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Conference Call Transcript

EW - Q3 2006 Edwards Lifesciences Earnings Conference Call

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PRESENTATION

Operator

Greetings, ladies and gentlemen, and welcome to the Edwards Lifesciences third quarter 2006 earnings conference call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Mr. David Erickson, Vice President, Investor Relations. Thank you, Mr. Erickson. You may begin.

David Erickson - *Edwards Lifesciences - VP - IR*

Welcome and thank you for joining us today. Just after the close of regular trading, we released our third quarter 2006 financial results. During our call today, we will focus our prepared remarks on information that complements the material included in the press release and the financial scale schedules and then allocate the remaining time for Q&A.

Our presenters on today's call are Mike Mussallem, Chairman and CEO, and Tom Abate, Edwards' CFO and Treasurer. Before I turn the call over to Mike, I would like to remind you that during today's call we will be making forward-looking statements that are based on estimates, assumptions and projections. These statements include but aren't limited to our ability to achieve 2006 financial goals for sales, gross margin, net income, earnings per share and free cash flow; the effects of competition on the continued success of recently reduced products and the regulatory approval for additional products in our heart valve therapy product line; the continued adoption and sales of FloTrac and LifeStent; the success of Brazilian clinical trial; the timing and progress of clinical studies relating to our percutaneous and minimal access valve technologies and the market opportunity for these products, and the impact on our results of stock option expensing, foreign exchange and special items.

Although we believe them to be reasonable, these statements involve risks and uncertainties that could cause actual results or experiences to differ materially from the forward-looking statements. Information concerning factors that could cause actual results to materially differ from those in the forward-looking statements may be found in our annual report on Form 10-K and our other SEC filings which are available on our website at Edwards.com.

With that, I will turn the call over to Mike Mussallem. Mike.

Michael Mussallem - *Edwards Lifesciences - Chairman and CEO*

Thank you, David. We are very pleased to report our earnings performance, even though our heart valve sales fell short of our expectations this quarter. Our solid results were made possible by strong profitability and the increasing contribution from growth drivers, as evidenced by the continuing traction of our new Critical Care and Vascular products. Additionally, we are continuing to make important progress in our Ascendra and percutaneous transcatheter heart valve programs.

On a reported basis, total sales for the quarter grew 2.7% to \$247 million and grew 4.7% on an underlying basis. Year-to-date, our underlying sales growth was 6.6%.

Now let's shift to a more detailed review of our product line sales, as well as provide an update on our transcatheter heart valve programs, and then Tom Abate will take you through the financials.

For the third quarter, heart valve therapy sales grew 3.9% to \$117 million, which included a \$1 million contribution from foreign exchange. The continued strength of our premium-priced tissue valve and repair products, including Magna and Magna with ThermaFix, were the primary contributors to our growth. International sales of our tissue and repair products remain strong. A competitive valve introduction in the USA late last year and our de-emphasis of mechanical and porcine valves globally were partial offsets.

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In the U.S., we estimate this competitive valve accounted for all of our shortfall, reducing our third quarter expected sales by approximately \$3 million. This product impacted our mechanical valve conversions and to a lesser extent took share from our more mature based tissue valves. However, we believe it is approaching its market potential.

Magna Aortic remains the number one tissue heart valve worldwide and accounts for an increasing percentage of our global aortic sales, representing over half of this total. The addition on our proprietary ThermoFix tissue treatment drove Magna sales growth to 24% this quarter and further increased its price premium. We expect strong customer adoption of these premium products to continue.

Our new Magna Mitral valve with ThermoFix is doing well in Europe. With regard to its U.S. approval, we recently received a request for additional information from the FDA. Although we will respond promptly, approval is now not likely to occur until next year. We plan to launch the PERIMOUNT Theon aortic valve in the U.S. early next year. This valve combines the clinical superiority of our PERIMOUNT product line with our ThermoFix tissue treatment and is backed by the strongest published data. This new valve, together with our robust Magna pipeline, gives us confidence that we will accelerate our growth.

Global heart valve repair sales demonstrated another quarter of strong growth. Driven by continuing adoption of our newest disease-specific products, including the MC3, IMR and GeoForm rings. We expect to further extend our leadership in the valve repair market by introducing another new and innovative mitral repair system during the fourth quarter. We look forward to sharing more detail on our entire new valve product pipeline, including additions to the Magna line at our investor conference in December.

Our initiative to address under-treatment of valve disease made progress in the third quarter. Evidence in the medical literature continues to build. We now have preliminary findings from two of our growing list of retrospective studies, confirming earlier research that many patients with aortic stenosis who should receive surgery do not. Another Edwards sponsored study to be presented at next month's AHA meeting which shows a gender bias in aortic stenosis management with women being treated at lower rates than men.

In Critical Care, which represents one-third of Edwards' overall revenue, third quarter reported sales grew at 8.7%, including a modest contribution from foreign exchange. Sales of FloTrac were the biggest driver of growth this quarter, with core critical care products in hemofiltration also contributing to the results. FloTrac continues to enjoy strong adoption in all regions, including Japan, which has been particularly receptive to the product's minimally invasive characteristics.

As we previously mentioned, we introduced software enhancements to the FloTrac monitoring system in the third quarter. Over the past couple of months, several single-center studies demonstrating the utility of FloTrac were presented. We expect additional studies demonstrating both the accuracy and cost-effectiveness of the technology to be completed next year. Overall, we're on track to reach the mid range of our 2006 sales goal of \$10 to \$20 million.

And to update you on the Vigilance recall we had mentioned last quarter, the recall of these older monitors has gone very well and is now substantially complete. We are pleased to report there was no adverse sales impact, and the actual expenses associated with the recall were in line with our reserves.

In our Cardiac Surgery Systems franchise, reported sales for the quarter declined more than 21% due to the discontinuation of our Japan perfusion product business last year. Excluding the impact of the divestiture and a modestly positive foreign exchange gain, underlying sales were 3.6% lower as the decline in TMR sales overshadowed growth in our cannula business driven by share gains.

Sales of our Optiwave 980 were lower than expected as a result of our decision to pursue a slower, more controlled release of our system to implement reliability enhancements. As a result, we do not expect a meaningful contribution to this year's sale.

Total sales of vascular products grew 12.8% on a reported basis this quarter, including a modest gain from foreign exchange. LifeStent products drove all of this quarter's growth, while sales of base vascular products were essentially flat.

As expected during the quarter, we announced the launch of our new FlexStar self-expanding stent delivery system, which helps ensure the easy and accurate delivery of our uniquely flexible stent technology. Customer response to FlexStar has been very positive, and in September we aggressively upgraded the U.S. field inventory to this new system.

Toward the end of the year, we introduced the FlexStar XL, our line of longer length stents, into the U.S. market. The success of these new products reinforces our confidence in achieving our goal of doubling stent sales in 2006.

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Also during the quarter, we completed the enrollment of the 225 patients in the pivotal phase of our RESILIENT trial. At the TCT conference next week, we expect interim RESILIENT trial data and patient cases to be presented. We still expect to cement our PMA in the first quarter of next year, which keeps us on track to receive an SFA indication by the end of 2007.

