Edward's Lifesciences Corporation
Second Quarter 2024 Results
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Daveen Chopra, Global Leader of TMTT
Wayne Markowitz, Global Leader of Surgical Structural Heart
Katie Szyman, Global Leader of Critical Care

Q&A Participants
Larry Biegelsen – Wells Fargo
Robbie Marcus – J.P. Morgan
David Roman – Goldman Sachs
Joshua Jennings – TD Cowen
Travis Steed – Bank of America
Matt Taylor – Jefferies
Vijay Kumar – Evercore ISI
Patrick Wood – Morgan Stanley

Operator
Greetings, and welcome to the Edwards Lifesciences Second Quarter 2024 Results. At this time, all participants are in a listen-only mode. A brief question and answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press star, zero, on your telephone keypad. You may be placed in the question queue at any time by pressing star, one, on your telephone keypad. As a reminder, this conference is being recorded.

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

Mark Wilterding
Thank you very much, Kevin. Good afternoon and thank you all for joining us. With me on today's call is our CEO, Bernard Zovighian and our CFO, Scott Ullem. Also joining us for the Q&A portion of the call will be Larry Wood, our Global President of TAVR and Surgical Structural Heart; Daveen Chopra, our Global Leader of TMTT; Wayne Markowitz, our Global Leader of Surgical Structural Heart; and Katie Szyman, our Global Leader of Critical Care. Just after the close of regular trading, Edwards Lifesciences released second quarter 2024 financial results.

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

Please note that management will be making forward-looking statements that are based on estimates, assumptions and projections. These statements include, but are not limited to, financial guidance and expectations for growth opportunities, strategy, leverage and integration of acquisitions, regulatory approvals, clinical trials, litigation, reimbursement, competitive matters and foreign currency fluctuations. These statements speak only as of the date on which they are made, and Edwards does not undertake any obligation to update them after today.

Additionally, the statements involve risks and uncertainties that could cause actual results to differ materially. Information concerning factors that could cause these differences and important safety information can 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 the call are also included in the company's press release.

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

Bernard Zovighian
Thank you, Mark, and thank you all for joining us. This afternoon, we issued two press releases, which the team and I will review in more detail with you now. The first, outlining our Q2 results, and the second, highlighting our acquisition of JenaValve, a pioneer in the transcatheter treatment of aortic regurgitation, or AR. And Endotronix, a leader in heart failure management solutions.

I will start with our second quarter performance. Total company sales of $1.6 billion increased 8% on a constant currency basis versus the year ago period. In addition, we made important advancements in our clinical research, new product introductions (ph) and efforts by Edwards employees to address the unmet needs of many more patients around the world.

TAVR growth in the second quarter was lower than expected, yet we are pleased with the increasingly significant contribution from TMTT. Our vision for TMTT is becoming a reality and our strategic commitment has developed into a growth portfolio of differentiated technologies. Overall, Edwards remain well-positioned to deliver strong, sustainable growth.

We also announced this afternoon two acquisitions, JenaValve and Endotronix. We have known this company for many years. Discussions with the companies have been ongoing for some time and the timing of these acquisitions coincided with earnings. We are pleased to expand into two new structural heart therapeutic areas, AR and heart failure, and we will leverage our

innovation capabilities with world-class science and clinical evidence to ensure accelerated access to life-saving technologies for patients around the world.

Now, I will provide some additional detail on Q2 results by product group. In TAVR, second quarter global sales of $1.04 billion increased 6% year-over-year, lower than we planned. Edwards competitive position did not meaningfully change globally, although we experienced some regional pressure, and we maintain pricing. We are confident in our differentiated technology, high-quality evidence and the value we continue to demonstrate to patients, clinicians and the healthcare system. We remain focused on continuing our deep commitment to advancing evidence for AS patients.

At the New York Valves meeting in June, we presented additional analysis from the PARTNER trials, which demonstrated excellent clinical outcome up to five years in women and patient with small annuli. Adding to the global body of evidence on the platform, we also anticipate additional data from the RHEIA study to be presented at the upcoming ESC meeting in London. RHEIA is a prospective randomized study in more than 400 patients across 35 sites in Europe, comparing the safety and efficacy of TAVR versus surgery in women with severe symptomatic aortic stenosis.

We are actively pursuing significant opportunity to grow TAVR globally over the long-term and are proud to continue our deep commitment to advancing science for aortic stenosis patient through the progress and early TAVR trials, which could fundamentally change how AS patients are treated. Early TAVR trial results will be presented at TCT this year, and we believe if the data are compelling, it could have a meaningful impact on the timing for patient treatment, while also streamlining referral and patient care for all severe AS patients.

In the US, our year-over-year second quarter TAVR sales growth was slightly below our global constant currency growth rate. We believe our US competitive position was largely unchanged. Second quarter US TAVR sales grew slower than expected. The continued growth and expansion of structural heart therapies, including newly approved tricuspid therapies and other fast-growing structural heart therapies put pressure on hospital workflows, which impacted TAVR. These pressures were also observed in the recent spike in emergent TAVR cases, as reflected in claims data.

As centers adopt these new therapies and they become part of extended processes, we expect this will stabilize. We know from experience that hospital have historically demonstrated the ability to scale to support transcatheter procedure growth over time. We believe significant undertreatment of severe AS persists. Evidence demonstrates that a large number of in-system patients currently go untreated.

