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Edwards Lifesciences Corporation (EW) CEO Mike Mussallem on Q3 2019 Results - Earnings Call Transcript

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Q3: 10-23-19 Earnings Summary

Press Release *10-Q*

EPS of $1.41 beats by $0.19 | Revenue of $1.09B (18.78% Y/Y) beats by $58.3M

Earning Call Audio

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00:00 -57:07

Edwards Lifesciences Corporation (NYSE:EW) Q3 2019 Earnings Conference Call

October 23, 2019 5:00 PM ET

Company Participants

Mark Wilterding - Vice President, Investor Relations

Mike Mussallem - Chairman and Chief Executive Officer

Scott Ullem - Chief Financial Officer

Conference Call Participants

Bob Hopkins - Bank of America

David Lewis - Morgan Stanley

Larry Biegelsen - Wells Fargo

Vijay Kumar - Evercore ISI

Robbie Marcus - JPMorgan

Matt Taylor - UBS

Jason Mills - Canaccord Genuity

Raj Denhoy - Jefferies

Matt Miksic - Credit Suisse

Rick Wise - Stifel

Chris Pasquale - Guggenheim

Josh Jennings - Cowen & Company

Pito Chickering - Deutsche Bank

Jayson Bedford - Raymond James

Adam Maeder - Piper Jaffray

Operator

Greetings and welcome to the Edwards Lifesciences Third Quarter 2019 Results Call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. [Operator Instructions] As a reminder, this conference is being recorded.

I would now like to turn the conference over to our host, Mark Wilterding, Vice President of Investor Relations. Thank you. You may begin.

Mark Wilterding

Thanks, Diego and thank you all for joining us. With me on today's call are Mike Mussallem, Chairman and Chief Executive Officer; and Scott Ullem, Chief Financial Officer. Just after the close of regular trading, Edwards Lifesciences released its third

quarter 2019 financial results. During today's call, management will discuss the results included in the press release and accompanied 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 aren't limited to financial guidance and expectations for longer-term growth opportunities, regulatory approvals, clinical trials, litigation, reimbursement, competitive matters and foreign currency fluctuations.

These statements speak only as of the date on which they 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 product safety information may be found in the press release, our 2018 Annual Report on Form 10-K and Edwards' other SEC filings, all of which are available on the company's website at edwards.com.

Finally, a quick reminder that when using terms underlying and adjusted, management is referring to non-GAAP financial measures, otherwise they are referring to GAAP results. Reconciliations between GAAP and non-GAAP numbers mentioned during the call are included in today's press release.

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

Mike Mussallem

Thanks Mark. We're very pleased to report strong third quarter results, which reflected a large increase in the number of patients who were treated with transcatheter heart valve therapy.

Our sales growth this quarter was significantly higher than we expected. Sales grew in the double digits in all regions globally and increased 19% on an underlying basis to $1.1 billion led by transcatheter aortic valve replacement.

We're also pleased to report growing investments in new therapies and clear progress in numerous clinical trials that we believe will have meaningful future impact. More importantly, even more patients are benefiting from our lifesaving technologies than ever before.

In TAVR, third quarter global sales were $700 million, up 27% on an underlying basis. Growth was led by continued strong therapy adoption across all geographies with notable strength in the U.S. We estimate global TAVR procedure growth was comparable with our growth in the mid-20% range. Globally our average selling price remains stable as we continue to exercise pricing discipline.

In the U.S., we estimated total TAVR procedures grew around 30% on a year-over-year basis and that Edwards' growth was comparable. Stronger than expected growth was driven by an unexpected bolus of TAVR treatments following the strong PARTNER 3 evidence that led to the recent FDA indication expansion for our SAPIEN 3 and SAPIEN 3 Ultra systems. This approval represents a significant milestone, which allows all patients diagnosed with severe AS to be considered for TAVR based on their individual needs and anatomical considerations versus traditional risk warning.

Growth this quarter was broad-based across the U.S. Outside the U.S. in the third quarter we estimated total TAVR procedures grew just over 20% on a year-over-year basis and Edwards' growth was comparable. We continue to be encouraged by the strong international adoption of TAVR particularly where overall therapy penetration is still very low.

In Europe, Edwards' growth was in the teens and we estimate that our competitive position was stable. Although transcatheter valves have been commercially available for over a decade in Europe, it's encouraging to note that demand remains strong.

Outside the U.S. and Europe, we continue to see strong TAVR adoption driven by SAPIEN 3. Sales growth in Japan and other regions was very strong as aortic stenosis remains an immensely undertreated disease, and we remain focused on increasing the availability of TAVR therapy.

As we've discussed, we remain pleased with the SAPIEN 3 Ultra valve's performance and clinician feedback continues to be very positive. The valve offers the modified outer skirt which includes a proprietary material designed to further reduce paravalvular leaks.

We decided to accelerate the previously announced migration to the proven SAPIEN 3 delivery system, and at the same time are finalizing improvements of our Ulta delivery system.

The updated rollout plan is expected to ramp over the next several quarters. As such, we now believe that SAPIEN 3 Ultra will account for most of our TAVR sales in U.S. and Europe in 2020. This updated plan contributed to a charge to this quarter. I'm pleased to provide an update to our early TAVR clinical trial, which is now approximately half enrolled.

