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Conference Call Transcript

EW - Q4 2006 Edwards Lifesciences Earnings Conference Call

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Greetings, ladies and gentlemen, and welcome to the Edwards Life Science's fourth quarter 2006 earnings conference call. At this time, all participants are in a listen-only mode. A brief question and answer session will follow the formal presentation. [OPERATOR INSTRUCTIONS] If anyone should require operator assistance during the conference, please press star zero on your telephone key pad. 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 - IR

Welcome and thank you for joining us today. Just after the close of regular trading we released our fourth quarter 2006 financial results.

During our call today, we'll focus our prepared remarks on information that complements the material included in the press release and financial schedules and allocate the remaining time for Q&A. Our presenters on today's call are Mike Mussallem, Chairman and CEO and Tom Abate, CFO and Treasurer.

Before I turn the call over to Mike, I'd 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 2007 financial goals for sales, gross margin, net income, earnings per share, and free cash flow. Regulatory approval of new products in and competitive dynamics associated with our heart valve therapy product line, the continued adoption and sales of FloTrac and LifeStent. The success of our RESILIENT clinical trial. The timing and progress of clinical studies related to transcatheter valve technologies and the market opportunity for these products and the impact on our results on 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 differ materially 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'll turn the call over to Mike Mussallem.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Thank you, David. 2006 was a solid year for Edwards with total underlying sales that increased 6.3%. Our market leading heart valve therapy franchise continues to be an ideal platform for future growth, however, our sales performance was lower than we expected last year at 5.2%. At the same time, our critical care and vascular franchises emerged as increasing contributors to our underlying sales growth in critical care of 8.6% and a healthy 14.7% growth in vascular. For the year, we met or net income and cash flow goals and exceeded our earnings per share guidance.

Further, we're able to grow net income while increasing R&D investment. With total sales of 1.037 billion, we achieved our original goals of sales between 1.020 billion and 1.060 billion and excluding stock option expense in special items we improved our gross margin 190 basis points and achieved net income growth of 13.2%, which was within our original 12% to 15% range. We continue to generate strong free cash flow this year totaling \$150 million, which was at the high end of our \$140 to \$150 million range. And we finished the year with a very strong balance sheet. As we've done consistently since becoming a publicly traded company almost seven years ago, we continue to prioritize investments in 2006 and sharpened our strategic focus on opportunities that provide greater growth potential.

During the year, we discontinued our Laser Ablation program and divested our remaining profusion products business. Additionally we sold our angiogenesis program and a small pharmaceutical product line.

In our innovative transcatheter valve programs, we completed enrollment of our 55 patient US feasibility study and generated very promising results. We also completed more than 80 transcatheter cases in Europe and Canada and introduced our new SAPEIN valve, which incorporates the latest Edwards Valve technology.

Now turning to fourth quarter results on a reported basis, total sales grew 6.4% to \$266 million and grew 5.7% on an underlying basis. Reported sales for heart valve therapy grew 5.8% to \$121 million, which included a \$2 million contribution from foreign exchange. Our Premium Tissue Value and Repair products including Magna and Magna with ThermaFix were the primary contributors to our growth offset by the continuing decline of Mechanical and Porcine Valves. U.S. Heart Valve sales were sequentially stronger in the fourth quarter. Our Aortic Valves showed healthy growth although mitral sales were below our expectations. Our PERIMOUNT mitral valves are considered by many clinicians as superior in terms of durability and hemodynamic. However, some perceive them to be more challenging to implant. We expect the launch of Magna Micro to fully address this issue and we continue to expect FDA approval in the fourth quarter of this year.

Our premium Magna Aortic Valve remains the number one tissue heart valve worldwide representing over half our Global Aortic Sales. The recent addition of our Proprietary ThermaFix Tissue Treatment, continued to drive Magna sales growth and increase its value. We expect strong customer adoption of these market-leading products to continue. Global heart valve repair sales demonstrated another quarter of strong growth driven by the continuing adoption of our newest disease-specific products, including the MC Cubed, IMR and GeoForm Rings.

For years, Edwards has held strong convictions about the life style benefits of tissue valve and the avoidance of long-term anti-coagulation required with mechanical valves. The growing body of clinical data highlighting the significant compromises to the quality of life associated with mechanical valves has led to recent changes in the ACCAEA treatment guidelines. As we stated at our investor conference, we've decided to exit the mechanical valves segment in 2007. Sales in this product segment, which were approximately \$12 million in 2006 will be roughly half that amount this year.

At the SDS Cardiac surgeon meeting last week, we announce the U.S. launch of our Aortic PERIMOUNT Thelon Valve and the Myxo ETlogix Micro Repair Ring. The introduction of the new Theon Valve offers clinicians the proven durability of our PERIMOUNT Aortic technology plus ThermaFix. The Mitral Ring is the first mitral valve repair product specifically designed to address the unique needs of myxomatous disease with the ring that can reduce implant challenges and facilitate reproducibility. Both of these products were well-received and will contribute to our growth in 2007.

Also at the SDS, we launched Edwards One, a cardiovascular education program to help prepare surgeons for future technology innovations. Edwards One, provides cardiac surgeon with exposures to innovative heart valve technologies, basic transcatheter training and education about the underserved heart-valve patient population. The Edwards One basic endovascular skills simulator training generated a tremendous amount of surgeon interest. Two additional product launches planned for 2007 include our next generation aortic valve in Europe, the Magna Ease and a new PERIMOUNT mitral valve in Japan. Several Magna Ease implants have already taken place. Its low profile makes it easy to implant, even in patients with small aortic roots or a-typical coronary anatomies. Magna Ease builds on magna's best in class hemodynamics and ThermaFix enhanced tissue treatment.

In Japan we continue to expect a first half approval of our PERIMOUNT mitral valve which represents the first new PERIMOUNT valve approved there in several years. Overall, the strength of our product portfolio and customers' preference for our clinically superior products gives us confidence that we'll increase our heart valve therapy growth rate throughout 2007.

Our critical care franchise is transforming into a faster-growing and increasingly profitable product line and this quarter's results continued that trend. For the fourth quarter, reported sales grew 11.5%, which included \$1.7 million contribution from foreign exchange. Sales of FloTrac were the biggest growth driver this quarter and we achieved our targeted full-year sales of more than \$15 million.

Sales of core critical care and hemofiltration products also contributed to our fourth quarter results. I'll remind you that our core critical care business is made up primarily of cardiovascular monitoring systems. Edwards continues to maintain its global leadership position in Hemodynamic monitoring with our Swan-Ganz catheters, which are used to measure a patient's heart function in surgical and intensive care settings. The majority of our sales are comprised of our advanced technology catheters, which provides this information on a continuous basis. This product line, which is considered the gold standard in the industry enjoys very strong customer loyalty and sells at a premium.

Edwards is also the world leader in disposable pressure monitoring products and has continued to gain share in this relatively stable market. A smaller portion of our critical care product line, but one that's been growing quite well in recent quarters is our European-based hemofiltration business, which provides continuous renal replacement therapy.

The most recent addition to our critical care portfolio is FloTrac which measures hemodynamic parameters with a high degree of accuracy, but in a much less invasive way. It is also considered best in class in terms of ease of use. We believe these attributes make FloTrac an ideal product for a much larger population of patients. FloTrac continues to enjoy growing adoptions in all regions, particularly in Japan where the products minimally invasive characteristics are highly valued.