We are accelerating our efforts to improve referrals and treatment rates for patient already in the hospital system who are suffering from severe symptomatic aortic stenosis. We recently launched the Edwards ENACT patient activation program, which leverage a comprehensive

cardiovascular AI platform and world-class support to bring real-time insights to TAVR program and improve quality of care for patients. This first of its kind program is focused on streamlining the identification, evaluation and treatment of severe aortic stenosis patient within the hospital system.

Outside of the US, in the second quarter, our constant currency TAVR sales growth was slightly above our global TAVR growth. In Japan, we generated double-digit sales growth driven by SAPIEN 3 Ultra RESILIA. We continue to focus on expanding the ability of this therapy and believe AS remain a significant undertreated disease among the substantial elderly population in Japan. In Europe, while share is down slightly on an annualized basis, we were pleased with the momentum, driven by the launch of SAPIEN 3 Ultra RESILIA. We are pleased with high procedure success rate and exceptional patient outcome. We expect the momentum to continue to build as more centers have experience with the first-choice valve for lifetime management.

In closing, we now anticipate second half TAVR sales growth similar to the first half year-over-year growth rate, a 5% to 7% full-year growth rate versus previously guidance of 8% to 10%. This equate to full-year global TAVR sales of $4 billion to $4.2 billion. We believe hospitals are motivated to continue scaling to accommodate increasing volume of transcatheter procedures, which will bring tremendous value to patients and the healthcare system. We remain confident that Edwards is positioned for healthy and sustainable TAVR growth, driven by our differentiated TAVR portfolio, our deep commitment to advancing patient care for high-quality clinical evidence and new indications and our investment in patient activation initiative.

Turning to TMTT. Our deep structural heart expertise has enabled us to significantly advance our portfolio of differentiated technologies, including the PASCAL repair system, the EVOQUE tricuspid replacement system and the SAPIEN M3 mitral replacement system. Our exciting pipeline of innovations is addressing the large unmet needs for patients with mitral and tricuspid disease.

In Q2, we achieved positive results with sales of $83 million, representing a 75% increase versus the prior year. Q2 sales were led by PASCAL globally and early commercial introduction of EVOQUE in the US and Europe. PASCAL adoption is growing, reflecting its premium differentiation and the value it brings to physician and patients. We believe the mitral tier market continues to grow double-digit in both the US and Europe. We are excited to bring this therapy to more geographies, more physicians and more patients.

The EVOQUE commercial launch continue to progress well. Our disciplined strategy is focused on outstanding patient outcome in centers investing resources required to grow a successful tricuspid program. We are now opening new centers both in Europe and the US after having started with our clinical trial sites. We continue to see strong interest in the therapy, which reflects the significant unmet need in this population of patient who have few options for treatment.

Our early real-world commercial experience has demonstrated excellent clinical results. Consistent with those from the TRISCEND II trial. We look forward to presenting the full cohort of TRISCEND II data at the TCT Conference in October. Last month, CMS announced the opening of a national coverage analysis for transcatheter tricuspid valve replacement. Since EVOQUE was granted FDA breakthrough status and is utilizing the CMS parallel review process, we believe CMS can move quickly to finalize national coverage.

SAPIEN M3 remains on-track to be our first transcatheter mitral valve replacement therapy to gain regulatory approval and launch around the world. We are also pleased to have received a breakthrough designation from the FDA, and we completed enrollment in the mitral annulus classification or MAC arm of our ENCIRCLE study. We now expect SAPIEN M3 to receive CE Mark earlier than previously expected, by mid-2025, with FDA approval in the US to follow in 2026.

Earlier this month, we announced the acquisition of JenaValve. JenaValve early-stage technology will add to our growing pipeline of innovative therapy in TMTT and we expect to close the acquisition later this year. We further expect that JenaValve technology, combined with Edwards expertise in mitral disease, will enhance the company TMVR technologies to address large unmet structural heart (ph) patient needs and support sustainable long-term growth. Based on the first half 2024 momentum and the ongoing global adoption of our differentiated technology PASCAL and EVOQUE we are increasing full-year sales guidance for TMTT to the higher end of our previous $320 million to $340 million range.

We remain confident that our unique portfolio strategy, with repair and replacement therapies for both mitral and tricuspid disease will offer clinician the broader set of options needed to treat this complex and diverse patients. The advancement of our long-term TMTT strategy has positioned us for strong, sustainable growth over many years, driven by a growing portfolio of innovative therapies.

In surgical structural heart, second quarter sales of $264 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 have completed enrollment in the US and Canada for our momentous critical trial studying RESILIA performance and the mitral position. MITRIS adoption in Europe is ramping up, and we are pleased to have been granted reimbursement for the device in France earlier than expected.

In summary, we remain confident that our full-year 2024 surgical sales will be 6% to 8% driven by continued adoption of our RESILIA portfolio and growth in overall heart valve surgeries. In Critical Care, second quarter sales were $246 million, which increased 7% versus the prior year. Growth was led by a pressure monitoring devices using the ICU, with strong contribution from

our SMART recovery technologies, including the Acumen IQ sensor. Demand was also strong for Swan-Ganz catheter. Critical Care remains focused on driving growth through SMART recovery and SMART expansion, which are designed to help clinicians make more informed decision and get patients home to their family faster. Since announcing the sales of Critical Care to Becton Dickinson in June, our team has made significant progress, and we plan to close by late Q3. I want to thank all of them for their hard work and dedication.