Recall that this is a large first-of-a-kind trial focused on indication expansion for patients suffering from severe AS, who haven't yet reported symptoms. Enrollment continues at nearly 65 sites throughout the U.S. and we now anticipate completion in 2021 versus our initial expectation of 2020. We continue to believe that Early TAVR has the potential to change the way that clinicians approach and manage AS patients to prevent irreversible damage.

Finally, as you heard at last month's TCT, clinical trial results were presented demonstrating early and sustained quality-of-life advantages for severe AS patients at low surgical risk treated with SAPIEN 3. Taken together with the clinical superiority demonstrated in the PARTNER 3 trial these quality-of-life findings further support the use of TAVR in these patients.

In summary, given the strength of our year-to-date performance, we're raising our full year TAVR guidance. We now expect underlying growth of nearly 20% versus our previous expectation of around 15%.

In addition, while still early in the 2020 forecasting process and difficult to predict, we are modeling a return to low-double-digit growth TAVR procedures globally next year. This is consistent with our estimate of a $7 billion opportunity in 2024.

Based on the trend of our 2019 results, it's likely that in 2020 we will report slower second half growth given the higher year-over-year comparisons. We are encouraged that the TAVR opportunity remains robust and believe that our continuing innovations will sustain our strong global position.

In transcatheter mitral tricuspid therapies or TMTT, we made important progress in the third quarter in advancing our portfolio of technologies to bring meaningful solutions to underserved mitral and tricuspid patients with few options today.

In the third quarter, global revenue was $10 million. The bulk of this was commercial sales of PASCAL in Europe. We are pleased with the disciplined rollout of PASCAL focusing on physician training, procedural success and patient outcomes. While we continue to receive positive physician feedback on this differentiated therapy, our premium-price strategy was a contributor to the slightly lower than expected revenue.

And now I'll give you a brief recap of select developments. In mitral valve repair, we continue to enroll our CLASP IID U.S. pivotal trial to study PASCAL in primary or degenerative mitral valve disease.

We have also initiated enrollment on our CLASP IIF pivotal trial for patients with secondary or functional mitral valve disease. In line with our commitment to build a strong body of clinical evidence, we recently presented positive one-year results in 30 patients from our European CLASP study at TCT.

We were especially encouraged by the low rate of cardiovascular mortality and heart failure hospitalization as well as an impressive substantial and sustained reduction in mitral regurgitation. Patients also experienced clinically and statistically significant improvements in functional status, exercise capability and quality of life.

In mitral valve replacement, we're pleased with the ongoing early feasibility study experience with both EVOQUE and SAPIEN M3 transseptal therapies and we remain on track to initiate a U.S. pivotal trial of SAPIEN M3 before the end of the year. Data highlighting the latest clinical experience with these platforms were presented at TCT demonstrating feasibility, an acceptable safety profile and a significant MR reduction with both therapies.

Turning to transcatheter tricuspid repair, in the second quarter we made the decision to accelerate a PASCAL tricuspid pivotal trial by the end of this year. We were pleased that in September, we received FDA approval for our Class II TR pivotal trial to study PASCAL in patients with symptomatic severe tricuspid regurgitation. We plan to start activating sites by the end of the year.

At TCT, we highlighted the latest data from our Cardioband tricuspid early feasibility study demonstrating acceptable safety and performance with significant TR reduction at 30 days.

In summary for full year 2019 Edwards now expects TMTT revenue to be below $40 million as the company continues a disciplined introduction and premium pricing strategy which is moderating site activation.

In addition, while still early in the 2020 forecasting process, our plan anticipates doubling 2019 TMTT sales in 2020. We remain on-track to achieve our ambitious 2019 clinical milestones which include continued enrollment in our CLASP pivotal trials as well as initiating the SAPIEN 3 pivotal trial -- the SAPIEN M3 pivotal trial by the end of the year.

We continue to estimate the global TMTT opportunity to reach approximately $3 billion by 2024 and our passion about bringing a portfolio of solutions for patients in need.

In Surgical Structural Heart, sales for the third quarter of $204 million increased 3% on an underlying basis. Our growth was driven by continued adoption of our premium high-value technologies and strength outside the U.S. This was partially offset by lower surgical aortic valve procedures in the U.S. as TAVR adoption expanded.

We remain very encouraged with the steady adoption of INSPIRIS RESILIA tissue valves. In the third quarter, valve utilization grew in all regions driven by increased demand among younger and more active patients. INSPIRIS is becoming the surgical valve standard of care in many geographies around the world.

Separately we continue to expect European regulatory approval for our HARPOON beating heart mitral valve repair system around the end of the year. HARPOON offers the potential for earlier treatment of degenerative mitral valve disease and faster recovery at

more consistent outcomes for surgical patients.

In summary although the superiority results of PARTNER 3 in the recent indication expansion for TAVR are expected to provide an incremental headwind to our aortic surgical sales, we continue to expect full year underlying sales growth of 1% to 3% based on our year-to-date results.

We remain excited about our ability to provide innovative surgical treatment options for more patients and to extend our global leadership in premium Surgical Structural Heart technologies.