Other distributed product sales declined on a reported basis this quarter or a recorded modest growth on an underlying basis. Recall that last quarter, we divested a non-strategic pharmaceutical product line representing approximately \$2 million in annual sales.

In summary, even with the lower than expected third quarter heart valve therapy, we expect total reported sales for 2006 to be at the low end of our previous range of \$1.40 billion to \$1.60 billion, assuming current foreign exchange rates. These projections include an expected negative impact of approximately \$25 million from discontinued products and foreign exchange. For the fourth quarter, we are projecting total reported sales of \$265 to \$270 million.

For Heart Valve Therapy, we now expect total reported sales of approximately \$120 to \$122 million for the fourth quarter. Projected sales results for the rest of our product lines remain unchanged compared to previous expectations. In Critical Care, we expect fourth quarter sales of \$93 to \$95 million. In Cardiac Surgery Systems and Vascular, we project fourth quarter sales of approximately \$25 million and \$20 million, respectively. Lastly, we expect fourth-quarter sales of Other Distributed Products to be approximately \$7 million. All of these projections assume foreign currencies remain at a current level.

Now I would like to provide a brief update on our transcatheter valve programs. Recall that during the second quarter, we had completed enrollment of our 20 patient U.S. feasibility trial and begun enrolling in additional 35 patients while we collect follow-up data on these cases. During the third quarter, we completed enrollment of 34 patients. We plan to perform additional feasibility cases and still expect to commence the pivotal trial early next year. Interim data on the first 54 patients in the U.S. feasibility trial will be presented next week at TCT.

In our percutaneous program, outside the U.S., the multi-center CE Mark study is ongoing in Europe and Canada, and we continue to train positions and add new sites. We expect to complete enrollment in early 2007 and still anticipate receiving approval by the end of 2007.

In our Ascendra transapical program, we continue to make significant progress during the third quarter. The first two compassionate use cases were performed in Dallas. This represents the first time in the U.S. that a heart valve has been replaced with minimal access surgery while the heart is still beating.

To date, more than 80 of these cases have been performed in Europe and Canada and single-center experiences will also be presented at the TCT. We are continuing to pursue clinical and regulatory strategy for Ascendra that would result in simultaneous approval with our percutaneous system, thereby broadening the range of treatable patients. If we are successful, CE approval for both could be received by the end of 2007.

During the quarter, we began phasing a new valve into our clinical studies for use in both percutaneous and minimal access cases. This new valve incorporates our decades of experience in the design, development and testing of market-leading surgical tissue valves with the successful design of the Cribier-Edwards percutaneous valve. The valve features bovine pericardium that has been treated with our ThermaFix tissue treatment and has undergone precise characterization testing for tissue properties. The valve has already been used successfully in a number of cases and replaces the Cribier-Edwards valve.

With more than 250 transcatheter implants to date, Edwards is the clear leader in the development at this important and market expanding technology. Further, we are uniquely positioned to provide an exceptional opportunity for the collaboration of cardiologists and cardiac surgeons in the treatment of aortic valve disease.

In percutaneous repair, our feasibility work with the MOBIUS leaflet repair system is ongoing in Europe and Canada; and we still expect to complete our study this year. Our MONARCH annuloplasty system has demonstrated an excellent stake the profile and ease-of-use in its own feasibility study. We are continuing to enroll additional patients and expect interim data on our 30 patient feasibility study in Europe and Canada to be presented at the TCT.

As I had mentioned, at TCT next week, there will be a number of clinical discussions and case presentations featuring our transcatheter technologies and peripheral vascular products. In addition, on Wednesday we will be hosting an analyst lunch featuring Dr. John Webb, who has some of the broadest clinical experience with our percutaneous and Ascendra technologies, as well as our Monarch mitral system. For more information or to RSVP to this event, please contact our Investor Relations department.

Now I will turn the call over to Tom Abate. Tom.

Tom Abate - Edwards Lifesciences - CFO and Treasurer

Thanks, Mike.

Once again, we achieved strong bottom-line growth into third quarter. Most noticeably, our gross margins showed a significant improvement. Additionally we continue to use a portion of our strong cash flows to reported shares. Reported earnings per share were \$0.45, compared to a prior year loss of \$0.07. Excluding special items and option expense, our non-GAAP EPS grew to \$0.53 compared to the prior year of \$0.46, a 15.2% increase.

As we go through the results, I will detail the impact of FAS 123(R) on the developmental line items. We will also continue to provide an updated table detailing 2006 stock option expenses by quarter on our Investor Relations website.

This quarter, our gross profit margin improved to 64.7%, which is up 240 basis points over last year. Option expense reduced the margin by approximately 20 basis points. The two major contributors to the improvement over last year were manufacturing performance and a favorable product mix, which resulted primarily in last year's divestiture of our perfusion product line in Japan. For the fourth quarter, we expect our gross profit margin to be between 64 and 64.5%, including option expense.

Third-quarter SG&A expenses were \$91.7 million or 37% of sales, which included a 1.4% impact from options. The remaining SG&A growth was due primarily to an increase in sales and marketing expenses in the U.S. For the fourth quarter, we expect SG&A as a percentage of sales to be slightly above 36%, once again including option expense.

R&D investments grew \$4 million to \$28 million this quarter or 11.4% of sales. Excluding option expense of \$1 million, R&D was higher than last year, reflecting additional expanding in our transcatheter valve program. For the fourth quarter, we expect R&D investments to be approximately 11% of sales, including option expense.

Net interest expense of \$800,000 was \$1.4 million lower than the same quarter last year. This decrease was a result of higher interest income earned on our U.S. cash balances, combined with a greater proportion of our debt in low interest rate countries. For the fourth quarter, we continue to expect net interest expense to be less than \$1 million.

During the quarter, we recorded a \$2 million special charge. This represents the final payment related to last year's acquisition of percutaneous valve manufacturing rights from 3F Therapeutics. This charge is included in the net income reconciliation table that accompanies the press release.

For the third quarter, our recorded tax rate was 24.3%; excluding special items and option expense, our effective tax rate was 25.6%. We expect the rate to remain at approximately the same level for the fourth quarter and full year, including the effect of option expense.

When compared to the same quarter last year, FX rates positively impacted third-quarter reported sales by approximately \$1.6 million. This was more than offset by our natural hedges, creating a slightly negative bottom-line result. Using current FX rates, we now estimate full-year sales to be negatively impacted by approximately \$8 million.

Free cash flow generated during the quarter was \$44 million, which we define as cash flow from operating activities of \$60 million minus Capex of \$16 million. Year-to-date free cash flow was \$97 million. For 2006, we continue to estimate free cash flow of 140 to \$150 million.

During the third quarter, we repurchased approximately 900,000 shares of common stock for \$41 million, bringing our year-to-date total to nearly 2.9 million shares. We continue to believe our shares are an attractive investment.

Turning to the balance sheet, long-term debt at September 30th was \$253 million resulting in a debt-to-cap ratio of 25.8%. Net debt at the end of the quarter was \$102 million, a decrease up \$11 million from the second quarter. Including receivables and our asset-backed securitization program, basis sales outstanding for the quarter was 71 days and inventories increased by \$10 million from the prior quarter. The impact on net income related to stock option expense in this quarter was \$3.5 million or approximately \$0.06 per share. And we expect the fourth-quarter expense to be between \$0.05 and \$0.06. For the full year, our total costs will be approximately \$0.21 per share.