Studies that seek to demonstrate both the accuracy and cost effectiveness of this technology will be completed by the end of this year and we expect those findings to help us sustain FloTrac's growth for the next several years. For 2007, we expect FloTrac sales to be double the level reported in 2006.

In our cardiac surgery system franchise, reported sales for the quarter declined 15% due to the discontinuation of our Japan profusion products business in 2005. Excluding the impact of the divestiture and a modest foreign exchange gain, underlying sales were 8% lower as a decline in TMR sales overshadowed growth from share gains in our cannula business. Reported sales for the year declined 13% while underlying sales were essentially flat.

Additionally, at the end of the quarter, we completed the sale of the Brazil-based international profusion business, which was announced last August. As we mentioned at our investor conference in December, we decided to exit our Laser Ablation program after concluding that the

surgical demand was not as robust as originally believed and the technology would have required substantial investment. The resources for this program have been redirected to more promising strategic opportunities.

Total reported vascular products grew 21% this quarter. On an underlying basis, excluding the impact of foreign exchange, vascular sales increased 18% for this quarter and 15% for the year. Growth in this product line was driven by peripheral stents where we achieved our goal of doubling LifeStent sales in 2006. Sales of base vascular products grew modestly in both the fourth quarter and for the full-year. Our recently launched FlexStar self-expanding stent delivery system, which helps ensure the easy and accurate delivery of our uniquely flexible stent technology continues to generate positive customer feedback. Together with our line of longer stents, we remain competent in our ability to double stent sales again in 2007.

During the fourth quarter, we began a substantial increase in our U.S. sales force and expect to be at 40 by the end of the first quarter. During 2007, we'll continue to add sales resources in a disciplined manner. At last week's ISET peripheral vascular conference, Dr. Barry Katzen presented 12-month interim results from our resilient trial which demonstrated robust outcomes with our novel flexible stent design. Further he reported a low fracture rate, 80% clinical patency and no safety issues. We now anticipate submitting our PMA for an SFA indication in the second quarter to incorporate acute data from both FlexStar and our longer stents. We continue to anticipate LifeStent approval by the end of the year.

Finally, during the quarter we successfully completed the sale of our angiogenesis program to Sangamo. The transfer allows this important program to continue and preserve the continuing economic interest while freeing up additional Edwards resources to drive more strategic R&D priorities.

In summary, for full-year 2007, we're projecting total reported sales dollars of 1.075 billion to 1.125 billion assuming current foreign exchange rates. This guidance incorporates an estimated year-over-year reduction in sales from discontinued products of approximately \$36 million. For heart valve therapy, we continue to expect total annual sales of \$520 to \$540 million. We expect heart valve sales in the first quarter of 2007 to be between \$130 to \$135 million with growth ramping up throughout the year. In critical care, we project reported sales of \$375 to \$390 million for the full year 2007. In cardiac surgery systems we project the annual sales of \$65 to \$70 million, in vascular we project sales of \$85 to \$95 million for the year, and lastly we expect annual sales of other distributed products to be between \$25 and \$30 million. All of these projections assumed foreign currencies remain at current levels. For the first quarter of 2007, we're projecting total reported sales of \$263 to \$273 million.

Turning to our valve programs, we made significant progress in our Aortic Replacement program in 2006 from both the clinical and product development standpoint. In addition to completing enrollment in our 55-patient transfemoral US feasibility trial, we developed a transcatheter procedure and demonstrated its feasibility in European and Canadian studies. Additionally, we initiated a transcatheter US feasibility study and began enrollment during the fourth quarter.

During the fourth quarter, we also introduced the Edwards SAPIEN, our next generation transcatheter valve, which is already been used in clinical studies in the U.S., Canada, and Europe. SAPIEN takes advantage of all of our core heart valve manufacturing capabilities and technologies including bovine tissue, precise tissue characterizations, and our ThermoFix tissue treatment. The SAPIEN valve is delivered using either our RetroFlex system through a transfemoral approach or our Ascendra system through a transcatheter approach. Transcatheter valve technology is highly complementary to our existing heart valve business as it offers treatment option to a large, currently untreated population. Additionally, having two delivery systems uniquely positions Edwards to partner with both cardiac surgeons and interventional cardiologist to treat the broadest range of high-risk patients.

With more than 300 transcatheter implants to date, Edwards remains the clear leader in transcatheter heart valve field and most importantly remain confident that we can begin our U.S. pivotal trial during the current quarter and continue to expect receipt of a CE mark by the end of this year. In anticipation of our European launch, we are actively engaged in the variety of pre-commercialization activities. We're continuing to train interventional and cardiac surgeon teams using advance simulation training, case observation and proctoring. In order to expand the number of available clinical reference centers. In addition, we're making progress in securing reimbursements in key European countries.

Our Monarch annuloplasty system has demonstrated an excellent safety profile and ease of use in its own feasibility studies. We remain focused on completing enrollment of our 60 patient EVOLUTION I feasibility study by the end of the first quarter. If data continues to be encouraging and feasibility is established, we plan to initiate the evolution to follow-on trial, which will also measure clinical and quality of life end points. Data generated from EVOLUTION II would support a CE mark and additionally support a US pivotal trial which we could start as early as next year. Now, I'll turn the call over to Tom.

Tom Abate - Edwards Lifesciences - CFO

Thanks, Mike. Our solid fourth quarter financial results included continued strength in our gross profit margin and strong free cash flow. Reported earnings per share for fourth quarter were \$0.34 compared to \$0.61 for the prior year. Excluding special items and option expense, our fourth quarter non-GAAP EPS grew to \$0.61 compared to the prior year of \$0.53, a 15.1% increase. For the full-year 2006, our non-GAAP EPS increased 14.6% on a year-over-year basis. For comparative purposes to the first [call being] estimate of \$0.53, our non-GAAP EPS should include the impact of stock option expenses. Including option expense, our non-GAAP EPS was \$0.55 for the quarter and \$2.06 for the full year.

To assist you with future comparisons, we will be posting on our website a 2006 net income reconciliation that excludes only special items. For the fourth quarter, our gross profit margin was 63.3% compared to 64.1 in the same period last year. Excluding a \$2 million inventory write-off related to the discontinuation of the Company's Laser Ablation sale and the impact of option expense, gross profit margin for the quarter increased to 64.3%. For the full-year, excluding these adjustments, the gross profit margin increased 190 basis points to 64.4%. Excluding special items, we expected an improvement of 100 to 150 basis points in 2007 to more than 65%.

Fourth quarter SG&A expenses were 95.1 million for the quarter or at 35.8% of sales, including a 1.2% impact from option expense compared to 34.9% in the year ago period. For 2007, we expect SG&A as a percentage of sales to be approximately 36.5%. In the fourth quarter, R&D investments grew \$4.2 million to 30 million or 11.3% of sales. Excluding option expense of \$1 million, R&D was higher than last year as a result of additional spending on our transcatheter valve development programs. For 2007, we expect R&D investments to be approximately 11% of sales. Net interest of 400,000 was \$1 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 lower average debt balance.