In Critical Care sales for the quarter were $180 million and grew 7% on an underlying basis. Our product lines and geographies contributed to this performance with strong growth boosted by HemoSphere, our all-in-one monitoring platform.

We received FDA clearance in the third quarter to use FORE-SIGHT a cerebral oximetry technology from the CASMED acquisition on HemoSphere. The integration of our full range of technologies at HemoSphere will create a unique offering of enhanced recovery tools and predictive analytics capabilities to further strengthen our leadership in smart monitoring.

In summary, given the sustained growth through the first three quarters of the year and the expected momentum from the fully integrated HemoSphere platform in the fourth quarter, we continue to expect full year 2019 underlying sales growth of 8% to 10%.

And now I'll turn the call over to Scott.

Scott Ullem

Thank you, Mike. We continued our impressive top line performance this quarter with underlying sales growth of 19% reflecting global strength across all regions. Particularly strong was our 27% underlying growth in TAVR, which benefited from the recent clinical evidence supporting our SAPIEN 3 therapy.

Growth in the quarter was aided by onetime items contributing approximately 200 basis points to growth, largely related to the increased number of billing days versus prior year and forward buying ahead of the consumption tax change in Japan.

Our adjusted earnings per share in the third quarter of $1.41 grew 32% over the prior year driven by our notable sales performance. We achieved this growth while maintaining our significant investments in research and development, primarily on our transcatheter structural heart programs.

During the third quarter, we recorded an additional $27 million charge primarily inventory related to the last quarter's strategic decisions regarding our transcatheter aortic valve portfolio. This charge combined with other normal recurring adjustments reduced our third quarter GAAP earnings per share to $1.30.

Including the second quarter charge, the 2019 impact of the discontinuation of CENTERA and revised Ultra rollout plan is $73 million. A full reconciliation between our GAAP and adjusted earnings per share is included with today's release.

I'll now cover the details of our third quarter results and then discuss guidance for 2019. For the quarter, our adjusted gross profit margin was 75.9% compared to 75.5% in the same period last year. This improvement was driven primarily by the favorable impacts from foreign exchange and product mix, partially offset by spending in support of the new European device regulations and manufacturing variances. We expect our full year 2019 adjusted gross profit margin to be consistent with our year-to-date rate.

Selling, general and administrative expenses in the third quarter were $306 million or 28% of sales. This 14% increase over the prior year was driven by transcatheter structural heart field personnel-related expenses including expanding the transcatheter mitral and tricuspid therapy field organization in Europe. We continue to expect SG&A excluding special items to be between 28% and 29% of sales for the full year 2019.

Research and development expenses in the quarter grew 21% over the prior year to $195 million or 17.9% of sales. This increase was primarily the result of significant investments in our transcatheter structural heart programs including generating clinical evidence. For

the full year 2019, we continue to expect R&D excluding special items to be between 17% and 18% of sales.

Turning to taxes. Our reported tax rate was 8.9% for the quarter or 10.8% excluding the impact of special items. Stock appreciation this year drove a 580 basis point benefit or $0.09 from the accounting for employee stock-based compensation. Our tax rate also benefited from recently passed tax reform in Switzerland. We now expect our full year 2019 tax rate excluding special items to be at the bottom of our previous guidance range of 12% to 14%, which reflects the increased benefit of the accounting for employee stock-based compensation.

Foreign exchange rates decreased third quarter sales growth versus the prior year by less than 1% or $6 million versus the prior year. At current rates, we continue to estimate an approximate $60 million negative impact or about 1.5% to full year 2019 sales compared to the prior year. FX rates positively impacted our third quarter gross profit margin by 130 basis points versus the prior year. Relative to our July guidance, FX rates had less than $0.01 impact on earnings per share reflecting our effective currency hedging program.

Adjusted free cash flow for the third quarter was $319 million defined as cash flow from operating activities of $437 million less capital spending of $76 million and excluding a $42 million tax benefit related to our previously announced global intellectual property litigation settlement. Our year-to-date, adjusted free cash flow which excludes the litigation settlement and related tax benefit was $735 million.

We now expect full year 2019 adjusted free cash flow to be above the top end of our previous $800 million to $900 million guidance range. We remain on track in implementing capital expansion projects, in line with our strategy to increase global capacity.

Turning to our balance sheet. At the end of the quarter, we have cash, cash equivalents, and short-term investments of $1.4 billion. Total debt was $594 million. Average shares outstanding during the quarter remained level with the prior quarter at 212 million. We continue to expect average diluted shares outstanding for 2019 to be between 211 million and 213 million.

And now finishing up with our 2019 guidance. Given our strong year-to-date performance, we are increasing our sales guidance ranges for Edwards and for TAVR. For total Edwards, we now expect sales around the top of our previous $4.0 billion to $4.3 billion range. And for TAVR, we now expect sales around the top of our previous $2.5 billion to $2.7 billion range with underlying sales growth of nearly 20%.

For TMTT, we now expect sales to be below $40 million. We continue to expect Surgical Structural Heart sales of $810 million to $850 million; and Critical Care sales including CASMED around the top end of our $700 million to $750 million range.

We are raising our full year adjusted earnings per share guidance range to $5.50 to $5.65, up from our previous guidance of $5.20 to $5.40. For the fourth quarter of 2019, at current foreign exchange rates, we project total sales to be between $1.12 billion and $1.16 billion and adjusted earnings per share of $1.40 to $1.55.

