because we want to paint the full picture, including top line growth, when we get to the investor conference in December.

Travis Steed
That's fair. I don't know if there's any way to quantify the JenaValve addition on that 27% to 28% op margin, but that's going to be the follow-up. But the other question I was going to ask was, the 5% to 7% TAVR growth that you've kind of been at this year, is that the way to think about kind of your ongoing steady state, or do you think there's kind of catalyst that could reaccelerate that, going forward? Just trying to think about like bigger picture how you're thinking about the TAVR opportunity for Edwards.

Scott Ullem

Yeah. Travis, we're thinking about it really positively. We've got a lot of positive catalysts for TAVR. And at the same time, it's just premature to start talking about what the growth rates look like. We're excited to lay it all out for you when we get to December.

Bernard Zovighian
Maybe adding a general comment about profitability and all these kind of things. As you have seen in Q3, we took action to optimize the company. We are looking very seriously at, in a very thoughtful fashion, about cost optimization, resource allocation. So what we want to deliver is sustainable, healthy, profitable growth for the years to come, as a company.

Travis Steed
Thank you.

Scott Ullem
Great, thanks a lot.

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

Matt Taylor
Hi, thanks for taking the question. So I want to ask about the results, but I just want to ask about the timing of impact. If these trials are positive next week, how quickly do you think you could see some positive lift on TAVR and/or TMTT from early TAVR and the tricuspid results?

Bernard Zovighian
Matt, thanks for the question. Again, look, we are going to discuss this in full detail on Monday. It is a little bit not easy for us to discuss before Monday. The trial is embargo, it is a blinded study. We cannot go there right now. But for sure, on Monday, please attend the event and also at the investor conference. Larry is going to talk about TAVR.

Matt Taylor
Okay, fair enough. Thank you.

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

Matt Miksic
Hey, yes, thanks so much for taking the question and for the color on 2025. I just wanted to maybe ask Scott, if I--I'm not sure if I missed it, but I appreciate the color on the operating margin. Wondering if, at this stage, you're ready to say anything about the gross margin, FX related or otherwise.

Scott Ullem
Yeah, thanks a lot for the question. Yeah, I think for gross margin, we're expecting in the fourth quarter that we'll be back to the high end of our original guidance range of 76% to 78%. And that high end of 76% to 78% is also a reasonable preliminary modeling assumption for 2025.

Obviously, there's a lot that can change between now and then. We got foreign exchange running through there. But at this point, that's as much as we can do to help you out.

Matt Miksic
Fair enough. Thanks so much.

Operator
Thank you. Our next question comes from Joanne Wuensch with Citibank. Please state your question.

Joanne Wuensch
Good evening, and thank you so much for taking the question. I'll put them both at the front. Can you quantify the onetime impacts for the fourth quarter for TAVR? It seems like that's causing a wee bit of confusion as people are thinking about how that's progressing, sequentially.

And then my second question has to do with products. I haven't heard you here or talk about for M3 for mitral replacement in a while. And I don't know if you can just give a little bit of update on the timing of that or when we might see anything incremental. Thank you.

Scott Ullem
Hey, Joanne, thanks for the question. On the first one, the specific impact that we know is relating to the China distributor adjustment, which is about $5 million. The other items that we mentioned are not something that we're ready to quantify at this point. Obviously, we'll talk about everything that happened in the quarter, once we finished the quarter, but that's the one number that we can give you right now.

Daveen Chopra
Great. And a follow-up question you had, Joanne, just on about M3. No, we still continue to be excited about SAPIEN M3. This is the first transfemoral sub-30 French mitral valve replacement system, and it's really built off SAPIEN, which we know has been put in thousands of different mitral positions.

So right now for Europe, we continue--last quarter, we announced we continue to anticipate European launch in mid-2025. And we would have the U.S. at some point after. Specifically related to the U.S., we are in the 1-year follow-up period this year of the M3, and then it takes some time, obviously, to put the data together, get the PMA in. And then there as a standard

kind of FDA time line review whether there's a panel or not. But we continue to be excited about SAPIEN M3. But Larry had a comment, too.

Larry Wood
Just a follow-up on Scott's comment, Joanne. We can't exactly quantify the hurricane in the IV solution issue. We know that we did--were impacted with cases early in the quarter. But I think that that's also behind us. Largely, there--and I don't expect this to be a lingering thing ,throughout the quarter.

And as Scott said previously, we are anticipating our average daily cases to be increasing, Q4 over Q3. So I don't want to overstate the impact of these one-timer things, when you look at it in the bigger picture.

Joanne Wuensch
Excellent. Thank you so much.

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

Danielle Antalffy
Hey, good afternoon, everyone. Thanks so much for taking the question. Congrats on a good quarter, considering everything. Just a quick question on how we should think about the competitive dynamics. And particularly in the U.S., we'll see some competitive data next week, might see a fourth valve come to market.

Would love to hear, appreciate you guys have said today, your share is stable, but how you're thinking about the future. And even the receptivity so far with three valves of centers for taking on a third valve, who's losing share to that third valve? And also the pricing dynamic. Sorry, that was a lot, but that's my only question. Thanks so much.