For 2007, we expect net interest expense to be less than \$500,000 per quarter. During the quarter, we recorded special items that resulted in a net \$18 million pretax special charge. The components were a \$10 million obligation for achieving a clinical success milestone related to our 2004 acquisition of transcatheter heart valve technology from PVT. A previously disclosed \$6.8 million loss related to the exit of our Laser Ablation program and a \$7.3 million global realignment charge. These charges were partially offset by \$6.1 million gain on the sale of our angiogenesis program.

Additionally, during the quarter, we settled prior year tax audits resulting in a \$3.2 million income tax benefit. These items plus the \$2 million inventory write-off impacting gross profit margin resulted in a reduction to net income of 13 million. A net income reconciliation table accompanies the press release.

For the fourth quarter, our reported tax rate was 12.7%, excluding special items and option expense, our effective tax rate was 23%. The 23% includes a favorable \$800,000 impact from the renewal of the federal R&D tax credit.

For 2007, we expect our rate to be approximately 26%. When compared to the same quarter last year, FX rates positively impacted fourth quarter reported sales by \$4.7 million. This was substantially offset on the bottom line by our hedging program and natural hedges. At current FX rates we estimate a small benefit to 2007 sales. Free cash flow generated during the fourth quarter was 53 million, which we defined as cash flow from operating activities of 70 million minus CapEx of 17 million.

For the full year 2006, we generated record free cash flow of 150 million. For 2007, we estimate free cash flow of \$160 to \$170 million. During the fourth quarter we repurchased approximately 426,000 shares of common stock for \$18.7 million. For the full-year, we repurchased a total of 3.3 million shares or \$146 million.

Turning to the balance sheet, long-term debt at December 31st was 236 million. Net debt at the end of the quarter was 53 million, a decrease of 49 million from the third quarter. Including receivables in our asset back securitization program days sales outstanding for the quarter improved to 67 days, inventories decreased by \$7 million from the prior quarter. The impact on net income related to stock option expense this quarter was \$3.7 million or approximately \$0.06 per share. For the full year, our total cost was \$0.21 per share. And with that, I'll turn it back over to Mike.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Thanks, Tom. Overall, we're pleased that we once again increased the value of Edwards in 2006. We look forward to 2007 with great enthusiasm highlighted by the expected start of our U.S. pivotal trial and receipt of a CE mark for our Transcatheter Aortic Valve. We will remain focused on achieving our previously stated financial goals which include generating total sales dollars between 1.075 billion and 1.125 billion, increasing our

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gross profit margin from 100 to 150 basis points, delivering non-GAAP net income growth of 12% to 14% and generating free cash flow of \$160 to \$170 million.

Finally, we estimate that first quarter 2007 diluted EPS will be between \$0.55 and \$0.57 and for the full year between \$2.28 and \$2.37. And with that, Tom and I are ready to answer your questions.

QUESTION AND ANSWER

Operator

Thank you. [OPERATOR INSTRUCTIONS] Our first question is coming from Tim Nelson with Piper Jaffray. Please proceed with your question.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Tim, are you there?

Tim Nelson - Piper Jaffray - Analyst

Can you hear me?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Now, we can.

Tim Nelson - Piper Jaffray - Analyst

Just a couple questions on the quarter particularly in the heart valve group and surgery. Can you tell me what the repair rate was? You said it was stronger than the underlying heart valve business? How did that grow geographically?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, I think the growth rate in was right around 10%.

Tim Nelson - Piper Jaffray - Analyst

So that continues in line with the previous targets. Is that equal OUS in US?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, it's very similar.

Tim Nelson - Piper Jaffray - Analyst

When I look at the -- you also mention that in the surgery side that TMR sales were down. It's been a while since we've checked in with you on how those were going. Could you give us a little bit more granularity to that?

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Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Sure, Tim, let me take a quick look. The TMR sales declined, Tim around \$1.5 million verses the prior year.

Tim Nelson - Piper Jaffray - Analyst

Okay.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

That's not typical of what we've been seeing. And that was really lower hardware orders.

Tim Nelson - Piper Jaffray - Analyst

Okay. A minute for your heart valve guidance and the growth rate for the year verses what we're looking at for next year. You grew 5%, I believe for the year and underlying basis and if you take the midpoint it's going to be around 8% for the year. How do you think about that in terms share gain, price increases? I know you've got new products are going to come along and the underlying growth in the market, I assume nothing's changed with that. How are you going to get that growth rate up?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, Tim, a couple things. One is the guidance that we gave at the investor conference for heart valves I think was in the 7 to 11 range. And we continue to believe that that's the range that we're going to operate in. And I think hopefully that is consistent with the numbers that you have. A couple of things in 2006, we felt that we realized the impact in that valve that was improved in the U.S. and we believe that the impact of that will be greatly diminished during 2007. So we expect a growth rate to start picking up throughout the year, probably be more than, at least at the level, probably more than it in Q1 and stepping up throughout the year, Tim. And other things that turn out to be variables are the new products that are approved. And Mitral Magna we expect to be a lift when that's approved. And right now we're anticipating fourth quarter approval.

Tim Nelson - Piper Jaffray - Analyst

So given -- that being the biggest impact on average selling price, I would think that most of your growth increase is going to have to come from increased units, is that a fair assumption?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, I think most of the increase will come from units as opposed to price.

Tim Nelson - Piper Jaffray - Analyst

And then, I didn't hear how the RESLIENT trial turned out. There was a low fracture rate, can you tell me specifically what it was?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, I think the fracture rate was 3 and change. So it was between 3% and 4% was the fracture rate that was reported on the 12 month results at the meeting. And then we feel that that's substantially better than how other stents performed in the SFA.

Tim Nelson - Piper Jaffray - Analyst

And that's not the -- that included the longer versions?

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

There's not data on the longer version. These are the stents that would have gone through the trial. One of the things that we'll be doing is data on the longer version of the stents, as well. Tim, we probably need to let other people get in the queue.

Tim Nelson - *Piper Jaffray - Analyst*

Thanks.

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

Thanks.

Operator

Our next question is coming from Dhulsini de Zoysa with Cowen & Company. Please proceed with your question.

Dhulsini de Zoysa - *Cowen & Company - Analyst*

Hi, good evening. Wondering if you could just clarify, did you say that Theon and Myxo are in full launch in the first quarter? Or do you expect that to roll out sort of closer to Q2 or mid year?

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

Yes, thanks. Actually at the meeting which occurred just last week, we did a full launch of both of those products. And so those are in full swing.

Dhulsini de Zoysa - *Cowen & Company - Analyst*

Okay, so by the second half any sort of guess of what percentage of your mix beyond will be in the U.S.?

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

You know what? We think that the Theon Valve will contribute, but compared to how much Magna and Magna ThermaFix is, it's going to be relatively small. What we continue to see is just the growth of the combination of Magna and Magna with ThermaFix and that actually is going to be a greater factor even though we're going to get growth.

Dhulsini de Zoysa - *Cowen & Company - Analyst*

Okay. That's the easy one that I knew you'd answer. Here's one I'm not so sure about. Looking ahead to the U.S. pivotal, for SAPEIN can you talk about your -- how you're thinking about site selection? I know there's a lot of interest in participating, but obviously not everyone has an integrated OR case lab facility. So site selection, physician training, and patient selection, those three seem key to favorable outcomes.