And with that I'll pass it back to Mike.

Mike Mussallem

Thanks Scott. We're very pleased with our strong year-to-date performance. As patients and clinicians increasingly choose TAVR, we remain optimistic about our long-term growth opportunity. We are committed to aggressively investing in our future, consistent with our focused innovation strategy. We remain confident that the innovative therapies resulting from our investments will benefit a broader group of patients suffering from structural heart disease and continue to drive strong organic growth.

And with that I'll turn it back over to Mark.

Mark Wilterding

Thanks Mike. Before we open it up for questions, I would like to remind you about our 2019 Investor Conference on Thursday, December 5th in New York City. This event will include updates on our latest technologies, news on longer-term market potential, as well as our outlook for 2020. More information and a registration form are available on our website. 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.

Question-and-Answer Session

Operator

Thank you. At this time, we'll conduct a question-and-answer session. [Operator Instructions] Our first question comes from Bob Hopkins with Bank of America. Please state your question.

Bob Hopkins

Great. Thanks and good afternoon. First off just congratulations on such a nice third quarter. Mike I just wanted to make sure that I'm hearing the messaging right on your kind of new views on the TAVR market -- or updated views I should say.

I guess the message I'm hearing is that despite obviously a very, very strong performance in Q3, you're not really changing your views on the ultimate size of the market or the time that it will take to get there.

I guess my first impression of that related to strength is that that seems increasingly like a conservative estimate and timeframe unless I'm missing something else that's new. I'm just wondering if you could comment on that.

Mike Mussallem

Yes. Thanks Bob. Well, you know we've always felt the TAVR opportunity was large and growing and we know that the superiority results are helpful. We caution reading too much into one quarter's result. We continue to think that we'll know more about it over time, but right now, we would encourage you to think about this broad growth rate that we've talked about over time.

We struggled some time to estimate quarters accurately. We -- if you go back to our guidance in December, we thought that the TAVR opportunity would grow from $3.5 billion in 2018 to $7 billion in 2024. We still think that that's a reasonable trajectory. We'll take a hard look at it, and if we have an update we'll share that certainly in the future.

Bob Hopkins

Great. That's fair enough. And then just one quick follow-up for Scott, you offered a few things about 2020 that we should consider. Just curious, if there's any other things that you think we should consider for 2020 modeling purposes? And I know you have like for example, one thing that I think people are curious about is just you have a lot of trials going on great revenue growth. Is 2020 a year where you still think you can – you'll deliver leveraged earnings growth? Thank you.

Scott Ullem

Well, that's certainly our objective. We try to inch up operating profit margins every year. And we're not perfectly consistent at it, but that's certainly the objective over the long term. I think the other things to think about in 2020 are we are going to continue to invest aggressively in research and development. And every time we think we've gotten it right we end up with programs coming online and other programs rolling off. But I think you're going to see us continuing to address it at relatively high levels of R&D. Don't expect it to go back down to 14% or 15% where we were a few years ago.

The last thing, I'd say is just on gross profit I think we're going to see downward pressure on our gross profit margin, because we've got the benefit of some of these FX – currency hedges rolling through FX this year. And so we're not ready to quantify that yet, but I expect our gross profit guidance probably will not be as robust next year as it was this year.

Bob Hopkins

Great. Thanks for taking the questions.

Operator

Our next question comes from David Lewis with Morgan Stanley. Please state your question.

David Lewis

Great. Good afternoon. Just two quick ones for me. Mike, I thought I'd just start with PASCAL here. Just, if you could parse out sort of the PASCAL launch dynamics. Like initially, it was a disciplined launch focused on outcomes. This quarter you raised your premium pricing strategy. So, what's the bigger rate limiter? Is it more this disciplined launch or is it more your pricing strategy? And then what changes in 2020 to give the comfort that this business can double? And I have a quick follow-up for Scott.

Mike Mussallem

Yeah. Thanks David. So know that this launch plan has always been there. That's what we called for. We go through very careful site selection position training patient screening and case support so that's not really different. But we are executing a premium price strategy, because of the differentiated technology that we have and also this high-touch clinical support. That premium price strategy is moderating our site activation plan. So that's what's changed it. Was there a second part to the question David?

David Lewis

What changes Mike in the next year? I mean, this business is going to double as you suggested. Do you change your strategy next year or do you think the this strategy you're employing in 2019 can get you to doubling this business next year?

Mike Mussallem

It – we do believe it's a strategy. It will be an increase in the number of sites. They are limited today and we'll be adding sites in a disciplined fashion. We've gotten great feedback from clinicians and so that will be the primary driver.

David Lewis

Okay. Very helpful. And then Scott you talked about gross margins for next year and I appreciate the update. When you just think about this particular quarter obviously given the strength in TAVR gross margins probably weren't as strong as we were expecting so you mentioned manufacturing variances. But can you just help us quantify any impact from Ultra CENTERA or FX on gross margins this particular quarter? Thanks. Thanks so much.