Larry Wood
Hi, Danielle, maybe I'll start, and then I'll let maybe Bernard comment on just kind of broader company aspects. Yeah, we do charge a premium for our platform. We believe our S3 UR represents absolute best-in-class technology and best-in-class performance. It takes all of the things that we've always loved about SAPIEN 3 Ultra, but added our RESILIA tissue which we have a deep history with from our surgical business. So, we think our platform deserves the premium that we charge, globally.

I think we always think carefully about competition. We have deep respect for our competitors. But I think when you look at the body of evidence that we've put on the table through our clinical trials, you look at things like PARTNER III, 99% of our patients were alive and well at a year. You look at five years, 90% of our patients were still alive. We think that the technology but also the clinical evidence support our best-in-class premise.

But it's our responsibility and it's our job to make sure we're always communicating that with our customers. And it's not just about the price of the device, it's the value we bring to their system. And we just simply think that we offer the best there is in lifetime management of these patients and also running a very efficient TAVR program in terms of procedure time and predictability and discharge. But it's our job to continue to make that case, and I think it's about us being able to do that and execute at a high level.

Bernard Zovighian
Yeah. So if I look at the entire company, I look at, for instance, surgical, 65 years of pioneering innovation. Today, we are, by far, a global leader in premium pricing. Our valve, surgical valve, are the best valves.

When I look at TAVR, we are the global leader with a premium pricing, and it is the valve--our TAVR valve is the valve of choice. If you look at what we are doing with EVOQUE, again, we are the first--we are a pioneer again, creating category, leading the space. We bring value to the entire health care ecosystem.

So we are--one is we are proud about our history. We like our strategy. It's working. What we are bringing is breakthrough technologies, bringing value to patients and all stakeholders. We know that competition is coming, and it has been there for many years. The structural heart is a large space. There are many patients. It is growing. It is attracting a lot of competitors.

But we like our position. We like our technology. We like our strategy. And there are more patients to treat in surgical, in TAVR, in TMTT, in heart failure. And this is why we are so confident in us being able to deliver sustainable, profitable growth in the many years to come. Thanks for the question.

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

Patrick Wood
Beautiful, thank you. I just had one quick one to follow up on that, which was for TAVR. Could you--I can get a sense, but could you maybe give us a sense of how you're seeing growth in some of the larger centers, relative to the smaller? I'm thinking about the commentary about where EVOQUE and PASCAL have been rolling out and the disruption from that. So for the smaller programs, have you seen a different kind of a growth profile than what you've seen in the larger?

Larry Wood
Yeah. This is Larry. That sort of moves around a little bit, quarter-to-quarter. I will say that the larger academic programs are the ones that are most likely to be adopting the new therapies

and really putting more focus. And those are oftentimes places that are obvious--that are closer to their capacity wall. So we maybe see a little bit of impact in those larger academic programs that are kind of on the forefront of utilizing these new technologies.

But it's hard to generalize. We have probably close to 850 centers in the U.S. And to a degree, they all have different challenges. But just broadly speaking, I think the large academic centers were the early adopters is probably where we feel a significant amount of the pressure.

Patrick Wood
Amazing. Thanks for the color, everyone. Larry, thanks.

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

Adam Maeder
Hi, good evening. Thank you for taking the questions. I'll keep it to one. I wanted to ask about EVOQUE and, specifically, the NTAP that went into effect on October 1. I'm just wondering if you've seen any kind of noticeable impact to uptake in the past couple of weeks. How do you think about the impact of improved reimbursement, going forward?

And then the second part of the question is just on the 56-millimeter valve size, now that that's FDA approved, just curious how big of a patient population does that valve size serve? Thank you.

Daveen Chopra
No, I appreciate the question, Adam. So talking a little bit first about the NTAP and EVOQUE. Obviously, I think the incremental reimbursement obviously provides a tailwind to people wanting to use EVOQUE. There were some centers who were maybe holding off a little bit or taking a little bit more time to get the EVOQUE training curve leading up to NTAP, then they're waiting for NTAP to get on board.

But that being said, we're still just seeing such strong demand across the board from different centers to open up new centers that I think it provides a little bit catalyst, but we just have consistent demand from centers we haven't got a chance to open up yet, across the board. So that's probably mainly a comment on NTAP.

Specifically on the 56, we're excited with the 56 approval at that fourth size, now larger size on. We think from--we don't have perfect data, but based on what we've seen from previously screened patients, it maybe adds 20% or 25% applicability to the overall pool. So we're glad to have the size available for those patients who need it.

Adam Maeder
Thank you.

Operator
Thank you. And we have run out of time for questions at this point. So I will now hand the floor back to Bernard Zovighian for closing remarks. Thank you.

Bernard Zovighian
Yeah. No, thank you for your continued interest in Edwards. Scott, Mark, and myself welcome any additional questions by telephone. Thank you, everyone. And see you next week at TCT.

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