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

Yes. Those are all obviously key factors. And the FDA's going to have something to say about it in terms of how many centers that we get to put on. But one of the things that we know is having very well trained clinicians having real partnerships between surgery and cardiology and having folks go through sufficient training and this is the combination of some simulator training and some proctoring really allows them to come up to

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speed. I would anticipate that we're going to continue to ramp those during the course of the year, but there's going to be many more centers that want to participate than are going to be required for the trial.

Dhulsini de Zoysa - Cowen & Company - Analyst

So you're comfortable with the simulation and some hands on training that obviously the results we've seen from Webb and out of Columbia are at kind of the high end of what we can expect --

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, one of the things that we felt good about, remember that we -- Dr. Webb did a contrast of his first 25 patients compared to the second 25 patients got much better results. Then when we flipped over to the U.S. trial, they pretty much replicated his results that he got with his second 25 patients. We think there is, this is something that's learnable. It can be learnable through the techniques we've just talked about. And we look forward to actually getting on a pretty good curve right from the start.

Dhulsini de Zoysa - Cowen & Company - Analyst

That's a good answer. Can I bother you for one more?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Sure.

Dhulsini de Zoysa - Cowen & Company - Analyst

What do you consider -- what do you think FDA would consider an acceptable perivascular leak in mortality rates?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

The FDA's going to have all of our data from our feasibility trial. And I think what we'd like to do is to replicate what we find in our pivotal trial what we saw in our feasibility trial. So I think if we find that, certainly we're on a path to a good approval. It'll go through the full trial protocol by comparison.

Dhulsini de Zoysa - Cowen & Company - Analyst

Thanks for answering all that. I'll get back in queue.

Operator

Our next question is coming from Larry Biegelsen with Prudential. Please proceed with your question.

Larry Biegelsen - Prudential - Analyst

Hi, can you hear me okay?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, Larry.

Larry Biegelsen - Prudential - Analyst

Thanks for taking the question. First, I had a question regarding the pivotal trial in the U.S. for the SAPIEN. I think at the investor conference you mentioned that you hope that the follow-up would be one year. Can you talk a little bit more about your degree of confidence in the follow up being one year verses say two years or maybe two year follow-up on cohorted patients?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Larry, is your question specifically about what will be the follow up period in the pivotal trial?

Larry Biegelsen - Prudential - Analyst

Yes.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

We decided we're not going to share details of what the follow up of the pivotal trial will be until we actually get it approved. Our clinicians were willing to speculate there would be a one-year follow-up. But we just decided we're not going to share details of how many patients we think it's going to be or how long the follow-up periods going to be.

Larry Biegelsen - Prudential - Analyst

Fair enough. Mike, at an investor conference in January, you said something to the effect when we think about our situation on cash these days, we're anxious to add growth opportunities. It sounds like something may be eminent. Can you give us a little more color on the type of addition you're looking to make?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, Larry. As Tom mentioned, we do have a strong balance sheet and we -- we are in a good cash position. And our first use of that would be to add sensible growth to our portfolio. And we exercise a very disciplined process as you're aware of. And there's really no change in that process from what we have done. We look for opportunities that lie close to home for us. We look at heart valve areas, look at critical care monitoring; we look at areas within the treatment of peripheral vascular disease. We also have discipline in the process. We haven't in many cases, even though we screen a lot of opportunities, we haven't necessarily pulled the trigger. We're going to continue to aggressively, screen, Larry, but I hope I didn't signal anything was eminent.

Larry Biegelsen - Prudential - Analyst

Thanks, I'll get back in the queue.

Operator

Our next question is coming from Paul Choi with Merrill Lynch, please proceed with your question.

Paul Choi - Merrill Lynch - Analyst

Hi, guys, can you hear me?

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Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, Hi, Paul.

Paul Choi - Merrill Lynch - Analyst

Thanks for taking the question. If you could maybe focus a little bit on the mitral side, Mike, with respect to your comments to the fourth quarter. Can you comment seasonal or one-time blip here, or is something the way physicians are thinking about the procedure that is making them reassess how challenging it is?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

It's a good question, Paul. You guys might be aware that the surgery in the mitral position is more difficult. It's a more challenging exposure than it is in the aortic. We keep hearing more comments back about ease of use. And this is growing as a factor compared to what we've heard in the past. And so we believe what we're seeing in the fourth quarter is more than just a little seasonality. We think there seems to be more interest in ease of use. And we're surprised sometimes that people are even willing to compromise on their valve design for ease of use. Not broadly, but in a small way, enough to make a difference on the margin. And it's one of the reasons why we have a lot of emphasis on Mitral Magna, which will give us all the advantages of great hemodynamics and great durability and TheraFix and still have a valve that's really easy to implant because such a low profile.

Paul Choi - Merrill Lynch - Analyst

That's great. But with your targeting the fourth quarter launch or potential approval for the Magna in the mitral position, is it your sense then that the growth you've been targeting for the heart valve therapy business will have to largely driven by your core aortic business with the Magna is that what I'm hearing?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, I think there's an element of that that's absolutely true. But at the same time, we expect repair to be a real growth driver in the mitral position, as well.

Paul Choi - Merrill Lynch - Analyst

Okay. Fair enough. And then lastly, with respect to the training that's going on in Europe, can you give us a sense of how many physicians you've had participate to date? And maybe a mix of whether it's surgeons versus cardiologists?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, I don't know if I can -- if I could rip off specific numbers, Paul. But we have probably a similar number of intervention and cardiac surgeons that have already been through the training. And our expectation is that we'd like to get somewhere between 10 and 20 centers up and going full blast before the launch, which will happen around the CE mark approval toward the end of the year. And that probably means that we'll have more than 100 clinicians that we'll want to have trained by that time. We'll be ramping up, pretty consistently throughout the year.

Paul Choi - Merrill Lynch - Analyst

Great. Thanks a lot, I'll jump back in queue.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Thanks, Paul.

Operator

Your next question is coming from Kristen Stewart with UBS. Please proceed with your question.

Kristen Stewart - UBS - Analyst

Hi, good afternoon.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Hi, Kristen.

Kristen Stewart - UBS - Analyst

I was wondering if you guys could talk a little bit about the Japanese market just in terms of what you're seeing from a reimbursement side with any kind of pressure there and also the valve opportunity and then also for FloTrac?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

And again you're talking about the Japanese market, Kristen?

Kristen Stewart - UBS - Analyst

Yes.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

First of all the heart valve market in Japan is a little larger than \$100 million. And it's been in the past it used to be, it's sort of trailing the U.S. and sort of having a large percentage of mechanicals. It's now at a place now where there's probably a few more tissue valves than mechanical valves, but there's still a lot of penetration to take place and that's why we're enjoying probably higher growth rates in Japan, sort of mid teens or even slightly north of that because we're seeing a conversion from mechanical valves to tissue valves. That continues to go well for us. And again, we're hopeful another new valve approved here in the first half and we'll continue that momentum. In FloTrac, the Japanese customers have a real attraction to less invasive products that can deliver precision. And so FloTrac really seems to hit the mark for this customer base. And we have seen very strong adoption. As a matter of fact, the adoption, the Japanese market has even exceeded what we've seen in the U.S. and Europe. And so there's, we expect this to be an important product line in Japan.