And with that, I will turn it back over to Mike.

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Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Thanks, Tom. Despite softer heart valve sales growth in the U.S. this quarter, overall, Edwards' core business remains a strong. The recent success of our FloTrac and LifeStent products is driving growth and contributing to an increasing percentage of total sales. And our progress in transcatheter valve programs represents the potential to open up new markets by providing important new therapies to an otherwise untreated patient population.

Based on our results thus far, we are expecting a strong 2006 and remain confident in our ability to achieve our original financial goals. These goals are generating total sales between \$1.20 billion and \$1.60 billion, increasing our gross profit margin by 150 to 200 basis points, delivering non-GAAP net income growth of 12 to 15%, and generating free cash flow of \$140 to \$150 million.

At current foreign exchange rates, we expect our 2006 sales to come in at the lower end of our estimated range of \$1.40 billion to \$1.60 billion. And for full year EPS, we are tightening our estimate. Excluding special items and option expense, full year EPS is expected to be \$2.24 to \$2.26; and excluding only special items, EPS would be \$2.03 to \$2.05. This puts fourth quarter EPS at \$0.52 to \$0.54, including approximately \$0.05 to \$0.06 per share of option expense.

Before we open it up to questions, I would like to remind you about our 2006 investor conference, which will be held in New York on Friday, December 8. At this event, we will provide an update on our new technologies and detailed financial outlook for 2007. We have also lined up several leading clinicians who will share their experiences with our transcatheter valve technology and their views on the future of the heart valve market. Additional details will be sent out shortly.

With that, Tom and I are ready to answer your questions.

Operator

(Operator Instructions). Dhulsini de Zoysa, Cowen & Company.

Dhulsini de Zoysa - Cowen and Company - Analyst

Mike, I know you're looking forward to seeing the first data from the revival trial. I was wondering if you could help frame the background of what we should expect. Specifically in September at the PICS meeting, I think Dr. Leone commented on the procedural success in the first 51 patients and I think that the valve was properly delivered in 45 cases. I understand that this is a very difficult high-risk surgical patient set. What do you consider success in this operation?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Yes, we're really looking forward to the TCT meeting. There are going to be a number of presentations there, and I think one of the presentations that will be most interesting is how the feasibility trial of the percutaneous valve is going in the U.S. And I mentioned that there will be some interim data on these 54 patients. We will have quite a bit data on the 20 patients that we mentioned that were done some time ago, but less data on the others.

For the most part, we see the complications and so forth tend to happen pretty early on; and I hate to really trump what is going to be presented at that meeting. I know you were the beneficiary of getting some preliminary data at the PICS meeting and those people that were there and saw that data probably have a pretty good idea of what is going to be presented at TCT. But I think, come out and take a look.

Dhulsini de Zoysa - Cowen and Company - Analyst

CoreValve has been talking about their experiences, in I think approaching maybe 100 patients, in using a retrograde approach. I believe the Company expects to begin a pivotal in 2007 in the U.S. just as you do. I think there has been some speculation that it might be 250 to 300 patients or so in a high-risk surgical/ high-risk nonsurgical patients, randomized to re-valving versus valvuloplasty.

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Do you think it is fair for us to think about your trial on similar terms? I imagine that the FDA is looking at the two programs and would want to construct parallel programs, if you will.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Thanks, Dulsini; and I understand that there is a high level of interest in what the clinical trial is going to look like, the pivotal trial for Edwards' percutaneous valve. And we are in some very productive discussions with FDA right now, and I really would not want to speculate exactly where that is going to come out.

I will point out that we started our feasibility study sometime ago here last year, and I am not sure that CoreValve has done a case in the U.S. yet. So I guess it remains to be seen just exactly what sort of timeline that they are able to be on. We're looking forward to beginning our pivotal trial in early '07, as we've said. And so that sort of anticipates that we are going to have a successful outcome, but I am not prepared to comment at this point what that trial is precisely going to look like.

Dhulsini de Zoysa - Cowen and Company - Analyst

Okay, well, I hope you will in December, then.

Operator

Tim Nelson, Piper Jaffray.

Tim Nelson - Piper Jaffray - Analyst

On the valve market, and the competitive impact, it appears to me that the competitor has been out there for just about a year now. Would you expect a percentage improvement in growth to anniversary in the next quarter and more normal growth in line with sort of your 10% objectives going forward?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Yes, we also see that same anniversary, in fact, that is going to take place next quarter. What is not clear to us is that you can see that we gave guidance that's below the 10% rate for the fourth quarter, and we are just trying to be thoughtful and conservative about what our estimates are at this point, Tim.

Tim Nelson - Piper Jaffray - Analyst

That competitor, I believe, is planning sometime in '07 to bring out and an anti-mineralization treatment to that valve. Would you expect to have another incremental impact on the market in your sales?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Part of what we have seen go on we think with this valve is the conversion of their own valves; and one of the things that maybe surprising to some extent is that they have actually, we believe, been converting some of their own mechanical valves to the BioCor valve. I do not know if when the new valve comes out, they may end up cannibalizing some of their own again. That may be what goes on.

I think one of the things that we have seen when somebody gets a new valve approved in the U.S., is that even though the heart valve business is extraordinarily stable, and our business is very predictable, on the margin it can cause the percentage growth rate to change.

I think what remains to be seen here is actually what Edwards does as well, right? Because we have a line up of new valves that we are also anticipating to be approved. We are not sharing details of that at this point. We will have a little bit more to share when we get to the investor conference. But I think new products on the margin will make a difference.

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Tim Nelson - Piper Jaffray - Analyst

That new product could be in the Theon aortic -- I haven't heard of it. I was wondering if you are going to tell us more about it in December.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

This is the first time that we shared that we would be introducing this Theon aortic valve, which is really our PERIMOUNT valve, which has all the data and all the great history with a ThermaFix treatment process. So it has our most modern and best treatment process on it. But no, when I am talking about a lineup of a new valve, I am also saying that we have line extensions in the Magna product line that will be coming.

Tim Nelson - Piper Jaffray - Analyst

And then finally, speaking of Magna, I assume given the positive comments you made about how that continues to grow, the mix improvement associated with Magna accounted for most of the growth? Is that correct?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Yes. As you know, we did not have a lot of growth this quarter, but clearly we did get mix improvement from it. And actually some of the mix improvement offset some of the unit decline.

Tim Nelson - Piper Jaffray - Analyst

How have ASPs tracked, given that mix improvement? Can you give us a ballpark for where they reside now?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Yes. ASPs have just done really well through this whole process. I think you know that our standard PERIMOUNT valve has an ASP in the \$4,500 to \$5,000 range that we have consistently gotten a 20% premium or \$1,000 on the Magna valve; and Magna with ThermaFix is tracking with an additional 10% premium of that. So ASPs have been solid.

Tim Nelson - Piper Jaffray - Analyst

And a financial question on gross margin and I will get back in queue. The improvement in gross margin, given this lower heart valve mix, is a little surprising. Is it at all attributable to the perfusion business decline? And as the mix changes toward critical care now with that growing faster, is that going to impact margins going forward?