Scott Ullem

Sure. Let me take you through some of the different moving pieces that hit gross margin. We had the benefit of these hedged contracts, I've mentioned before. That was probably about 130 basis point contributor to the 75.9% non-GAAP gross margin. It was offset by these manufacturing costs. And I think one of the good examples of what's flowing through there is these new European EU device regulations that end-up costing us money. There were some inefficiencies associated with moving delivery system production around in connection with this Ultra delivery system strategy we've talked about. So that did run through manufacturing cost and was contributor to some of the negative variances. We also had some benefit of mix. And you roll that all up together again and that's how we gone up 40 basis points versus 2018 third quarter.

David Lewis

Is it possible Scott that the impact of CENTERA and Ultra was more than 100 basis points this quarter?

Scott Ullem

Well, I think there are two pieces – were called out. One was a special charge, right? But in terms of the gross margin impact, no I don't think it's more than 100 basis points this quarter. I think it would be less than that.

David Lewis

Okay. Thanks so much.

Mark Wilterding

Next question, Diego.

Operator

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

Larry Biegelsen

Good afternoon. Thanks for taking the questions. And congrats on a really strong quarter here. Mike, I wanted to start with the 2020 outlook for TAVR procedure growth in the low double-digits that you talked about in the press release and in your prepared remarks. I mean you're calling for about 20%, this year you've grown in line with the market. You just got the low-risk approval in late August. So why do you think the market will slow so much next year? And I had one follow-up.

Mike Mussallem

Yes I'm not so sure. We struggle with this Larry, because it's tough for us to call these quarters. I'm not sure it's about slowing next year. I think we saw a bolus this year. So we believe that most of what we saw last quarter and this quarter was the result of those spectacular results in PARTNER 3 which ultimately led to an FDA approval.

And we think that that stimulated patients, educated physicians, it increased awareness and that combination started patients moving through the system. They don't move through the system so fast but we think it was a real stimulus to the system. So if you will we might have even pulled a little bit of that forward. So that's the way that we end up thinking about we're still going to have half the usage next year. The growth rates are going to look lower in comparison to the second half of 2019.

Larry Biegelsen

That's helpful. And then Mike your surgical heart valve business, I heard your comments in your prepared remarks, but I'm curious about 2020 and beyond. We've heard anecdotes that TAVR procedures could be down 20% to 30% next year in the U.S. given the strength

of the low-risk data and indication. How confident are you feeling you could still kind of state -- keep that business growing or even flat looking ahead? Thanks for taking the questions guys.

Mike Mussallem

Yes, thanks, Larry. One of the factors although not as big as new patients coming off the sidelines were patients that might have been treated with surgery or treated with TAVR even now in the third quarter. So when you think of a big TAVR growth rate and that we've withstood that and grew 3% in the third quarter, it bolsters our confidence about the future. Is it going to be challenging?

Do we think TAVR is going to continue to have an impact on surgeries? Of course, it will. But I'm not sure that that's going to get much worse in the future. We think there's probably been kind of a step-change here with the PARTNER 3 data and that over time that probably moderates as well.

Larry Biegelsen

Thank you.

Operator

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

Vijay Kumar

Hey, guys congrats on a really nice quarter here. But back on the TAVR 2020 question. I want to approach it from a slightly different angle. Given the headline numbers on PARTNER 3 data, they came in much better. Shouldn't we be expecting maybe Edwards to do better than the market? I mean the overall market could be low doubles but shouldn't the better clinical data reflect in numbers?

Scott Ullem

Of course, we're proud of our data. Nobody is more proud. And we do everything we can to have that message out there but you have to also recognize that in the single biggest market in the world, the U.S. we've got new competitors that are coming in. And at this point I don't think we've really felt that in a large way. So whether it's trialing or an actual adoption we think that will have some impact. And so we stay kind of balanced on if we can grow like the market that's really not so bad.

Vijay Kumar

That's helpful, Mike. And then one on mitral. So the M3 trial, which was slated the start of year-end is that -- do you have clarity on what the trial design is what the comparator arm is? Will this be a key F approach or -- I'm just curious on any additional details.

Mike Mussallem

Yes, thanks, Vijay. We don't have anything to share at this point. We're in discussions on that. And for competitive reasons while it's still early and it's not clear we don't share exact trial design. So at this point we really don't have anything new to add in that regard. Once it's clear of course it will get posted on clinicaltrials.gov and then we'll make it clear to everyone.

Vijay Kumar

Thanks, guys.

Operator

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

Robbie Marcus

Thanks and congrats on a nice quarter. I appreciate the volume commentary to let us back into Japan growth. It's starting to become a more material contributor here. Wondering if you could help us with the financial impact from the stocking ahead of the tax starting? And also maybe just some color on the market and what you're seeing there?

Mike Mussallem

Yeah. So in Japan there was a consumption tax that was put in place, I want to say around the 30th of September. And we heard reports that some Japan customers did some TAVR stocking. We think it's just less than $2 million worth of stocking that took place there. So that gives you a rough idea of that if that's your question.

Robbie Marcus

Yeah. No, that's helpful. And now with the new NCD in place, how are you thinking about the -- not just the expansion of TAVR centers, but the shifting in volumes of TAVR centers? Do you expect these – well, a, how many of new centers are you expecting and over what time frame? And b, are you expecting them to be incremental volumes to the system? Or do you expect them to cannibalize from the existing volumes out there? Thanks.