Kristen Stewart - UBS - Analyst

Anything on the reimbursement front in terms of cuts this year to look for?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

In Japan in particular, we already received reimbursement for FloTrac, I think in the second quarter of last year. So that's in place and that really does help us sustain and encourage a growth rate. In heart valves, we fall within existing reimbursement rates and so the new products are

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approved automatically are reimbursed. We think we're going to be in a robust position, even though there are some challenges sometimes with reimbursement rates in Japan, we don't expect to have an issue within heart valves or critical care going forward.

Kristen Stewart - UBS - Analyst

Last question is just on the RetroFlex II? Any update there?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

RetroFlex II still looks good, we're very encouraged by this design. We think it makes it easier to cross the aortic value with our THV and we continue to have its introduction by the end of the first quarter.

Kristen Stewart - UBS - Analyst

Thanks very much.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Thanks, Kristen.

Operator

Our next question is coming from Rick Wise with Bear Stearns. Please proceed with your question.

Gil Gabbay - Bear Stearns - Analyst

This is Gil Gabbay for Rick Wise, good afternoon.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Hi, Gil.

Gil Gabbay - Bear Stearns - Analyst

I had a quick question on the U.S. pivotal trial protocol has that been finalized yet? Do you know what valve or what type of procedure you might compare the SAPIEN valve to at this point?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, we think we finalized it and this is the kind of thing we had the discussions with the FDA on. We're hoping to have that confirmed and something to share with you in the not too distant future. We did share those of you who were at the investor conference what you believe what the trial design looked like. It continues to track what we told you at that time. No real changes of Gil.

Gil Gabbay - Bear Stearns - Analyst

Okay. That's excellent. And just wanted to ask a question about the stock buy back program. You got about 2.5 million shares unauthorized?

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Tom Abate - Edwards Lifesciences - CFO

That's close, yes.

Gil Gabbay - Bear Stearns - Analyst

Okay. And does your guidance include any assumptions about share buy backs?

Tom Abate - Edwards Lifesciences - CFO

No, you know the guidance pretty much assume that we keep the shares at the level that we finish the year.

Gil Gabbay - Bear Stearns - Analyst

Okay.

Tom Abate - Edwards Lifesciences - CFO

Not much change.

Gil Gabbay - Bear Stearns - Analyst

Wonderful. Thank you very much.

Tom Abate - Edwards Lifesciences - CFO

Sure.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Thanks, Gil.

Operator

Our next question is coming from Glen Reicin with Morgan Stanley. Please proceed with your question.

Glen Reicin - Morgan Stanley - Analyst

Good evening, folks. Wanted to discuss two businesses. Firstly on the vascular side, you saw this ramp in sales Q3-Q4, looked a bit more dramatic than it's been in recent years. Wondering what that is. I was assuming that stents were around 16 million for the year. Was there something else? Or was that 16 million too low? Maybe you can give us a little bit of insight there.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, I think actually turned out around 16 million, is that what you said?

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Glen Reicin - Morgan Stanley - Analyst

Yes, 16.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

That's what it turned out and actually that was a step up. That kicked the growth rate. And we really had FlexStar out there for a full quarter for the first time in the U.S. As a matter of fact we don't have FlexStar in Europe yet. That's yet to come. So the other thing that probably helped it out some is that this is our first quarter of sales on our long stents plan and that helped.

Glen Reicin - Morgan Stanley - Analyst

Okay. Is there any growth in the non-stent businesses?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

In the non-stent business? Very low rate. It's low single, yes. It's 1 or 2 or 3%.

Tom Abate - Edwards Lifesciences - CFO

It was slightly positive.

Glen Reicin - Morgan Stanley - Analyst

Right. And it sounds like it's more positive for the full-year than it was in the quarter for the non-stent stuff.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

For the non-stent business?

Tom Abate - Edwards Lifesciences - CFO

I don't know that that's the case, let me check. The quarter was a little bit more favorable than the year, actually.

Glen Reicin - Morgan Stanley - Analyst

Okay. That's what I'm looking at. And maybe you can help us out a little bit on the valve business. I'm trying to understand this a little bit better. I'm hoping you can explain it however you want. But if you look at the total business and growth in that business, I'd love to understand what you think growth was in the first in the mechanical piece, the declines and then try and understand a little bit about the whole franchise and what that grew at. Because you've been saying that's over 50% of your business for a while, 50% of your aortic business for a while. Trying to understand the whole business versus the rest of the tissue business. And then also versus the rest of the tissue business. And then also trying to understand a little bit about what's happening from a unit perspective, a unit growth perspective.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Okay. I'm not sure where to start.

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Glen Reicin - Morgan Stanley - Analyst

You can start with mechanical, which is the easiest.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Are you talking about decline? Just for us or for the total --

Glen Reicin - Morgan Stanley - Analyst

For you, this is all you.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Okay. Well, let's see -- I'll try and dig this out. On a percentage basis, I think mechanicals were actually down almost between 15 and 20% for the quarter.

Glen Reicin - Morgan Stanley - Analyst

Okay.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Okay.

Glen Reicin - Morgan Stanley - Analyst

So that puts the whole tissue valve business up how much?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Total tissue, let's see if I can -- there's a lot of different ways to cut this. Let's see. Well, if we take total tissue it was up around 3%, total tissue if you take porcine out of it was up over 5% for the quarter.

Glen Reicin - Morgan Stanley - Analyst

Okay.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Okay.

Glen Reicin - Morgan Stanley - Analyst

And if you look at Magna versus some business is up 3, what is Magna up as a family?

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Mike Mussallem - Edwards Lifesciences - Chairman, CEO

So Magna up as a family in the quarter was over 20%, between 20 and 25%.

Glen Reicin - Morgan Stanley - Analyst

Okay. And so that means -- does that mean that the rest of the business is down?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, I don't know, basically --

Tom Abate - Edwards Lifesciences - CFO

You're leaving out porcine, which definitely porcine down.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Right.

Glen Reicin - Morgan Stanley - Analyst

You're saying -- I'm saying the 20 -- I'm trying to understand, you always say 50% of your business but really your aortic business not your total business. Right so I'm trying to understand the weighting here between Magna and the rest of that gives you, I guess I can figure out gives you the 5% total. So what does that mean for the rest of it?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, if -- the rest of the business is probably, you're right, since the rest of the business is heavily weighted with porcine and mechanical, it probably is down.

Glen Reicin - Morgan Stanley - Analyst

I'm talking about your non-Magna tissue business.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, non-Magna tissue business would probably be down.

Glen Reicin - Morgan Stanley - Analyst

Okay. And if I look at the entire franchise and we say up 5% without porcine, what are units?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Units are approximately flat.

Glen Reicin - Morgan Stanley - Analyst

Okay. Your units are flat?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

That's correct.

Glen Reicin - Morgan Stanley - Analyst

Okay. That's -- that helps a lot. And then finally, I'll get back in line. I'm trying to understand a little bit for the year how you did in the perfusion, sorry how you did in the cannula business. And where'd you end up in the way of booking revenues for perfusion looking at 22 million for '06? Is that the right number to use?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Okay. I'm sorry --

Tom Abate - Edwards Lifesciences - CFO

I don't think we give a sales number. The growth rate was in the 7% to 8% range.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

For cannula.