Tom Abate - Edwards Lifesciences - CFO and Treasurer

It was not a big factor this quarter. The competition at this point is generally directed at the lower-priced valves. So within the product line, it did not really have the negative impact. But mix was not such a big piece this quarter. We had a great manufacturing performance in the quarter that more than offset that.

Operator

Larry Biegelsen, Prudential Securities.

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Larry Biegelsen - Prudential - Analyst

St. Jude's tissue valve sales have been in the \$14 to \$15 million range for the past three quarters, I believe. Mike, is there something else going on here? For example, is the overall heart valve market slowing?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Thanks for the question. Overall, we do not really see any differences in the heart valve market. The heart valve market tends to be driven by demographics and procedures; and year-in, year-out, it operates very close to that 5% growth range.

One of the things that you do see, when you see the units moving toward the valve that was just recently introduced, it does not get the extra kick of growth. The market does not get the extra kick of growth that comes from Edwards converting the market to its Magna valve. That normally adds maybe a percentage or two. But that is only on the margin. Overall, it is a very steady market.

Larry Biegelsen - Prudential - Analyst

And on the Magna mitral, is it impossible that the FDA will require additional clinical data?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

We really are not sure at this point. At this point, they have sent us a communication that requested more in vitro data, the kind of data that we have not necessarily been requested in the past. I suppose they always have the right to request clinical data as well.

We would be surprised and disappointed by that. We think this is a simple amendment to what we already have in place, but it remains to be seen.

Operator

Alistair McKay. GARP Research.

Alistair McKay - GARP Research - Analyst

Thanks for telling us about the new valve for the percutaneous program. Would you be able to expand a little bit about that? Is it, for instance, is it designed to fit on a smaller catheter or is the cross sectional area different from the valve that has been in trial so far?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Thanks for the question. Here is the way to think about it. The valve from a design perspective and from what it looks like on a catheter is going to look exactly like the Cribier-Edwards valve, with a slight change. So the two real changes are that it's going to be a new material, so rather than the equine pericardial, it is going to be bovine pericardium. And it is going to use the same material and have all that extra processing that we have used on our market-leading surgical valves.

In addition to that, there is also a slight change to the skirt length that goes around the stent itself. But, really, the only impact is that it will have some improved performance on perivalvular leak. But other than that, the profile is going to be the same as you have seen in the past.

Alistair McKay - GARP Research - Analyst

And if I could switch gears for a second and ask whether you have any updates on any of the gene therapy trials that Edwards is doing in collaboration with Sangamo?

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Michael Mussallem - Edwards Lifesciences - Chairman and CEO

We have continued to move forward in our enrollment. As a matter-of-fact, I think in one of those trials, I want to say the Duke trial, we probably completed our Phase I enrollment. We do not have anything to share about the status of our Phase II trial at this point, but I think we will be prepared to share that when we see you in December at the investor conference.

Operator

Paul Choi, Merrill Lynch.

Paul Choi - Merrill Lynch - Analyst

Mike, I was wondering if you could perhaps give us your initial thoughts on what you have seen with Medtronic's valve. Admittedly, it is for the smaller pulmonary opportunity, but it suggests they are thinking about using that the potential platform for broader applications.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

From what I understand, and what I read, this is their pulmonic valve and they are going after the pulmonic market. You know everything that we have been pursuing here has been around the aortic market, which is obviously the really big market and the most important market. But although the pulmonic valve is important from a patient perspective and especially for these kids that need it, it is a pretty small market. And I guess we have a lot of confidence in terms of our ability to go after this aortic market and we're in a very strong position as well.

Paul Choi - Merrill Lynch - Analyst

And then we are also hearing some rumors, rumblings in the marketplace about conversions to some of your competitors' tissue valves -- specifically St. Jude, at some leading clinics such as the Cleveland Clinic. Have you gotten any push back from any certain thought leaders in terms of what they are liking as they trial St. Jude valves?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I am not sure where that rumor came from, to tell you the truth, about the Cleveland clinic. We do not talk to them every day, but as of about yesterday that was not the case. From the people that we know, the thought leaders are very much committed to, we think, the best valves. We know that St. Jude has some loyal customers that may transition from their mechanical valves to their tissue valves. But we are not aware of any sort of substantial change there.

Operator

Tim Lee, Kaufman Bros.

Tim Lee - Kaufman Brothers - Analyst

Just wanted to follow up on the previous question regarding the FDA and the Magna mitral. How extensive is the information that they are asking for and how quickly can you respond in terms of your deliverables to them?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

It is a good question. I hate to go through that in detail. It is a letter that had a substantial number of requests, and most of these requests were all for in vitro data. Many of the things they are asked for they would not have traditionally asked for, for this sort of a supplement, so we will have a combination of answers to things that are very easy for us to generate and also some arguments as to why we think the data is not necessary.

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We will have a rapid response to that, and one that we think is very sound from a scientific perspective. But again, it is going to be the FDA that is really going to sit in judgment of that, and it is not the typical standard that we have seen for surgical valves. That is why we are a little bit surprised by it.

Tim Lee - Kaufman Brothers - Analyst

Again, in terms of your response, would that be by year end?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

We would expect to respond certainly before that. But what is not clear, frankly, at this point is whether it starts another 180 day clock or not.

Tim Lee - Kaufman Brothers - Analyst

And then just one quick question on the heart valve side, given your temperate outlook for the fourth quarter, should we think that some of the reason is that competitive trialing has been stickier than expected? And, is this more of a permanent shift in share, rather than just a temporary one?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

You know, I think that remains to be seen. It is a good question. One of the things as I mentioned a little earlier that probably surprised us to some that extent is that it seems as though they are contributing to the conversion from mechanical valves to tissue valves. It felt in the past that we were the ones that were the primary driver and the primary beneficiary, and it appears as though some of these valves are actually going in place of mechanical valves.

We are very interested to see how it plays out. It would mean that mechanical valves which were probably used in many cases in younger patients under 65 years old might be getting this tissue valve of theirs, which I can't imagine is going to perform really well, and I'm hopeful that those surgeons who are currently making a choice based perhaps on a relationship, would ultimately make a comparison between Edwards' valves and this other tissue valve. And we like our chances in that.

Operator

Rick Wise, Bear Stearns.

Rick Wise - Bear Stearns - Analyst

Going back to the gross margin issue, you talked about the 64.5% for the fourth quarter. Are the efficiencies that you have achieved sustainable going forward? You have obviously demonstrated some very nice gross margin improvement over the last couple of years. Just without asking for specific '07 guidance, although feel free to give it, do we keep improving from here?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

This is a good one for Tom to comment on.

Tom Abate - Edwards Lifesciences - CFO and Treasurer

Sounds like a loaded question here. I will do my best. We have talked about 64% for the whole year, and we started out at the beginning of the year a bit lower than that. This quarter was a standout. I would have to think it is more of a one-time nature. We had a great manufacturing

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performance. We had a lot of volume due to the transition to the new delivery system on PVS. We had a very low expired and obsolete discard for the quarter. So I would stick with where we were in terms of overall and how we're going to finish this year.