Mike Mussallem

Yeah. So we were pleased with the way that the NCD turned out. And I think our estimate at that time is that it would add approximately 200 new sites. These would be sites that could achieve the eligibility.

Now I don't know whether all of those will do that in the near term except for some. It might take some time. I think by and large we believe, yes. Will it take from of some other centers, yes, probably to a small extent. We believe that there's still a greatly underserved market and that it is somewhat additive to the total as those new centers come on.

Robbie Marcus

Thanks a lot.

Mike Mussallem

Yeah.

Operator

Thank you. Our next question comes from Matt Taylor with UBS. Please state your question. Matt Taylor, your line is open.

Matt Taylor

Sorry about that. Hi. Thanks for taking the question. I just wanted to follow-up on the TMTT comments on next year. Could you talk about just in broad strokes, how much of that you expect to be from PASCAL? And how are you thinking about your annular devices? And also if you could give maybe an update on replacement that would be helpful?

Mike Mussallem

Yes. So, yes, just to go in the opposite order here. The bulk of this is likely to come from PASCAL. We'll try and paint a more complete picture. The replacement devices will be in clinical trial, so that won't have a big impact on the number. And right now our Cardioband product is still relatively small. We're gaining experience. We get a lot of positive feedback there, but by comparison, it's going to be more PASCAL.

Matt Taylor

Okay. Great. Thank you very much.

Operator

Thank you. Our next question comes from Jason Mills with Canaccord Genuity. Please state your question.

Jason Mills

Great. Thanks Mike. Sorry about the background noise. I'm traveling. Congrats on a great quarter. I wanted to start on mitral. With respect to your long-term views sort of a long-term question, $3 billion by 2024. How do you anticipate that breaking up U.S. versus OUS? And at that point in time understanding there's a lot of clinical evidence yet to be accumulated, do you expect Edwards will be if not a leader closing in on a leadership position at that point in time? Just trying to get a sense for trajectory as we look at your long-term projections in mitral.

Mike Mussallem

Yeah. So it's a great point. So I don't have an exact breakout of U.S. versus OUS. Given the earlier approval of OUS big head start for OUS, but you know that U.S. is a rapid adopter. So that's going to be a little tricky to predict. But that is -- it does include some bumps for the U.S. I think the bigger thing Jason is we're not suggesting $3 billion is where it stops in 2024.

We feel like that's just where it gets going. We're focused on the long term in that regard. We'll try and provide some more clarity as we get to the investor conference, but right now I would say that's sort of a signpost along the way.

Jason Mills

Okay. Thank you for that Mike. And then, Scott, on your commentary with respect to operating margins to Bob's question, if we assume that R&D is not a source of leverage next year and potentially SG&A is, maybe talk about SG&A trending as we look at not only 2020. But does your commentary of previous Analyst Days hold true as we stand today in terms of seeing downward pressure on that line as a percentage of sales and perhaps if we do see leverage in 2020 that's where we would get it?

Scott Ullem

Well, I think, there are a couple of things that are influencing it, both in 2020 and beyond. One is, we're trying to scale our growth and be really efficient with overhead and administrative and back-office type expenses that run through SG&A.

At the same time, we're investing aggressively in things like field resources who are supporting clinical cases. And so, I think, those two -- it's tuff to tell what the balance is going to look like, but over time, I guess, I'll just leave it as, we're going to try to be very efficient in SG&A. And we'll give you more update about what that looks like in 2020 in a couple of months when we get to our investor conference.

Jason Mills

Got it. Thank you both.

Mark Wilterding

Next question?

Operator

Thank you. Our next question comes from Raj Denhoy with Jefferies. Please state your question.

Raj Denhoy

Hi. Good afternoon. Maybe just a couple of clarifications. On the CLASP studies, the F&D studies in the United States, I don't believe you've given us time lines for U.S. approval. I know you're enrolling both of them, but you haven't really given us much in terms of how that enrollment is going and when we might see those products get approved in the United States.

Mike Mussallem

I think, that's right, we haven't talked about approval. So, we say that we are on track for our enrollment and so we'll -- we may have more details to report at the investor conference. But right now I think our report is that we're on track with enrolling and really we haven't put sort of completions in place, because we're still relatively early.

Raj Denhoy

Okay. That's fair. And maybe just a quick one on competition. You mentioned you are being a little conscious in your outlook, given potential competition in the United States. But as you mentioned, you haven't seen much yet from LOTUS and some of the updates -- or the update, I suppose, on Portico coming out of TCT was perhaps a little underwhelming. And so, I guess, I'm curious what your current thinking is on competition and the potential impact competition will have over the next, call it, 12 to 24 months in the U.S.

Mike Mussallem

Yes. We expect it to have impact. These are really good companies. We tend to think that our technology is pretty substantially superior, so we think that's going to give us a big advantage. But these are good companies that have great relationships out there and we

think that they will have some impact.

Raj Denhoy

Okay. Fair enough. Congratulations on a good quarter.

Operator

Thank you. Our next question comes from Matt Miksic with Credit Suisse. Please state your question.