Glen Reicin - Morgan Stanley - Analyst

For cannula. Okay. Yes. And you don't want to give those other numbers of the discontinued business?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

I think there's a schedule in there, Glen.

Glen Reicin - Morgan Stanley - Analyst

Well, it hasn't been discontinued yet. I'm trying to understand is it 22 million go into zero and the TMR business goes to zero, are those the two right numbers to think about?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Maybe we can help you with this one offline.

Glen Reicin - Morgan Stanley - Analyst

That's fine, I'll talk to David later, thank you.

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

Thanks, Glen.

Operator

Our next question is coming from Amit Bhalla with Citigroup. Please proceed with your question.

Amit Bhalla - *Citigroup - Analyst*

Hi, thanks for taking the question.

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

Sure.

Amit Bhalla - *Citigroup - Analyst*

I don't think I heard you quantify the impact a quarter this quarter. You've done it in the past.

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

Yes. Actually, we really didn't feel like we saw very much. We still had some impact in the quarter. We're not sure that we can characterize it by dollars at this point since it's diminishing. But one of the things we would say is -- we're still seeing in the mitral position not so much in the aortic position. And that was, that was a little bit of a change.

Amit Bhalla - *Citigroup - Analyst*

Is it fair to say that in absolute terms is down from the last quarter? Last quarter you said 3 million.

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

I think that's true. We still had some impact, but it's down from the last quarter.

Amit Bhalla - *Citigroup - Analyst*

Okay. You also mentioned that for Europe you started to do some work on reimbursement, anything you can share with us there?

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

Yes, we'd probably rather not get into the specifics of reimbursements. What we'd like to do is maybe a quarter from now when we're together is start laying out what we think '08 might look like and what the reimbursement environment might look like around that and that'll be a better time for us to give you a big picture.

Amit Bhalla - *Citigroup - Analyst*

And just two last ones. The Edwards One program, can you give the sense of the cost, how much you're spending on the program this year and with ACC coming up, any preview you can help us out with would be helpful. Thanks.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, it's pretty integrated within our heart valve program. Some of it's incremental and some of it's the way we might have spent our sales and marketing dollars in the past. When we give you estimates about what SG&A rates are, it's all buried in there. I'm sure we're spending more than a couple of million dollars in this area. As a matter of fact, it might be substantially more. I'm not sure that I have a specific accounting for you.

Amit Bhalla - Citigroup - Analyst

And then ACC?

Tom Abate - Edwards Lifesciences - CFO

What about ACC?

Amit Bhalla - Citigroup - Analyst

Anything you can help us out with? Planned presentations, data anything like that?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

I'm sure there's going to be some people that will present there, but it's not one that's been a primary focus for us.

Amit Bhalla - Citigroup - Analyst

All right. Thank you.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

You're likely to see more of what you've seen in the past.

Amit Bhalla - Citigroup - Analyst

Okay.

Operator

Our next question is coming from Michael Weinstein with JP Morgan. Please proceed with your question.

Michael Weinstein - JP Morgan - Analyst

Thank you. There's been a lot of ground that's been covered. First, in the quarter, the charge that you took had is part of it a global realignment, I just wanted to make sure I understood what that was?

Tom Abate - Edwards Lifesciences - CFO

The global realignment was related where we were sort of restructuring the businesses to better focus on the initiative.

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Michael Weinstein - JP Morgan - Analyst

The initiatives being?

Tom Abate - Edwards Lifesciences - CFO

Well part of it was related to the afib, and the initiatives being, the business -- we laid out some additions that we made in the various sales forces and so forth going into 2007.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, just the general -- I think we announced this back when we did it, Mike. So part of the resource -- part of the people that came out were supporting the program that we walked away from. This is the business, the afib business, which we discontinued. And the other was just the general realignment across Edwards. As we have divested business and changed over time, what we did was to just sort of take some resources out that we thought were going to be less relevant to our long-term growth to that we can make sure that we're applying our resources to where it's going to be needed in the future.

Michael Weinstein - JP Morgan - Analyst

Understood. Mike, just so I can get a sense of how you're thinking about the importance of the product. Magna Mitral and the assumption that you have an approval in the fourth quarter of this year, at this point, if you not going to have it just for whatever reason something happens with FDA would that-- would that alter your guidance for the year?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

I think it might. It would probably just make a difference in the fourth quarter. We still think that we've got, we're not counting on it in the second and third quarter. So in the fourth quarter wouldn't be quite as big as we have planned, although I can tell you we don't have a lot in there. So I don't think it's a big impact. Maybe a couple of million dollars. There's not a lot in there. There might be, I don't know, maybe there's 3 in there, Mike.

Michael Weinstein - JP Morgan - Analyst

Okay and then maybe, I'm sorry, just one last one. Your competitors are all kind of working on new valves, as well, of course. And some of them are the second half of the year. I assume that's in your thoughts relative to your back half guidance?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, it is. The way we continue to look at that, Mike is we think that Mitral Magna is worth probably more than any of the competitive issue. The FDA process is a challenging one for everybody and a little bit uncertain. If everybody gets valves approved, then our guidance is good. If we really got surprised and we did not get approved, it would be a downside to our plan pushes down closer to that 7-side of the 7 to 11. And if we get approved and our competitors don't, then there is upside and we're pushing the high end. Thanks, Mike.

Operator

Our next question is coming from David Zimbalist with Natexis Bleichroeder. Please proceed with your question.

David Zimbalist - Natexis Bleichroeder - Analyst

Hi, thanks. Yes, most of the questions have been answered. Just a couple of follow-ups. First, the aortic mix shift towards Magna play a very important role in 2006. Could you give us some sense of quantification, what kind of role you expect to play in 2007?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, I think that it's going to, it'll continue, David, but probably not on quite a steep a ramp. There'll be a continued lift towards more premium products but not be as dramatic a driver whereas I think, for example, Magna Mitral gets approved it greatly increases the curves here of Magna adoptions across the mitral position.

David Zimbalist - Natexis Bleichroeder - Analyst

Okay. Second is excluding Japan, what was the growth from the FloTrac? Was Japan the majority of that doubling? Or is it more broad geographic distribution?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Let us dig that out for you. I'm going to say off the top of my head that no, we had nice growth in all the regions, but --

Tom Abate - Edwards Lifesciences - CFO

We don't have a subtotal --

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

We probably don't.

Tom Abate - Edwards Lifesciences - CFO

We know the U.S. is comparable, Europe was a good growth rate.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

What we had, our growth rate's probably running somewhere. It was in the U.S. we more than doubled. I think we were less than doubling in Europe. I think if you put the U.S. and Europe together you probably come pretty close to doubling, as well.

David Zimbalist - Natexis Bleichroeder - Analyst

All right. On the aortic notes you've been doing work on aortic stenosis, can you give us a sense as to where that's at and when you expect to be able to broaden that marketing campaign for awareness of aortic stenosis?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes. We feel like the data that we've been collecting continues to reinforce our hypothesis that maybe for everybody that gets surgery there's another person out there that would really benefit from surgery. And actually we've already started to launch that. So within the Edwards One program, are materials that we're communicating to the surgeon community to help educate them on what we've already generated. And this is both for their benefit and to help them educate their referral basis. It's something that's already rolling out.