Now longer-term, we have said that we are not finished by any means. And the fact is mix. We look on each year to pick up around 200 basis points. And I do not see any reason for that not to be the case next year. But we will get a lot more specific come December.

Rick Wise - Bear Stearns - Analyst

In terms of the LifeStent rollout, it obviously sounds like the rollout is going well. I would welcome any color on early market uptake and any thoughts. I appreciate your perspective on how you are setting goals and how are you defining success as this product rolls out?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

We set a goal early this year that were going to double our stent sales in 2006 versus 2005. We anticipated rolling out this new product line when we set those goals. I think I want to say is our three quarter numbers in stents is somewhere around \$11 million. And so we expect the fourth quarter to be our strongest.

But frankly, the feedback from the field has been just great. People just love this FlexStar delivery system, and we expect the uptake to be very solid. It did not do much for us in the third quarter. As I said, we aggressively replaced product, so actually we even had some returns that were mixed in with the numbers. But we would expect it to make more difference in the fourth.

And then, we are evaluating adding more sales reps. We may make a modest addition in the fourth quarter, but are evaluating much more substantial additions as we go through our operating planning process this fall and we will have something more to share in December.

Rick Wise - Bear Stearns - Analyst

And last, I understand that the under-treatment initiatives are very long-term in nature and take time to implement and to drive. Maybe you could just discuss what impact you think you're going to see or should we expect to see an impact over the next 12 to 18 months? Help us think through that again.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Good question. The more we dig into this, the more we get validated that there are a substantial number of patients somewhere between 30% and 50%, probably 50% of patients with severe stenosis and symptoms that really should go through surgery that do not go through it. And these studies that we are doing right now are echocardiography studies that really look at echos and follow whether these patients actually receive surgery.

So, if are we able to influence today's rate of surgery is not clear. It gives us a tremendous amount of confidence that as we have our new minimal access procedures in surgery and our percutaneous procedures that it is going to spell market growth. Whether it's able to drive market growth in the near-term, we're still not sure.

Operator

Glenn Reicin, Morgan Stanley.

Glenn Reicin - Morgan Stanley - Analyst

A bunch of questions here. What did your repair business grow at this quarter?

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Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Our repair business grew just under 10% this quarter.

Glenn Reicin - Morgan Stanley - Analyst

And then is there any way you can give us your perspective about unit growth for both you and for the market in terms of your tissue business?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I am happy to take a shot at that. Let's just walk through it. Let's start with the market. We have typically said that market growth in total is around 5%. That is intended to include both price and units. What happens is when Edwards has been growing with a premium price, which we have been getting, we probably we add 1% to 2% of premium price on that 5%. So units are probably growing somewhere in the 3% range.

Glenn Reicin - Morgan Stanley - Analyst

Can we talk about Europe, U.S. and Europe separately?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I do not know if I can detail unit growth in Europe off the top of my head, but I am happy to do it. I am prepared talk about the U.S., or if you want to talk on a global basis, we can do that.

Glenn Reicin - Morgan Stanley - Analyst

So why don't we do both? U.S. and global?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Okay. I think that you're going to find U.S. growth rates probably around 3% from a U.S. perspective, probably slightly higher outside the U.S. Probably closer to 4% or 5%.

Glenn Reicin - Morgan Stanley - Analyst

So you are saying price in the U.S. is 3% or 2%?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Price, well probably this last quarter, I do not think it added anything. Typically, it has added a couple of percentage points to the market growth.

Glenn Reicin - Morgan Stanley - Analyst

And then on a global basis this quarter you think it was flat, too?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

The price piece of it?

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Glenn Reicin - Morgan Stanley - Analyst

Yes.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I think price piece was probably pretty flat. It might have added a little bit, Glenn, but it is really on the margin.

Glenn Reicin - Morgan Stanley - Analyst

Okay, so you think that the market grew between 3 and 4% in total.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

On a global basis?

Glenn Reicin - Morgan Stanley - Analyst

On a global basis in Q3.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Yes, I think that's right. There is a heavy influence by the U.S. markets because it really accounts for half the heart valve market.

Glenn Reicin - Morgan Stanley - Analyst

And then what was your unit growth in Q3?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Our units were negative in Q3. We're talking about in the U.S. in particular?

Glenn Reicin - Morgan Stanley - Analyst

Yes.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I am just giving the U.S., because I think just to give you a perspective, what has gone on outside the U.S. in the third quarter has been very typical of what has been going on for the past several quarters, several years. So really, no change. I think from an analysis perspective, where you really see the change in the third quarter is in the U.S. And it is the biggest part of the market. Our units actually declined in the U.S.

So we still have price in the U.S., probably 3 or 4%, and we probably lost 3% and 4% in terms of unit decline in the quarter.

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Glenn Reicin - Morgan Stanley - Analyst

A couple of other clarifying questions. You said, I think, on your opening comments that in vascular, it was really stents that was driving everything. But then when Rick asked you a question about stents, you said it really didn't contribute much. So what is a number this year that we should be using for stents?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I am sorry if I misled you. But all of the growth in vascular came from stents. That was the driver. The base vascular business was essentially flat. What I am inferring is, that it has been typically growing strong, so quarter-over-quarter, we did not get a big kick out of stents.

Glenn Reicin - Morgan Stanley - Analyst

And you are saying \$11 million was year-to-date?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

\$11 million was year-to-date.

Glenn Reicin - Morgan Stanley - Analyst

Okay. So we can assume you're going to come in somewhere in the mid-teens for the year?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

That is correct. What we said last year we did eight. We said our goal was to double. We feel good about that.

Glenn Reicin - Morgan Stanley - Analyst

And then you said FloTrac would be around 15 this year?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

That is right.

Glenn Reicin - Morgan Stanley - Analyst

And then clarifying, when we look at '07, I know you're not giving guidance. You do have the perfusion business sale. Can you give us a sense what the gross margins were for perfusion?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Clearly, they were lower than the corporate averages. There are a couple of different pieces of perfusion that you have to take apart. There was the business in Japan, and we exited that one -- it was going to be first off this year. And we announced that we were going to be exiting our Brazil perfusion business, and actually that one is not closed yet. That should close before the end of this year.

Tom, is there anything to characterize in terms of margins on those businesses? They probably were in the maybe 30% to 40% range.

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Glenn Reicin - *Morgan Stanley - Analyst*

And you said it was around \$2 million of net income in total?

Michael Mussallem - *Edwards Lifesciences - Chairman and CEO*

I'm sorry, say that again.

Glenn Reicin - *Morgan Stanley - Analyst*

On the last press release, I think you said it was around \$2 million in net income on the business you're about to close.

Tom Abate - *Edwards Lifesciences - CFO and Treasurer*

That was the Brazil piece.

Glenn Reicin - *Morgan Stanley - Analyst*

Okay, I am just thinking about next year. So 30% to 40% and \$2 million in net income if we're trying to take that into accounts?

Tom Abate - *Edwards Lifesciences - CFO and Treasurer*

Right.

Glenn Reicin - *Morgan Stanley - Analyst*

Can you give us a sense of what happened with hemofiltration in the quarter? And I will get back in line.