Turning now to the strategic acquisition of JenaValve and Endotronix. These acquisitions provide an expanded opportunity in new therapeutic areas to address the unmet needs of AR and heart failure patients around the world. Furthermore, the acquisition reflects our deep commitment to advancing patient care through our unique strategy and reinforce our confidence in Edwards sustainable long-term growth. Starting with JenaValve, a pioneer in the transcatheter treatment of AR, a deadly disease that impacts more than 100,000 patients in the US alone and is largely untreated today.

Edwards anticipate US FDA approval of the JenaValve Trilogy Heart Valve System in late 2025, which will represent the first approved therapy for patient suffering from AR. Edwards will invest to accelerate development of this novel technology to enable earlier patient access. As the pioneers in valve innovation, we believe we are best positioned to lead this next frontier of aortic valve disease treatment. We expect this to be the beginning of a long-term iterative strategy similar to TAVR.

Turning to Endotronix. Edwards made its first investment in the company in 2016, so we are very familiar with the technology, the opportunity and the employees. Many structural heart patients Edwards serves today also suffer from heart failure, with limited options. This acquisition will expand Edwards structural heart portfolio into a new therapeutic area to address the large unmet needs of patients suffering from heart failure, which we believe has a significant long-term growth opportunity. Last month, Endotronix received FDA approval for Cordella (ph), an implantable preliminary artillery pressure sensor that directly measure the leading indicator of congestion following the publication of a successful US pivotal trial.

We are pleased to enter the structural heart therapeutic area with innovation, world-class science, and clinical evidence to provide access to life-saving technologies for patients around the world. We anticipate this investment will strengthen its leadership in structural heart innovation and represent long-term growth opportunity. Minimal revenue contribution from JenaValve and Endotronix is expected to begin late in 2025. As you can tell, we have a lot of positive momentum and many catalysts across our core businesses, TAVR, TMTT and Surgical combined with opportunities to reach new patient population.

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

Scott Ullem

Yeah. Thanks a lot, Bernard. (Inaudible) not satisfied with our quarter total company sales performance, where TAVR sales growth came in below our expectations. However, it's important to understand broader context. We were pleased that TMTT continues to outperform our expectations. And overall underlying sales growth, including Critical Care was nearly 8%, adjusted EPS was $0.70. GAAP earnings per share of $0.61 included one-time separation expenses related to the sale of Critical Care. A full reconciliation between our GAAP and adjusted earnings per share is included with today's release.

So, now I'll cover additional details of our P&L, which reflect total company results, including Critical Care. Note that Critical Care will be presented as a discontinued operation in the 10-Q we will file next week. As we noted in the press release, we'll provide Q4 2024 information reflecting the sale of Critical Care and the acquisitions announced this month when we report third quarter results.

For the second quarter, our adjusted gross profit margin was 77.1% compared to 77.7% in the same period last year. Last year's second quarter gross profit margin benefited from a more favorable impact from foreign exchange rates. We expect Edwards Q3 adjusted gross profit margin, including Critical Care, to be in line with Q2, driven by high-value technologies that yield strong gross profit margins.

Adjusted, selling, general and administrative expenses in the quarter were $509 million, or 31.2% of sales, compared to $469 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. Adjusted research and development expenses in the second quarter grew 12% over the prior year to $303 million or 18.6% of sales. This increase was primarily the result of continued investments in our transcatheter valve innovations, including increased clinical trial activity.

Turning to taxes. Our reported tax rate this quarter was 5.2% or adjusted 8.4%. Our unusually favorable non-GAAP rate in the second quarter reflects several positive one-time items that were recorded during the quarter. This unexpected favorability in our tax rate benefited earnings per share by $0.04 in the second quarter. Foreign exchange rates decreased second quarter adjusted sales growth by 120 basis points or $17.6 million compared to the prior year. FX rates negatively impacted our second quarter adjusted gross profit margin by 60 basis points compared to last year's second quarter.

Free cash flow for the second quarter was reduced $47 million for payments associated with special activities relating to the separation of Critical Care. Excluding the impact of these items, adjusted free cash flow was $333 million. First half adjusted free cash flow was $539 million. We expect to receive cash from the sale of Critical Care in the third quarter.

Turning to the balance sheet. We continue to maintain a strong and flexible balance sheet with approximately $2 million in cash, cash equivalents and short-term investments as of June 30th.

Now I'll finish this update with comments about our previously announced sale of Critical Care, as well as guidance relating to our acquisition announcements. We announced on June 3rd that Edwards entered into an agreement to sell Critical Care to BD, and we are planning to close the sale late in the third quarter. During the second quarter, we recorded $80 million of one-time costs associated with the sale. Additional one-time costs will be incurred throughout 2024.

We expect Q3 sales, including the assumption that we own Critical Care for the full quarter of $1.56 billion to $1.64 billion and Q3 earnings per share of $0.67 to $0.71. We do not expect the recently announced acquisitions to contribute to Edwards sales in 2024. We intend to provide fourth quarter guidance reflecting the sale of Critical Care and the acquisitions announced this month when third quarter results are reported in October. We will also provide 2025 guidance at our Investor Conference in New York on December 4.