Matt Miksic

Hi. Thanks. Wanted to -- I think, we've covered the strength, really impressive I should say, strength in U.S. TAVR in the quarter again. But wanted to maybe get a sense of where sort of your activity is, or your involvement in new center initiation and training, just because it sounds like one of your U.S. peers has sort of redoubled their efforts on that front. And wondering if that requires a response from you, or you're sort of business as usual, or maybe just some comments on that front. And I have one follow-up.

Mike Mussallem

Yes. I'd probably call it a little bit more business as usual. We're fortunate to be the leader in this space and we still -- our approach on a regular basis. I'll say, one of the things that's been -- kept our team pretty busy this quarter, as you can imagine, with a 30% bump in U.S. procedures, we cover all those cases.

So our team did a pretty incredible effort just to be able to cover all this bolus of patients that's come through. So have we pivoted to starting new centers? No, not in a big way, but of course we support them. And we think that will be gradual and grow over time.

Matt Miksic

Okay. That's helpful. And then, just on the OUS environment. I know your focus is on the U.S. and there's been a lot of conversation around that, but you have a premium-priced strategy in TAVR OUS. I think this time last year, it seemed and it felt like -- duel check

and your comments, I think, that the pressure on pricing was maybe a touch heavier. And I don't know, if we're annualizing that, or you've seen a change in that environment incremental year-over-year. So, again, any color you have in that regard.

Mike Mussallem

Yes. Well the one thing I could speak of with certainty is our discipline. We continue to exercise a lot of price discipline. If anything, I would say, there might be even more price pressure. We've watched some competitors get even more aggressive over time so some pretty, pretty significant differences, which is disappointing. We think it may be one of those things where it's tougher to compete, are on evidence and technology and so they're turning to price a little bit more aggressively. But that's the general environment.

Matt Miksic

Well, congrats on the solid results there. Thanks.

Operator

Thank you. Our next question comes from Rick Wise with Stifel. Please state your question.

Rick Wise

Good afternoon, everybody. Mike, maybe if you could talk a little more about Ultra and the Ultra rollout from a couple of vantage points. What's left to do in terms of ramping the device? It sounds like it's going to ramp up in the next few quarters. You're very clear that it's going to be most of the product sales in 2020 -- for most of 2020.

How would you have us think about Ultra? Is it a growth accelerator? Is it a share gainer? And just as part of the question for you Scott how do we think about the impact on gross margins? Does it -- has it been a gross margin drag that turns into a positive as you launch it? Or no it's the opposite as volume grows and you move down the learning curve? Just any color on all of those kinds of things. That will be it for me. Thank you, Mike.

Mike Mussallem

All right. Thanks, Rick. So let's just start from the top. We're really pleased with Ultra. We think it's a great valve. We love this feature. We think the reduction of paravalvular leak is going to become more and more important over time. There's going to be increased competition. If Ultra allows us to just protect our existing positions as leader we'll be pleased with that. So I think that's probably what you should expect. From a margin perspective, I'll let Scott comment.

Scott Ullem

We're in the early days Rick as you know we've been making some changes here. There will be a headwind to gross margin but it's really not something you're going to see externally. And over time it'll have substantially similar margins to SAPIEN 3.

Rick Wise

Thank you.

Operator

Thank you. Our next question comes from Chris Pasquale with Guggenheim. Please state your question.

Chris Pasquale

Thanks. Scott can you circle back to the 200 basis point sales benefit you called out? How much of that was selling day versus Japan? And was that selling day impact making up for one less that you had in the prior quarter?

Scott Ullem

Days -- and yes we had about a 1% headwind in the first half. And so this third quarter we've had literally -- most of the 2% tailwind was in fact selling days. A very small piece was the Japan preorder.

Chris Pasquale

Okay. And then Mike just following up on Larry's question about the surgical valve business can you give us a sense of how much of your procedure mix at this point is those premium products INSPIRIS and INTUITY? Just wondering how long positive mix can still be a tailwind there to help offset the lower volumes.

Mike Mussallem

Yes, so at this point it's been growing pretty significantly. On the aortic side, it probably accounts for 50% or more of our volume and it's growing pretty quickly. So it's a pretty significant portion. It's becoming really the valve of choice in a number of regions.

Chris Pasquale

Great. Thanks.

Operator

Thank you**.** Our next question comes from Josh Jennings with Cowen & Company. Please state your question.

Josh Jennings

Hi. Good evening. Congrats again on the results. I wanted to start off on just asymptomatic opportunity. I think Mike you commented on EARLY TAVR I think enrollment being pushed out? And just wanted to get some updated thoughts on asymptomatic, and just is the enrollment pushed out due to some of these patients just screening in and being determined symptomatic upon sort of more rigorous interrogation by clinicians or stress testing?

Mike Mussallem

Yes. Thanks, Josh. So we've had really fast enrollment in all of our PARTNER trials. That's really been a remarkable. And PARTNER 3 was a homerun. But when we get into this trial now we're talking about patients that are not only -- not on indication, but they're not on guidelines. Right now what guidelines say is you only treat patients that have AS and symptoms. And so many centers don't even acknowledge these and save it. And so it's

been kind of bumpy and then it's just been a slower process because it's a first of a kind trial and it's a really big one. So we wish it was going faster -- not worried about the implications of this trial.