Michael Mussallem - *Edwards Lifesciences - Chairman and CEO*

I know it has clearly been a contributor. We can look it up. I think it is in the neighborhood of 20% growth.

Operator

Glenn Navarro, Banc of America Securities.

Glenn Navarro

Just to follow up on the stents. What was the actual LifeStent number in the quarter? It looks like by my calculation it came in under \$4 million, which would be down sequentially. If that is the case, why would it be down sequentially when you are launching a new stent, and I am assuming there is going to be probably some buying into the marketplace?

And then secondly, on the RESILIENT, you said, if I remember correctly on the call, you were going to show us interim results. Is that interim safety results? Nine-month results? If you could just clarify that.

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Tom Abate - Edwards Lifesciences - CFO and Treasurer

In terms of the sales number, you are very close. We would say it's something just under four, which is a little bit weaker than the second quarter. But you remember two reasons -- the third quarter being the cycle that we are on to be in the lowest of our quarters; and secondly, we talked about the transition to the FlexStar. And we took this quarter to take an opportunity and actually be very aggressive with moving to the new delivery system, which puts us in a better position for fourth quarter; but had a slight impact on the third quarter itself.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Did you follow that part of it, Glenn? So in other words, we even have some returns and so forth just because of the way we did this aggressive swap out. So we really did not get a kick out of growth in the third quarter and we had our normal seasonality. And so we would expect to see the difference in the fourth-quarter.

Glenn Navarro

So when you do the returns, does that mean that there could be in one of your hospitals, for instance, a few days where they actually do not have the stents on the shelves and therefore do not use it?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Yes, exactly. It is more an issue of having consignments in place right away. So getting the product there, but just a little bit of time we were working on the inventory. That is how we got the manufacturing performance. But there was a period where it was probably leaner than we would have liked.

Glenn Navarro

I understand. And then just the RESILIENT data?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Yes, on the RESILIENT data, I am not going to be able to tell you precisely what is going to be presented. What we are going to have here is substantially more data than has been shared in the past. I am not sure exactly how the clinicians are going to cut it, so in other words, how much six-month data there is going to be and how much one-year data, but I think we will have more of that than we have ever seen before. And I think we are going to be able to see more clear comparisons than we have seen.

That complete data set probably is not available until the first quarter, but I think this will be a pretty good leading indicator.

Operator

David Zimbalist, Natexis Bleichroeder.

David Zimbalist - Natexis Bleichroeder - Analyst

I am wondering if you could talk a little bit about your comments of parallel tracking or coincidental approval in Europe on Ascendra and the percutaneous version of that product. Is there anything you are doing in terms of pooling data on the devices, whether it is related to the valve material itself and can any of that translate to the U.S.?

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Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Yes, part of the discussion, as you can imagine as we go through, is that this is the same valve that is used with two different delivery systems. And so you get into the discussion from a regulator's perspective, is it one valve, two delivery systems?

So we're clearly able to make that sort of an argument. And so there is some rationale to say that as you are looking at the Ascendra valve that you can anticipate what performance looks like by looking at the percutaneous data. So you can potentially give regulators some comfort by sharing pooled data in that regard.

David Zimbalist - Natexis Bleichroeder - Analyst

And in the U.S. as well?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Well, to be precise here, of course we would do that. But I am not prepared to get into discussions of what that U.S. trial is going to look like. We are in active discussions and it is not productive for us to speculate on how that is going to come out.

David Zimbalist - Natexis Bleichroeder - Analyst

In the U.S., I am thinking more about the issue of the required number of people for a year of follow-up on the new material for the valve if you can pool Ascendra implants.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Because this is really a new valve platform, this is not one where we are going to necessarily just compare it to historical data. In this case, since this is a new valve, we will actually run a clinical trial here that will lay that out. And the actual numbers here are yet to be determined.

David Zimbalist - Natexis Bleichroeder - Analyst

Also, you made comments about St. Jude really impacting I guess it was your efforts to transition competitive accounts who have mechanical valves in the U.S., and they were essentially being successful in those accounts. Are there any other trends in where you're seeing St. Jude have more versus less traction? Are they in accounts with more than one tissue vendor already versus accounts where you are a sole provider? Can you give us any more color on that front?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I can give you a little more color. Recall we said last quarter we talked about trialing and we have continued to have reports from the field that people that have tried the BioCor valve are now switching back. And so that is still the case. But what we see is that St. Jude has gone to a greater number of accounts. And so they have gone to a larger group and you have new people that are basically trying that valve.

And so I think that number continues to grow. There may have been another 80 or 100 accounts that they have gone through in the quarter, but at some point here, just by its very nature, you are moving to smaller accounts.

David Zimbalist - Natexis Bleichroeder - Analyst

And then finally, on FloTrac, you said you have put the change in software in the field. I presume it is fully rolled out. Can you talk a little bit about what you are seeing in terms of sequential usage of the product with the new software? And, has the sales force actually been able to transition their time to new accounts versus going back to the old accounts?

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Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Yes, the rollout of the software has gone very well. I think it is in those accounts at this point. We have tried to move very aggressively on that. It just makes it better for clinicians because as we gain more experience, we find that there are certain patient groups we can track more accurately with the software just as we had gained visibility with that.

The new software itself is not extremely time-consuming for our sales force, so that really has not been a factor, if that is what you were sort of getting at. But there continues to be a long sales cycle in FloTrac, and we're working our way through that. But we are pleased with the uptake there. We have a combination of hardware and units, and we are continuing to see the actual disposables increase along the way. So the trends are favorable and we're going to hit our goals.

David Zimbalist - Natexis Bleichroeder - Analyst

Did you provide quarterly sales for FloTrac for the quarter?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I do not think we did. I think we have said this year that it is going to be in the midpoint of this 10 to 20 range, and it has been tracking and has had a nice lift. I guess that probably gets you pretty close. You can anticipate what that is.

Operator

Michael Weinstein, JPMorgan.

Michael Weinstein - JPMorgan - Analyst

Most everything was covered. I just wanted a little more discussion on two pieces. One was the valve market overall and the inroads that St. Jude is having in some of those accounts where you're seeing trialing. Does this price play a role in that at all, or is it just a relationship that opens some doors and gets some trialing?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

From what we have observed here, we really have not seen this to be a price issue. Their prices certainly are not what our prices are in Magna, but they certainly are comparable to our PERIMOUNT and our porcine prices. And it has not really been a price battle.

Michael Weinstein - JPMorgan - Analyst

Those of us who follow the ups and downs of the orthopedic industry, we spent the last few years wondering when they are going to introduce premium pricing products. And in the last couple of years, you guys have started the ability to do that. Help us get comfortable with this sustainability. I'm not talking this next quarter, but over the next couple of years of continuing to introduce products that have premium pricing to them.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I think maybe the best predictor of future performance has been what has happened here in the recent past. And the U.S. is the biggest market, and that is the one that has been the biggest driver for us in terms of premium pricing. We introduced Magna in late '03, early '04. And that product has been priced at a 20% premium. It now is most of the units. It is the number one prescribed valve and it has continued to track at a 20% premium to our PERIMOUNT valve.