In the meantime, I'll share a few early expectations for 2025. Next year we expect minimal revenue from acquisitions while we are planning on incremental operating expenses from these early-stage companies, partially offset by operational efficiencies we plan to realize following the sale of Critical Care. We do not expect increased operating efficiencies to completely offset the loss of profits from the sale of Critical Care in 2025, but we are planning healthy, long-term profit growth. In addition, we plan to maintain a strong balance sheet to support continued internal and external investments, as well as opportunistic share repurchase.

Most importantly, we are confident in the moves we have made to reshape our portfolio of technologies to focus specifically on structural heart. The sale of Critical Care provides extra management bandwidth, as well as additional liquidity to fund external growth investments. And at the same time, our original vision for TMTT is becoming a reality and the early-stage investments we made in companies like JenaValve and Endotronix position us to acquire high-quality and high potential businesses with talented employees.

We have other jewels in our portfolio of internal and external investments that will benefit Edwards in the years ahead. Over the long-term, we see an exciting future with expanded opportunities in large and growing market, which we believe will result in sustainable double-digit revenue and earnings per share growth.

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

Bernard Zovighian
Thank you, Scott. So let me share a few closing thoughts. In TAVR, we have significant opportunities, and we are committed to growing globally by advancing science over long-term. Progress and early TAVR trials could fundamentally change how AS patient are treated. In TMTT, our deep expertise has enabled us to significantly advance our exciting portfolio of innovation. And our long-term TMTT strategy has position us for strong, sustainable growth over many years.

In surgical structural heart, we continue to see strong global adoption of our premium surgical technologies. Our JenaValve and Endotronix acquisitions provide an expanded opportunity in new therapeutic areas. The buffer presents significant long-term opportunities. We remain 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. Our special (inaudible) increasingly recognize the significant benefit of transcatheter-based technology. We remain as optimistic as ever about the long-term growth opportunity.

With that, I will turn back to Mark.

Mark Wilterding
Thank you, 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 re-enter the queue and management will answer as many participants as possible during the remainder of the call.

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

Operator
Certainly. If you'd like to be placed in the question queue, please press star, one, on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, two, if you'd like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing star, one. One moment please while we poll for questions. And as a reminder, please ask one question and one follow up.

Our first question is coming from Larry Biegelsen from Wells Fargo. Your line is now live.

Larry Biegelsen
Hey, guys. Good afternoon. Thanks for taking the question. Two for me. Let me start with early TAVR, and then I had a follow up for Scott on 2025. So for early TAVR, what would be compelling to you? Do you need to show a mortality benefit to be more compelling? And how should we think about the impact on your TAVR growth? If the study is positive, do you expect it to accelerate the TAVR growth in 2025, above the 5% to 7% you expect this year? And I had one follow up.

Larry Wood
Sure. Hey, Larry. This is Larry. Thanks for your question. I think at a very high level there needs to be a compelling story for why early intervention is better and basically make the case against watchful waiting. And we've done a lot of work when we were powering the trial, and we obviously had a lot of belief in it. The primary endpoint is death, stroke and rehospitalization. And so, it's really the composite of all those. And winning that trial and obviously, the more you would win it by makes a more compelling case.

In terms of the individual components, we'll have to look at those. But when you think about it from the patient journey if they're waiting and bad things are happening to them while they're waiting, it's resulting in unplanned rehospitalization, or it's resulting in stroke, or it's resulting in mortality, all those are very meaningful things, and that's why they're all composites in the endpoint. So we'll have to wait and see the data, we'll have to see the story, but death, stroke and rehospitalization has kind of become almost a standard now for most of these trials because the clinical community believe these are all important considerations and endpoints.

Bernard Zovighian
Maybe let me add something to what Larry said. For sure, asymptomatic is very important to us and to the community and to patients. But it is one thing of one of the many things we are doing, and we are confident in growing this TAVR opportunity. So asymptomatic is one. Patient activation, we see some impact already, but also moderate. So if you think about over the next few years, we see many catalysts. It is why we are confident in this TAVR opportunity. Granted, we know that Q2 was lower than expected, and I guess we are going to talk about it, but in front of us, we see that this opportunity as a big one, like we saw it few years ago, still we see it, still we are confident, and we are doing all the things to realize this opportunity.

Larry Biegelsen
That's helpful. And Scott, thanks for the initial color on 2025. I'm sure you know that's important to everyone on this call right now, to try as best as we can to model that. So a couple of pieces, follow ups on that. The press release says strong sustainable growth. It doesn't say 10% operational growth for the remaining business in 2025. I just want to confirm that that 10% from the analyst meeting last year in December, you're not reiterating that today.

And second, on the dilution, I think most of us estimate about $0.40 of dilution from Critical Care spin. Any reaction to that? And the incremental spending you talked about from the acquisitions, any additional color on that? And just lastly, the use of the proceeds, should we just assume share buyback or additional M&A? Thank you.

Scott Ullem
All right. Well, it's a multi-part follow up question. Let me try to hit a couple of the things you asked about, Larry. First of all, on the 10% long-term top line growth, we're just not commenting on guidance at this point, it doesn't mean we're increasing it or decreasing it or changing it. It's just the kind of thing where we don't update that during the course of the year, so we're not providing an update today. We will definitely provide an update as we always do at our December investor conference.