David Zimbalist - Natexis Bleichroeder - Analyst

Is there any sense that during the course of this year you expect to move that beyond just direct to the cardiac surgeons towards the more general referring community?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

We don't have any plans to do that, David.

David Zimbalist - Natexis Bleichroeder - Analyst

All right, and the last question, in 2006 you spent essentially all your free cash flow on share repurchase. Absent acquisitions, is that something we should be expecting in the course of 2007? Or is this something you're going to be holding back on because you expect to be able to execute on significant acquisitions?

Tom Abate - Edwards Lifesciences - CFO

Well, they're definitely connected and we continue to do very aggressive screening and looking at things. And it's something that we wouldn't give guidance to at this point. But we're very bullish on the shares, we continue to be that way and it remains as our number two call on cash.

David Zimbalist - Natexis Bleichroeder - Analyst

Thank you.

Operator

Our next question is coming from Jason Mills with First Albany Capital. Please proceed with your question.

Jason Mills - First Albany Capital - Analyst

Good afternoon, Mike. Thank you for taking the question. First, wanted to piggyback on a couple of questions just asked. First on, you've been asked about it a lot and talked about Magna Mitral actually I think Mike asked with respect to the downside you mentioned, though that you didn't have anything baked into the second quarter and third quarter expectations. Perhaps you could talk about what the, what, if any, up side exists for improvement. I recall that you were a bit surprised with the FDA requested less than 6 or 8 months ago at this point. Perhaps give us a view of how these discussions are going. I know you've probably been very responsive to them and the possibility that you could possibly see a second quarter or third quarter approval and what it would -- what would be required to achieve that. And then, piggybacking on that, as well, assuming that you have no up side there and no downside with Magna Mitral or Magna Ease, what are your unit growth expectations piggybacking on Glen's question with respect to '06 and '07 with the heart valve franchise? Thanks, Mike.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Okay, thanks. I have to admit I'm a little gun shy to give any sort of regulatory projections based on what we've experienced in the past. Having said that, we have made our submission already here in 2007, which starts the 180-day clock. We think we're being somewhat conservative we think we'll be able to get through there because we believe we've adequately answered their questions. You can decide whether that's equal up side and equal downside just from that. On unit growth, I think unit growth, we're projecting right now I think sales growth for the heart valve business that's in the, it must be in the 7% to 11% range. We think that we'll continue to get a portion of that, say maybe 2% to 3% of that growth comes from premium price, so the rest of that is going to be units.

Jason Mills - First Albany Capital - Analyst

I would surmise that a big chunk of the 5% to 9% unit growth for new products, both in Europe, Japan, and the United States.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

That's certainly -- certainly it's a contributor, although I have to tell you that expect to get some Magna growth.

Jason Mills - First Albany Capital - Analyst

That's helpful. Over to the other business I wanted to talk about. I wanted to talk about. You're asked a question that's always hard to answer with respect to your M&A thoughts in any business. But perhaps you can talk about your -- when you look a business, and specifically in vascular, which is a business you do not have a mature sales force intact. You mentioned you think you're expecting, I believe to get to 40 by the end of the first quarter.

When you look at a business out there in vascular and you may contemplate buying, how much weight do you give to the quality and size of that sales force and acquiring that business would give you maybe a growth platform from a product perspective but also would you from going out and having to find guys in the field already stealing guys that are working at another firm that may be a little bit more difficult. You kind of see where I'm going. I want understand when you're looking at a business how much weight you're giving to intact sales force in addition to the products you're acquiring.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, it's a good question. I don't know if you're going to feel it fully answers your question, Jason, but a couple of things to consider. One is, we feel like we really have established the stent product line at this point and we have said right along that this was our first priority and we wanted to have that in place before we decided we were going to build around that business. So mission accomplished. We have not had difficulty attracting really top sales talent and I'm very proud of that in terms of what's going on right now. You're correct in observing that we are sub critical mass in that business. So having a much larger sales force carry these products is something that's very valuable to us. And naturally that also assumes that they would have sufficient products in that bag to get good leverage and drive overall profitability. So we're sort of working that overall equation and we continue to look at that aggressively for solutions, Jason. But I'm not sure that I can point you more specifically than that.

Jason Mills - First Albany Capital - Analyst

With respect to that, you mentioned 40, Mike, am I right by the end of the first quarter? What would you expect to see from a range standpoint sales head count being exiting the year? When you do have an approval that you'll be carrying into docs offices in 2008?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, we do plan to be at 40 by the end of the first quarter. And then given if things turn out the way we think it will, which is doubling, then we would start putting reps in place that could be fully effective in 2008. If we saw a more aggressive uptake that we might be more aggressive with that curve so that we put people in to have more impact sooner than 2008 and also the converse would be true.

Jason Mills - First Albany Capital - Analyst

So are we talking another 40 to 80 or 40 to 60 or any quantitative?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

No, I don't think you should think 40 to 80. I think it's going to be more incremental in terms of the way we add resources.

Jason Mills - First Albany Capital - Analyst

Lastly and I appreciate the time. On the P&L, the SG&A expense, even if you exclude the stock based compensation was quite a bit less in our expectation, perhaps I'm just not modeling it correctly but it is the lowest level as a percentage of sales since the first quarter of 2005 excluding against stock based compensation. So could you talk about a little bit about and give us a little bit more color there as to what went into that? Was it just not as much incentive or above quota sales money? Were there any programs that were contemplated earlier in the year that weren't executed? Can you talk about that?

Tom Abate - Edwards Lifesciences - CFO

Yes. It's as a percentage of sales, it should be pretty comparable to the prior year. I think we're a couple of tenths off the prior year, but it did increase in terms of dollars. So on a full-year basis, I think the sales on a reported basis are right around four and so was SG&A. Now the quarter, I don't think there's any other major signal there other than as a percent of sales you are correct to observe that it's about the same level.

Jason Mills - First Albany Capital - Analyst

Just looking at your P&L this year, you had the June quarter, roughly the same sales on the top line performance you did this quarter, but yet the SG&A excluding stock based compensation was a couple million lower. And again, fourth quarter, used to seeing since this is the last fiscal quarter of your year, used to seeing some of those incentive payouts for your sales force. I guess I just wanted to know how that jives.

Tom Abate - Edwards Lifesciences - CFO

There is a piece of that. At this point of the year, you've got the sales force compensation and you've got management bonuses and so forth. And probably in comparison to prior year, there's a difference there, but I don't think that's all that meaningful going forward. We're still sticking with the 36.5% including options. Next year, I think is still very good indication.

Jason Mills - First Albany Capital - Analyst

Okay. Okay. Thank you very much.

Tom Abate - Edwards Lifesciences - CFO

You're welcome.

Operator

Our next question is coming from Larry Keusch with Goldman Sachs. Please proceed with your question.