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And then a little better than a year ago, we introduced ThermaFix and actually ThermaFix has demonstrated it has been able to command an additional 10% premium on top of that. And today, out of all the Magna valves sold, Magna with ThermaFix is actually selling over 50%, just over 50% of the total volume is Magna with ThermaFix.

So, people are clearly gravitating toward the premium products and willing to pay the price. And so our belief is that considering the small amount of the total procedure cost that is the heart valve itself, with the premium that the new products command is certainly one that offers good value to clinicians and patients.

Michael Weinstein - JPMorgan - Analyst

Just one more question. It was really already asked, but I just want to circle back. St. Jude has said their tissue valves are actually down \$0.5 million sequentially. So they did not see not take up sequentially year-over-year, but obviously it still did. So if they did not pick up versus the second quarter and you guys obviously came in light of what you thought you'd do this quarter, are there any issues with the overall market and what we are seeing with the total procedures? We just think that this is a blip on the screen.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Yes, we really think that is normal fluctuation. We do not think there's anything unusual going with the market at all.

Michael Weinstein - JPMorgan - Analyst

And no concern that we are far along up the penetration curve on the switching mechanical to tissue, that maybe that's getting to the point where that move is slowing?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Clearly I think part of what it suggested to us is they are actually accelerating that and that the mechanical valves that we would typically see come and be part of the Edwards growth rate - converting a mechanical valve to a tissue valve - that number really got smaller for us in the third-quarter than we had typically seen.

I do not think that is because the conversion has slowed down. I think it is because we had this competitor who has relationships with all these mechanical valve guys that really helped drive that conversion.

Operator

Amit Bhalla, Citigroup.

Amit Bhalla - Morgan Stanley - Analyst

Are you still planning on introducing any repair systems in the fourth quarter? This is something you've talked about on prior conference calls.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Yes, we are. The only reason that I have not given you details on that is just for competitive reasons. We thought we would not necessarily introduce it on this call. But yes, we are still planning on that. It is going to be a premium product. It is going to be more disease-specific for a currently unmet patient need in mitral valve disease.

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Amit Bhalla - *Morgan Stanley - Analyst*

So is that still on track for early fourth-quarter or can you give me some better sense there? I want to understand if there is going to be a contribution here.

Michael Mussallem - *Edwards Lifesciences - Chairman and CEO*

Yes, I think we are actually going to begin the introduction this month and start ramping up from there.

Amit Bhalla - *Morgan Stanley - Analyst*

Can you give us a sense of what FloTrac sales were through the first three quarters of the year? You did that for LifeStent, so could you do it here for FloTrac?

Michael Mussallem - *Edwards Lifesciences - Chairman and CEO*

That is a fair question. Let's see if we can dig that up here. Tom said just under \$10 million.

Amit Bhalla - *Morgan Stanley - Analyst*

Lastly, on the heart valve therapy sales force, were there any changes in the incentive structure this past quarter or have it been business as usual in terms of how they were performing?

Michael Mussallem - *Edwards Lifesciences - Chairman and CEO*

I am not aware of any substantial changes to the sales structure or sales compensation for our people this quarter.

Amit Bhalla - *Morgan Stanley - Analyst*

Lastly, last quarter you mentioned that St. Jude had an impact on your mitral valve sales; you specifically highlighted that. Is that still the case or is it strictly the mechanical valves sales?

Michael Mussallem - *Edwards Lifesciences - Chairman and CEO*

Actually, just to be a little more precise on that. We felt it in the aortic as well as the mitral just because the aortic is a much higher-use position, although the size was somewhat similar in terms of number of units in both mitral and aortic. It is a bigger percentage of the mitral. We continue to feel it on the mitral side on a percentage basis more than on the aortic side. Both of those though, have a mechanical valve component to it.

Larry Keusch - *Goldman Sachs - Analyst*

Hi everyone. This is actually Charlie Chon on for Larry. I actually just want to switch gears here a little bit and get a better feel for how some of the other launches might be going. First of all, can you give me an update on the rollout of MICO? Have there been, and if so, what kind of challenges have you had to contend with on the rollout of the product? Perhaps, if possible, could you share what doctors might be saying about MICO when comparing it to your more conventional cardiac-output monitoring system?

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Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Thanks. Just for a reminder for the audience, MICO referred to minimally invasive cardiac-output and then we subsequently named that product FloTrac. We are very optimistic about FloTrac. We look at FloTrac as having the ability to help transform the critical care business into a fast-grower. So, as you know, traditional critical care has grown in the low single-digits and we think that with FloTrac we have already been able to push it into the high single-digits and we would like to think that we can push it over 10% with these new technologies.

The uptake of this has been pretty much what we predicted. It's been solid, but certainly not spectacular; but we did not expect that. These are very deliberate decisions that get made in critical care units. There are very large committees that include anesthesia and intensivists and nursing and people from the OR as well.

And so these actual conversion trials tend to take six months or more, from when we start them until we actually get a decision made. The comments we get are that certainly this is much easier to use. You do not have to float a swan. You do not need a clinician to be engaged, and actually nursing can put one of these in place. And you get instantaneous output.

The challenges have been if it is accurate because people come to trust the Swan-Ganz Catheter as the gold standard, and because they are treating these critically ill patients, they are giving it a very tough look in terms of accuracy. We are working our way through that.

And then for those that are more skeptical, there is a cost-effectiveness discussion. And we believe that ultimately the data will present itself and we are doing studies in that regard that speak to the fact that we think actually there is going to be savings involved because when you monitor a patient you can more accurately prescribe their drugs and really target their therapy such that their stays in the critical care unit, for example, can be shorter.

So that is sort of the big picture. Does that get at it?

Larry Keusch - Goldman Sachs - Analyst

It sure does. Thanks. That is terrific. And just another product line question for you on Optiwave 980. And please forgive me if I missed this on the call. Are you still maintaining prior revenue guidance of \$3 million to \$5 million for the full year? And also could you just run through what needs to happen to get this business off the ground going forward? What sort of challenges are you facing here?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

As a matter-of-fact, last quarter we said that we expected full year sales of Optiwave to be \$3 million. Since that time, we continue to encounter some liability issues that have caused us to slow down. So it did not contribute much in the third quarter. We do not think it is going to contribute much in the fourth. So we will do less than that. We will be closer to \$1 million.

What really needs to happen is we need to improve the robustness of this product platform. We still love the laser energy. There still is a big need for valve patients to get their atrial fibrillation treated. But our system just has not met our standards of reliability, and it is not that the procedure does not work. It is that our boxes don't necessarily fire up the way they should.

And that is what we have been working on, and the team there is hopeful that we will have that turned around shortly, but frankly, I do not think it is going to have an impact on 2006.

Operator

Jason Mills, First Albany capital.

Jason Mills Analyst

With respect to St. Jude, back to that just a little bit, in some ways I suppose you could say that Edwards experienced similar competitive ire, if you will, a few years ago from Medtronic, although it was not necessarily product-driven. It was more of a marketing focus-driven initiative for Medtronic.

You responded I believe at that time with sales force expansion and some surgeon education programs. How will you respond to it this time or how have you? Could you discuss initiatives that are either underway now or under contemplation?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

There are some similarities. The way we responded last time was -- as you correctly pointed out -- was with sales force, it was with head-to-head comparisons of product. And it also was with a new product. And actually all those are going to be key components to turning this around as well.