For dilution from Critical Care, yeah, a lot of this depends upon how we end up prioritizing investments in the company as we separate Critical Care. And as you can imagine, there are a lot of different moving pieces as we do that. So we're not going to be able to give you a specific figure on, I'll call it, remain co ex-Critical Care at this point. And it does tie to your question

about incremental operating expenses that we're absorbing with these acquisitions, and those depend upon a couple of things. One is when we actually close the acquisitions and start to realize that spending. Two, how we end up integrating them inside of Edwards. And as you can imagine, we just announced them today, so those plans are not completely developed.

Finally, in terms of use of proceeds from Critical Care. Yeah, as you know ,we're always interested in buying back stock. We're always looking for buying opportunities. But the first call on cash hasn't changed one bit, which is we're going to continue to invest in the company. We're going to continue to invest in the capacity that we need to support the growth of the company. We'll certainly be looking at other external investments. And then finally, we'll look at allocating capital to share buyback. So there's a little bit of color and we'll obviously give you a lot more as we get towards the end of the year.

Larry Biegelsen
Thank you so much. Yes, please.

Bernard Zovighian
Maybe (inaudible) Larry here, on the guidance. I agree with what Scott said about we are not planning to communicate the guidance on 2025. But if you look at the quarter, TAVR grew about 6%, the company about 8%. So you see a big contribution from TMTT, and we see that contribution to get bigger as we go. Because right now we are just at the beginning of PASCAL expansion. Just at the beginning of the EVOQUE expansion we have M3 coming. In TAVR, we have asymptomatic end of the year. So are we confident about sustainable growth over the long-term, yes. We are going to talk about guidance in December.

Larry Biegelsen
Thank you.

Operator
Thank you. Next question Today is coming from Robbie Marcus from J.P. Morgan. Your line is now live.

Robbie Marcus
Oh, great. Thanks for taking the question. Two from me. Maybe first, you talked about it in the script, but I was hoping you could give a little more, TAVR has clearly come in below your initial expectations for the year. The guidance has moved down. The US is slowing. OUS is facing pressure. We saw two of your smaller competitors, but still competitors, see pretty nice growth sequentially and year-over-year, so their TAVR is taking more in Europe and outside the US, Japan. How are you thinking just about the underlying growth rate of the TAVR market? And I appreciate it's a huge opportunity and it's still a lot to conquer in the future, but in, let's call it the short to medium term, how are you thinking about the overall market growth? And is there anything you can do to help accelerate it?

Larry Wood
Yeah. Thanks, Robbie. Well, obviously, we expected growth rate to be higher in Q2 than it was. We had a slow start in Q1, but we were exiting March and we felt good about where we were. So this did come as a surprise. I think when we reflect back on it, and we look more deeply at it, you have to think about all the things that have shown up that are going to the same structural heart team at all of these hospitals.

We're seeing rapid growth in mitral repair. We're seeing a lot of growth in other procedures, and we had two new therapy approvals recently in the tricuspid space. And I think a little bit we looked at the procedure volumes and the hospitals have shown a pretty good job of being able to handle these things. We probably underestimated the burden of even starting these new programs, even preparing to start these new programs, because you have to screen the patients early on. There's a lot of learning, screen failures, all of those things, and I think it's just tasking the teams.

Now, in terms of things we can do to help, there are certainly things we can do to help. We can do a lot of imaging workups and take some of the load off the team. We can do device prep. We can come in with our benchmark program and teach them efficiencies and do those things. But once a program has been optimized, that it really does come down to the hospital to add another team or add additional bays and do those sorts of things. So there are some things we can do, but we can't do everything.

I think the other thing is, I think highlighting this for the clinicians and we're very confident, this isn't some slowdown because there's a lack of patients. We didn't see any of the fundamentals change in terms of new data that was concerning or any of these things. I think it's just a matter of the workflow right now. And we need to be able to engage with hospitals, but two important things we saw, is we saw an increase in time from CT to procedure, which indicates patients are waiting longer. And the other thing that we saw was a sharp increase in the number of cases being coded as emergent versus routine, and I think that speaks to these patients waiting in the queue as these workflow issues sort out. So I think hospitals will certainly do that in time. These patients don't wait well, and we know that there's a lot of them, but we're going to have to continue to work through that with the hospitals.

Bernard Zovighian
Yeah. So let me add on what Larry said. To be fair, we are contributing a little bit on this pressure. At the same time, we are benefiting if you look at the TMTT growth in the quarter. So we are contributing and benefiting at the same time. Now, big picture. We have seen this picture in the past. Don't you think? We have seen hospital facing more to do, more technology to adopt, to be trying on new technologies, and we are very good at scaling. We are very good at learning. We are very good at adapting their workflows in the cath lab, so we believe it is temporary. And we are also in it with this team, with Larry partnering on this one, so we are fully focusing on this one, helping every hospital. But we have faith the hospital are going to do that, like they did it in the last 10 years.

Larry Wood
Thanks.

Robbie Marcus
Great. And maybe a follow-up to that. Guidance implies roughly stable TAVR first half into second half. I appreciate the need to be conservative, but it sounds like some of the learnings you saw in second quarter could possibly help in the back half of the year. Maybe just walk through the thought process of the 5% to 7% TAVR guide and kind of what you're baking into that? Thanks a lot.

Scott Ullem
Yeah. I mean, it's pretty straightforward which is we're baking into it similar market conditions. The year-over-year calculation is pretty similar. Fourth quarter comp gets a little bit tougher, but we think that all things considered, that 5% of the low end, 7% on the high end captures the likely scenario for the second half combined with the first half that we've already reported.