Larry Keusch - Goldman Sachs - Analyst

Yes. Thank you. Two questions. First, Mike, can you just again review what exactly is going on with the FDA now as it relates to the approval of the protocol? What exactly are you guys waiting on to get that over the finish line?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, we're really not waiting on them. It's our response that's driving this. We've had a lot of back and forth. We've had a lot of conversation, they've been very open and frank conversation about what would be an ideal trial design. And at this point we are really working through the details to make sure that we have solid statistical analysis that's going to support this so there are no surprises at the end of the trial. We tried to learn a lot of lessons, Larry, from those who have gone before us and be very thoughtful because we consider this trial very important. At this point, it's been a good give and take and we continue to feel optimistic. We wouldn't be saying that we think we're going to be starting this trial in the first quarter if we didn't feel pretty good at this point.

Larry Keusch - Goldman Sachs - Analyst

So you believe that you actually will enroll your first patient in the first quarter, just so I understand that?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

That's correct.

Larry Keusch - Goldman Sachs - Analyst

And just switching gears and this is something that came up in the third quarter call. I know that you have rolled out a second generation software for FloTrac. There has been some published journal articles that talk about the first generation software and really not seeing a lot of sort of correlation to intermittent Thermo dilution. Can you talk a little bit about what that second generation software does to more closely correlate you with Thermo dilution since people are going to, I think, pay attention to that as the gold standard, if you will?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, it's a great question, Larry. So you have to anticipate that when we introduced this sort of innovation like FloTrac, there are a lot of people that are very interested in studying this and they do a lot of comparisons. There are a lot of comparisons to the gold standard, our Swan-Ganz Catheter as well as to some competitive catheters. A lot of these things happen in single institutions, they're designed by institutions, and they're not necessarily randomized. And you're right, some of these are even done with our very first generation products. So you have to be a little bit careful on some of the stuff that's out there just because there's a multitude of those types of studies.

We've tried to do some pretty large multi-center that get at it, including studies that are going to include the next generation of software. In particular, what's in the next generation software, Larry is trying to address some of the groups of patients that weren't necessarily addressed in the first generation. So in other words, you might have patients that originally suffer from septic shock that we didn't necessarily have enough data already generated to be able to correlate the way we like to. And now that we have additional data generated for FloTrac we're able to upgrade our software algorithm so that it's sort of accommodates larger groups of patients than we did in the first generation. I hope that answers the question.

Larry Keusch - Goldman Sachs - Analyst

And I'll stop right after this. I think I understand. So the system essentially you input weight and age and a couple of other parameters the system has these algorithms that then try to, I guess compare that to the population. And so what you're essentially saying is that the second generation software is just broader and should theoretically and I guess we'll start to see some of this as your data comes out, increase that correlation to the more conventional invasive methods of measuring.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

That's right, Larry. You've got the right idea. Just to restate a little bit, this is a very broad based monitoring system. For people going through a very broad range of surgeries and intensive care units for a broad range of reasons. And as we get more experience, we find that there might be a small group of patients that we need to tweak to make sure that we appropriately track that. And so as we've gained experience and did this software, we picked up a lot of those patients that otherwise might have been outliers and we will continue to tweak it in but probable the change from generation one to generation two cover a lot of ground.

Larry Keusch - Goldman Sachs - Analyst

At last though of your installed base that's sitting out there, has it all largely been now switched over to the generation 2 software?

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Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, as a matter of fact across the board, we've got a nice system that makes it easy for us to upgrade software.

Larry Keusch - Goldman Sachs - Analyst

Thanks very much, appreciate it.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Thanks, Larry.

Operator

Our next question is coming from Glen Novarro with Banc of America Securities. Please proceed with your question.

Glen Novarro - Banc of America Securities - Analyst

Okay. Thank you. I just want to get some -- a better understanding of the U.S. tissue market. Mike, can you tell us what the U.S. tissue market grew in the fourth quarter? And in 2006 and what was Edwards' tissue growth relative to the market in 4Q?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Okay. Yes. Overall, we don't think that the market itself has necessarily changed, Glen, in terms of its overall dynamics. We think the unit growth that underlies this market probably tracks in the 3% to 5% range, 3 to 4% range and does that broadly.

Glen Novarro - Banc of America Securities - Analyst

I'm asking for tissue, though. You're giving me the tissue number?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

I'm giving you the overall and I'm sort of building my way there. I do think that the tissue is continuing to grow at twice the rate of the market growth. So tissue is probably, probably grew last year in the in somewhere in the 6 to 8 range this last year in terms of what tissue growth was. Typically there'd be even more growth that comes out of it because when Edwards sells its premium valves, you'd also get some price in there. But when some of the other valves are introduced, Glen, you don't necessarily see the price pick up that accompanies the unit growth. Does that make sense?

Glen Novarro - Banc of America Securities - Analyst

Sure. And what's the forecast for growth in 2007? It looks like you grew a little bit less than the market because you lost some share?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

That's correct.

Glen Novarro - Banc of America Securities - Analyst

And in '07, I guess you're assuming a similar forecast for the US market up 6 to 8?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, I think so. It might actually grow a little bit faster. We think we're going to grow a little bit faster than the market, Glen, and again, one of the key factors that will drive share will be new valve approvals. But even in the absence of that, we expect this to have small share gain.

Glen Novarro - Banc of America Securities - Analyst

And then if you look at the tissue market on a global basis, should we assume it's growing slightly faster than the U.S. market?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, you should. I think it's growing 1% to 2% faster than the U.S. market.

Glen Novarro - Banc of America Securities - Analyst

And then just the last question. Do you know where we are approximately in the split in the U.S. between tissue and mechanical? Kind of where we were in the fourth quarter? Where were we at the beginning of the year?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

I don't know if there is a lot of change in what we think the number is. If we put together aortic and mitral it's probably in the 70/30 range with it being higher on the aortic side and lower on the mitral side.

Glen Novarro - Banc of America Securities - Analyst

The only reason I was asking, at your analyst day, the guest surgeon just made a passionate plea for the market continuing to move towards tissue. And I'm just wondering if there wasn't as much of a change this year, why would it continue to change in the coming year?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, one of the big things that's going on, it's moving very fast on the Aortic side, like I said even though it's probably 70/30 overall, the aortic side is certainly substantially higher than that. On the mitral side, it's still lag, Glenn and a lot of it is there are some porcine valves and certainly Mechanical Valves that are just plain easier to implant in that difficult position and I think-- that's why we're really looking forward to have this really-- our really state of the art PERIMOUNT valve in the mitral position. And it'll pile up too. During the course of this year, we saw black box warnings come out on coumadin on AHA, ACC guidelines and if anything, I think it'll accelerate that movement.

Glen Novarro - Banc of America Securities - Analyst

Great. That was very helpful, thank you, Mike.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Thanks, Glenn. Okay. Thanks for your continued interest in Edwards. Tom, David, and I welcome any additional questions by telephone. With that, back to you, David.

David Erickson - Edwards Lifesciences - IR

Thank you for joining us on today's call. Reconciliations between GAAP and non-GAAP numbers mentioned during this 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 Relations section of our Website at Edwards.com. If you missed any portion of today's call, the telephonic replay will be available for 72 hours and to access this please dial 877-660-6853 or 201-612-7415, use account number 2995 and the pass code is 228427. I'll repeat those numbers. Area 877-660-6853 or area 201-612-7415 the account number is 2995, the pass code is 228427. Alternatively an audio replay will also be archived on the Investor Relations section of our website. Thank you.

Operator

Ladies and gentlemen, this does conclude today's teleconference. You may disconnect your lines at this time. Thank you for your participation.

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