Josh Jennings

Understood. And just on bicuspid if -- we've just had some anecdotal feedback about just the label and the current language maybe limiting some bicuspid utilization and just the low risk indication primarily. And the reason I asked the question is just -- the question is what are you getting from the field? Are low-risk bicuspid cases being done in these early days? Or is that a whole another leg where, with label updates, that bicuspid opportunity could open up more fully. Thanks for taking the questions.

Mike Mussallem

Yeah. So you're suggesting our growth rate could have been higher if we treated more bicuspid patients? No, I'm just being funny now, right? So it's -- I think as we indicated before bicuspid is not off-label and we do continue to see many of these patients who get treated. They're younger. They have other issues. They often need different procedures. And so, that's often the case why they don't require TAVR therapy.

Operator

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

Pito Chickering

Good afternoon, guys. Thanks for taking my questions. Mike, before you used the word bolus when talking about TAVR growth this quarter. How should we think the bolus that we're having with low-risk patients? And how long do you think this bolus can last?

Mike Mussallem

That's a good question. So, we think what started the bolus was the report on the PARTNER 3 results. The superiority was pretty eye-popping that we think that drove a lot of discussion, awareness and so forth. One of the things about that we've learned about

TAVR patients is even from when the decision gets made, they don't move through the system so fast. Many times it does take them longer than 90 days. So, if some of those patients got activated around that time frame, it's not surprising that they would show up in Q3.

So, we think we're seeing sort of a bump in demand here started in the second quarter, see it in the third, some more in the fourth and we reach a new level. But we think -- as we say, we think that growth rate moderates over time to what we think of as more consistent with our long-term expectations.

Pito Chickering

Okay. Fair enough. And then second question. So your U.S. sales force is obviously quite busy this quarter sort of filling that 30% demand you guys saw. When do you think you'll change your sales and marketing efforts to target more of the general cardiologists to help keep the low-risk patients coming in?

Mike Mussallem

Yeah. So we don't ever anticipate providing less service to our existing customers. Our model is a high-touch model, and we do everything within our power to make sure that each patient has a really successful result. You're on a good point. We do find high level of variability between the understanding the general cardiologists have. Some do a great job of staying current and others are somewhat dated in their understanding of what therapy options are. So there is a job for us to do there, and we are taking that on to some extent. We're -- that's one that we're ramping over time as we're learning how to do that and how to do that effectively.

Pito Chickering

Great. Thanks so much and great quarter.

Mike Mussallem

Thank you.

Operator

Thank you. Our final question for today comes from Jayson Bedford with Raymond James. Please state your question.

Jayson Bedford

Good afternoon. . Thanks for taking the questions. I just had a quick follow-up on PASCAL. Does the doubling of revenue in 2020 stem more from entering new geographies? Or are you expecting any change in reimbursement in the regions you're currently in to help stimulate growth?

Mike Mussallem

Yeah. A good chunk of it is indeed new geographies that -- we've probably gone to a very limited number of customers, a limited number of geographies so far. So yes, there'll be some more penetration in the existing geographies that we're in like Germany, but we'll be entering new geographies as well.

Jayson Bedford

Okay. And just as a quick one. The low double-digit TAVR growth in 2020, any way you can comment on U.S. versus international trends there?

Mike Mussallem

It was kind of preliminary for us. We wanted to put it out there just so to give you some kind of guidance. We're going to try and get into that more deeply. But rather than sort of speculate on something that turns into a foul ball, we just thought it'd be better for us to give you a high-level look and then we'll get deeper as time goes on.

Jayson Bedford

Got it. Thanks.

Operator

Thank you. And ladies and gentlemen, we do still have time for one more question. And that last question comes from Adam Maeder with Piper Jaffray. Please state your question.

Adam Maeder

Hi, guys. Congrats on the quarter end, and thanks for taking the question. Just one for me maybe on Critical Care, that business continues to be a positive driven by HemoSphere. How should we be thinking about the growth trajectory over the longer term? Is this level of growth sustainable? And can you remind us of the benefit you're seeing from a capital standpoint?

Mike Mussallem

Well, we're really pleased with what's going on in Critical Care. And you can tell the growth rate that we've enjoyed this year, has been a step-up from what we've done in the past.

The HemoSphere all-in-one platform has really been important. And it has stimulated our growth rate. Having said that, that team in Critical Care continues to add features to HemoSphere and there are new features that will be added even later this year and some more in the future.

So as those happen, we think it provides a lift to growth. Although, I don't know that you're going to see the same bolus. So we're going to share our expectations a little bit more discreetly or clearly, when we get together at the investor conference. But right now, we continue to feel like, we have a strong franchise there in Critical Care.

Adam Maeder

That's very clear. Thanks, guys.

Operator

Thank you. This concludes the Q&A session. I'll now turn it back to management for closing remarks.

Mike Mussallem

Well. Just thanks for your continued interest in Edwards. Scott, and Mark, and I welcome any additional questions by telephone. And I'll turn it back to you.

Operator

Thank you. And ladies and gentlemen, to access a telephone replay of this call, please dial 877-660-6853. If you're outside the U.S. you can dial 201-612-7415.

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This concludes today's conference. You may disconnect your lines at this time. Thank you all for your participation.