Robbie Marcus
Thanks.

Bernard Zovighian
We believe, to add on that one, we believe early TAVR, TCT, it will be already almost the end of a quarter, Robbie. So TCT is in late October, so we believe it will have a very minimal impact in Q4, so it is why we didn't want to take too much risk here.

Operator
Thank you. Next question today is coming from David Roman from Goldman Sachs. Your line is now live.

David Roman
Thank you, and good afternoon. I wanted just to come back actually on some of Larry's comments there regarding, and maybe you're characterizing it as capacity. And as you think about the myriad of therapies going into structural heart right now, whether that is some of the new valve therapies, whether it's Watchman, to what extent do you think hostile economics factor into the decision and prioritization making here and how does that, if it does in any way, impact your kind of pricing decision around TAVR or EVOQUE?

Larry Wood
Yeah. It's a good question, and I'll defer to Daveen on EVOQUE, but I'll start with the TAVR side of it. It doesn't really change the pricing, and we don't think this is an economically driven thing. I think when new therapies come forward, hospitals are competitive. They want to be able to offer all of the therapies, and that means they want to aggressively start these new programs

and make sure that they can offer all of the options for their patients. And so, I think that's what's driving some of this more than other things.

Larry Wood
And I think all companies before they're willing to bring a new technology in, the center has to demonstrate competence, right? They have to demonstrate they have the ability to screen. They have to have patients in queue and all those things. And I think it becomes a big thing, but I don't think this is an economically driven thing. I think it is just the result of all the new things that are coming into the cath lab. And again, I think that does get corrected with time.

Daveen Chopra
Yeah. This is Daveen. I'll just jump in for a second here. So we're seeing as we bring in new therapy like EVOQUE, right, while procedure times are relatively efficient, and they are, they're an hour-long procedures. It takes up a lot of energy, effort, thoughts, processes to start a new therapy, right? It takes a lot of bandwidth for people in terms of trying to find the patients. Where are the referrals coming from? How does it kind of work through the system? How we pre-case plan? And these are often the same groups of people, valve clinic coordinators, interventional cardiologists, etc., that are working on TAVR.

So as you bring in just a new therapy and start building it up, it takes a while, a lot of bandwidth and a lot of energy to get it going. But then over time, like we've seen for every other therapy, you create efficiency. It gets faster. And we're going to help them do that, but hospitals then figure out, OK, now this is how the therapy is going to work its way through the system, and it becomes more efficient and becomes better so that there is more capacity to do more procedures overall.

David Roman
That's very helpful. And maybe just a related follow-up to that. Can you maybe unpack the $83 million in the TMTT line for us in a little bit more detail? It sounds like minimal EVOQUE contribution with PASCAL accelerating. But maybe if you could sort of delineate a little bit the different product drivers within there, and then maybe some of the different geographic drivers? And then maybe if I could sneak a follow-up into the response there, how long do you think, Larry, it takes to dislodge the sort of capacity constrain or sort of that digestion of multiple therapies going through the systems?

Daveen Chopra
No, this is Daveen. I'll start off a little bit with TMTT. I mean, first, just at a higher level. We were actually super excited to see that in quarter two, our vision becoming more and more reality. We've made a strategic commitment that we need a portfolio of repair and replacement technologies for the many different mitral and tricuspid patients, and it was nice to see that step forward in Q2. Also, when you break it down on the level, Q2 sales were led by PASCAL, right? PASCAL is a larger pool. It continues to grow in adoption. We believe in this differentiated premium technology, and it was our largest growth driver.

Daveen Chopra
We also did see the early commercial introduction in the US and Europe of EVOQUE, right? EVOQUE got approved in Europe late last year, in the US earlier this year, so we're beginning that important process of training centers, getting up to speed, beginning to train our own internal people and start that kind of case cadence.

So those were kind of the two. And in terms of size and scale, just because in Europe we've been in Europe since 2019 now that's a much larger base. Since when you have a larger base, you have kind of a stronger growth coming off that, but the US is growing up quickly now and we're continuing to expand our technologies around the world beyond just the US and Europe.

Larry Wood
Yeah. And just to follow up, how long does it take to dislodge? It's hard for us to be exact, and I think we try to account for that in our guidance, that it's not a light switch. But the best analogy I can say is when we brought TAVR into all these hospitals, we heard repeatedly that there was impact on coronary procedures and other things that were going on in the cath lab, and we were kind of taking up a little bit of that mind share, and a little bit of that workflow space, but it wasn't sustainable. You can't just park your coronary patients forever and you can't park AS patients forever. So I think once centers have certainty of the added workload and certainty of the volume, I think they add the resource, and they do the things necessary, but nobody's going to go hire a bunch of people in advance as the new therapy show up. They always are kind of recovering as the workload gets high, and I think to a degree that's just how hospital systems operate.

Bernard Zovighian
Yeah. We are confident by experience that the hospital are going to learn fast, adjust their workflow, their processes. And it is why we are saying it is temporary. Obviously, these patients when they stay home, they have a terrible quality of life, and many of them are dying. So I don't believe it is sustainable, and everybody is committed. The hospital are committed. We are committed. So when you have a full commitment behind it, we know it is going to be resolved.

David Roman
Got it. Thank you for taking the questions.

Operator
Thank you. Next question today is coming from Josh Jennings from TD Cowen. Your line is now live.