We are already engaged in being able to talk about the attributes of our product line and we are very happy and think we come out on the positive side of that. We are always assessing the size of our selling organization and have not been shy about adding sales force, and we will continue to take that sort of stance. And you know where we are on the new product front. We have a jam-packed pipeline. We are hoping that we can make those products count. That is what is going to be a real trigger here for substantial growth.

Jason Mills Analyst

So are there any similarities to what is going on in the ICD market? Is there a need for expanded sales initiatives, referral initiatives into the referral source for heart valves?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

We have had a very predictable heart valve market that is consistently grown at 5% and there has been a consistent conversion from mechanical to tissue that has caused tissue to grow at 10%. And so we do not have that sort of market development effort in front of us like you do in ICDs.

What we do have, though, is upside. Because there are so many untreated patients and we are still starting to uncover that. If we can do the same kind of thing that is happening in ICDs, we can have the heart valve market grow much faster than it has traditionally grown.

But no, what you're seeing right now in the U.S. is more people taking share from each other, not really any sort of an indicator of market growth from our perspective.

Jason Mills Analyst

Thank you for that. That is precisely my point. Are these patients, you mentioned 30% to 40% to 50% of aortic stenosis patients, being treated? Is there something that you can do to get these patients in to see their surgeons?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

What we are mostly trying to do at this point, and we're not sure how fast we can actually drive the market -- first is to put the spotlight on them. That was largely unknown, and I think it was largely unknown by surgeons, and I do not know if it was known by cardiologists, but it probably was not focused on by them. So we're going to do everything we can to generate the data and get the spotlight there.

And what it is going to call into question is why are these patients not being treated? Now, are they going to change their treatment patterns when the option is surgery? We hope so. We are going to push at that. Do we think it will change their treatment patterns when the options become minimally invasive surgery and become transcatheter? We think certainly. We think that is where the big growth opportunity is.

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Jason Mills Analyst

Clearly the percutaneous valve initiative is an important one for you and the long-term growth strategy to not only protect, but I'm sure you're hoping to expand your valve leadership position. So that being said, in the near-term here, and we are just hearing a little bit of this from channel, but maybe it is coming from St. Jude reps -- are you experiencing any adverse impact to your heart valve therapy business near-term owing to some cardiac surgeons' frustration possibly with the amount of resources and emphasis you're appropriating to this technology that may in fact marginalize them as stents marginalize CABG, if you will?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

We do hear back from our sales force that we have some competitors that are talking about that, which I think is kind of interesting. There is probably no company that drives more sales or generates more new products for surgeons than Edwards. But some people actually are trying to paint us as somebody that is working against surgeons, which is absurd.

Frankly, our sales force has not said it has really had any impact on our procedures. And one of the things that we are quite proud of here is that we have this new Ascendra procedure coming, which is a great opportunity for surgeons to actually apply this transcatheter technology themselves.

Jason Mills Analyst

Just one or two more and I will get back in queue, and you are queuing me up because my next question was on Ascendra. I am just wondering why that product couldn't track to a more expeditious regulatory timeline. Maybe I'm thinking about this incorrectly, but it would conceptually maybe a step between an open heart and transcatheter may be easier for the FDA itself to conceptualize. Am I completely off my rocker here or is it possible that you could expedite Ascendra beyond a simultaneous path?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I think we would like to add you to our regulatory team. I think your arguments are terrific. No, but frankly, what is behind this as well is it is a new heart valve; and so I think the FDA is going to require that we go through some sort of a clinical trial to get this heart valve approved. Even though there may be some biases inside to cause the FDA to feel more comfortable with a great track record of surgery today.

Jason Mills Analyst

Last one, I promise. Your debt to cap, lowest level I think it's since you have been a public company, maybe ever. Will you use debt to acquire growth in core tangential cardiovascular markets?

Tom Abate - Edwards Lifesciences - CFO and Treasurer

You know, we said all along that our uses of cash, and I think that applies to debt equally, our priority would be to find things that add growth. Whether it is today or the future, one way or the other, it has to be close and stretch strategically; but yes, I think there is no hesitation there. It is not a target we shoot for. We're really not trying to maximize our debt to cap or minimize our debt to cap ratio.

Jason Mills Analyst

And, is there more opportunity there? Sarbanes-Oxley has really put the kibosh on a lot of smaller companies reaching profitability at a certain run rate.

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Michael Mussallem - Edwards Lifesciences - Chairman and CEO

You know what we focus on. We really have not changed our philosophy. We focus on heart valve therapy and critical care monitoring and critical vascular disease. And we continue to mind very aggressively those spaces; and if we thought there was something there that was a good addition, we would not hesitate. We would love to add it.

Operator

Alex Arrow, Lazard Capital Markets.

Alex Arrow - Lazard Freres - Analyst

My first question is about the longer skirt length to address the perivalvular leaks that you talk about adding to the Cribier-Edwards. You went over this a little fast, but how are you going to add that different valve to the inside of the catheter and not change the regulatory timeline since I think that would be a new valve and require new data?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I think the way this works is the FDA has a chance to assess what is different about this new valve. They get to decide whether they think it is very different. Remember what is going to happen here is we're going to go through a pivotal trial. And so it would be a different story if we changed the valve during the pivotal trial or after the pivotal trial, but we're talking about changing it first. And so we are just in feasibility right now, and the FDA has not judged that this is a substantial change.

Alex Arrow - Lazard Freres - Analyst

Next question is about the competitive impact you have been discussing either with the St. Jude valve or any other competitors; you mentioned the sales relationships as being a potential reason for the competitive trialing. Are any of the competitors bringing up durability? That has traditionally been your strongest suit. Is there anybody that's trying to attack you on durability, or are they not even touching that issue?

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

I think everybody probably goes through and muddies the water a little bit and talks about durability and tries to argue that durability is sometimes as good. We are the ones that drive the durability discussion for the most part. The things we do see occasionally, we see some competitors argue why don't you consider using our valve in really old patients because durability does not matter, you do not need such a good valve? We're not sure that is really a discussion that is going to go very far.

Operator

Mr. Erickson, there are no further questions at this time. I will turn the floor back over to you for any closing comments.

Michael Mussallem - Edwards Lifesciences - Chairman and CEO

Okay, thanks for your continued interest in Edwards. Tom, David and I welcome any additional questions by telephone. Back to you, David.

David Erickson - Edwards Lifesciences - VP - IR

Thank you for joining us on today's call. Reconciliations between GAAP and non-GAAP numbers mentioned during the call which include underlying growth rates and amounts adjusted for special items are included in today's press release and can also be found in the Investor

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Relations section of our website at Edwards.com. If you missed any portion of today's call, a telephonic replay will be available for 72 hours. To access this, please dial 877-660-6853 or 201-612-7415. Use account number 2995 and the pass code is 216570. (Repeats numbers.)

Alternatively, you can access an audio replay which will be archived on the Investor Relations section of our website. Thank you very much.

Operator

Thank you. This does conclude today's teleconference. We thank you for your participation and you may disconnect your lines at this time.

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