Joshua Jennings
Hi. Good afternoon. Thanks for taking the questions. Wanted to just start off with the TAVR outlook and kind of longer-term. You guys have put a $10 billion kind of TAM forecast by 2028 in the past. Should we eventually still be thinking about that TAM opportunity being in place,

but maybe pushed out a little bit, or maybe the aortic regurgitation indication gets you there by 2028? I know you may not be reiterating today, but it sounds like you're confident in the TAVR market in that $10 billion TAM, but not sure if you're reiterating it now.

Bernard Zovighian
Yeah. I think you said it in your question. We are confident. We are not updating the guidance for next year or for 2028 here on the market, but we are confident. We will do so in December at the investor conference in New York. Thank you.

Operator
Thank you. Next question is coming from Travis Steed from Bank of America. Your line is now live.

Travis Steed
Hey. Thanks for taking the question. I wanted to go back and circle back on Robbie's question on TAVR. It feels like there's a little bit more of a change here. Just three months ago, you thought TAVR was going to accelerate over the course of the year. I thought the 8% to 10% at the beginning of the year was supposed to be a conservative guide. So just want to understand, I hear what you're saying on TMTT, but that's a small number of faction versus the overall TAVR centers. So I don't know if there's anything else that you'd kind of call out or kind of what surprised you on the TAVR line. I know there was some of the European stuff and competition there that you called out last quarter, just understanding kind of the full change and why you got the initial TAVR guide wrong at the start of this year.

Larry Wood
Yeah. Thanks, Travis. Yeah. When we exited Q1, we thought we were on a good ramp, and we thought we were on a good pace, and that's why reiterated guidance and we felt good about it, and we just didn't see that play out in Q2 the way that we anticipated. And by no means do I mean to say this is all Daveen's fault and it's all EVOQUE because that's not accurate or fair when you look at the number of procedures. I think it's the cumulative impact of all the things that have hit the structural heart teams over the last year.

And it's one of those things, you can always increase a little capacity, work a little harder, increase a little capacity, work a little bit harder, but then at some point, you reach a breakpoint when it's simply too much. And the heaviest lift for centers is starting a program and it's not just the procedure volume. It's all that screening and all of the case reviews and all the interaction that just consumes a lot of resources and a lot of time. And the training, they have to go to training and observe cases, in many cases, and all of those sorts of things. And so, I think it's just the cumulative impact of those things that happen over time.

And we did see the slowdown more acutely in large centers and small centers, which fits a little bit of the model as well in terms of the centers that are most likely to be looking to start these new programs and are competitive about that. And again, I said it earlier, but we did see a spike

in emerging cases over routine cases, and I think that fits what we're saying as well, but that's not going to be sustainable for people. Emerging cases have more complications. They don't have as good a patient outcomes and people will have longer lengths of stay and that's going to adversely impact patients and the hospitals themselves. So I think people will have to adjust it over time and we're going to have to work closely with them to help them do that.

Travis Steed
All right. That's helpful. Any color on Q3 TAVR and kind of where that's settling out versus the full-year guide? I think you guys had extra selling days in Q3. And then on the dilution from the acquisitions, I know there's a range of outcomes. We all have a pretty good sense of Critical Care and the dilution there, but just to give a sense of kind of range of outcomes on some of the (inaudible) dilutions that you've got. I was thinking. $0.10 is kind of ballpark, but I don't know if you'd react to that at all?

Scott Ullem
Yeah. Thanks for the question, Travis. In Q3, you're right, we do have a little help from extra selling days in the third quarter. And that's factored into our guidance. It's in the guide that we provided. In terms of dilution from acquisitions, again, we've got to first close the acquisitions, then work on integrating them. Obviously, we spent a lot of time with the plan, but it takes some time before we actually get businesses inhouse and start recording what kind of financial implications there are before we can report out on those. We'll know a lot more by the end of next quarter when we've actually gotten further down the path, and we'll talk about it then. And of course, we'll give full guidance for EPS in 2025 at our investor conference.

Travis Steed
All right. Great. Thanks a lot.

Operator
Thank you. Next question today is coming from Matt Taylor from Jefferies. Your line is now live.

Matt Taylor
Hi. Thanks for taking the question. I guess I wanted to follow up on some of your US TAVR commentary and the workflow angle, because I'd like to understand better why you think it's showing up so acutely now, I guess, given you're still in a limited rollout of EVOQUE. Is this an issue that's been matriculating for a while and we're just seeing it more now? And could you help us understand your history there? You talked about the impact on coronaries. How long do you think it'll take for the hospital to adjust? Is this a one quarter or a three-quarter issue? Does it take years? What kind of time frame would you put on them adjusting to accommodate the additional workflows?

Larry Wood
Yeah. Thanks, Matt. The thing that I would say is, I guess if I were to draw an analogy, if you had a factory and you saw demand for your product going up, you can always add a little more

hours and you always have a little bit of excess capacity, and you can adjust to those things. I think there is just a point in time where you hit a wall, and it's harder to do those things, and I think that's a little bit of what we saw here. It's the cumulative effect of all of these things that have played out over time. If you look at total cath lab procedures for the structural heart team in the last three years, it's probably close to double during that period of time, which is a lot of growth that these teams are having to absorb and they're having to adapt to, and I think it will take time.

And again, when you're starting these new programs, these new therapies, that's the heaviest lift part of it. And again, I think this gets corrected over time, and we'll work closely with the hospitals to do that. But we reflected that in our guidance and just wanted to be realistic and not be tone deaf to what's happened. But the same thing I'll tell you, is none of us are happy with the growth rate. None of us are happy adjusting guidance and we're going to be working as hard as we can, to do everything we can to restore the growth to where we think it should be.

Bernard Zovighian
And we are not happy as a company, the patients are not happy, the physician are not happy, the hospital are not happy, so we are fully aligned about it is a problem, we need to solve it. So it is why also we are confident here.

Matt Taylor
Thank you.

Operator
Thank you. Next question today is coming from Vijay Kumar from Evercore ISI. Your line is now live.

Vijay Kumar
Hey, guys. Thanks for taking my questions. I guess one on, just based on what competition is saying, I know there's been noise on small and light (ph) trial. How do you respond to, this is not competitive dynamics what we're seeing in the US market?

Larry Wood
Sure. Yeah. We presented our data at New York Valve, and I don't think we've seen the impact of that in any meaningful way. I know some of the smaller competitors have reported, but you have to take their growth rates in consideration of the base they're growing off of versus the base that we're growing off of globally.

Vijay Kumar
Understood. And maybe Scott, one for you on the guidance here, EPS. I think prior guidance $2.70 to $2.80 inclusive of Critical Care, right? Is that still intact or what's the new range? I just want to get an apples-to-apples sort of EPS baseline.

Scott Ullem
Yeah. It's a fair question. We are not providing a new update. And the reason is because we know Critical Care is going to close sometime late in the third quarter. But as a result, fourth quarter will not include Critical Care. And so, obviously, looked at a whole bunch of different pro forma scenarios, but it didn't make sense to try to provide some kind of a bridge to the original $2.70 to $2.80 guidance. So sorry, but we've not giving an updated number for the full company just because it wouldn't be comparable with Critical Care coming out at the end of the third quarter.

Vijay Kumar
Or is there a comparable without Critical Care for the full-year, what the underlying number is?

Scott Ullem
Well, the underlying number is actually pretty similar in terms of growth rate with and without Critical Care. Our guidance for the full company is 8% to 10% underlying growth. That's similar, whether it includes Critical Care for the full year or excludes Critical Care for the full year, but we have not translated that down to EPS, with or without.

Vijay Kumar
Understood. Thanks, guys.

Operator
Thank you. Next question is coming from Patrick Wood from Morgan Stanley. Your line is now live.

Patrick Wood
Fabulous. Thank you so much. Just two quick ones. I guess, on the EVOQUE side and the initial rollout on the clinical feedback and success that you guys have had, how's that been going? There's been a little bit of volatility in the more database, so I'm just curious how the clinician feedback has been.

Daveen Chopra
Hey. Thanks so much, Patrick. This is Daveen. Overall, if you pull back, we've actually been very pleased with the initial rollout of EVOQUE in both the US and Europe. We continue to see really strong physician demand and it really, for us, reinforces the unmet need of these patient group who are looking for better solutions. As I mentioned earlier, we're seeing those predictable outcome times. We're seeing it similar to the clinical trials. And (inaudible), we're seeing very similar clinical results to what we saw in the clinical trials, specifically from TRISCEND II. So we've been seeing very similar rates there of kind of clinical outcomes. We've seen so far on the journey, especially in Europe now, where PASCAL is actually approved for EVOQUE, we see that--it reinforces the need for both the repair and the replacement technology to really treat

the maximum number of EVOQUE patients. So overall, we continue to be very excited and happy with where the EVOQUE launch is going.

Patrick Wood
Very helpful. And then maybe just quickly on Endotronix. I was with Harry and Ariel at THT, and like the conical data on their side looks very interesting. How do you see this fitting into the business overall? Because my understanding was that probably this would be initially used for fine-tuning medication management, right? Is this more about building the rolodex patients, so that you know them a little bit better further downstream when it comes to a trans catheter approach? How do you see it strategically fitting in? Thanks.

Bernard Zovighian
No, no, thanks for the question. So let me start big picture with first we have a patient. We decided to get into this field because we see very largely the patient population it needs. Heart failure is one of, if not the largest driver of healthcare spending in the US. We have (inaudible) company for a long time. We were an investor in the company. We believe that they have very unique technology, differentiated technology. As a matter of fact, they received a broad label from FDA last month. There is an NCD ongoing right now, so we see that as a big opportunity, a natural progression for us.

If you're asking about a very clear strategy about what we are going to do, where we are going to start, all of this, it is a little bit early. Again, we expect to close the transaction in the third quarter, correct, Scott, here? And in December, we will have a full deep dive on the strategy for Endotronix. We believe that many of these patients, heart failure patient are patient we are serving and treating today with our valve technologies, so it is in our space. So we are super-excited about it. We see this one as a great opportunity, a great long-term opportunity to expand our reach as a company.

Patrick Wood
Thank you.

Operator
Thank you. We reached end of our question and answer session. I'd like to turn the floor back over to Bernard for any further closing comments.

Bernard Zovighian
Thank you, everyone, for your continued interest in Edwards. Scott, Mark, (inaudible) and I welcome any additional question by telephone. Thank you so much. Have a great rest of your day.

Operator
Thank you. That does conclude today' teleconference and webcast. You may disconnect your line at this time and have a wonderful day. We thank you for your participation today.