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Conference Call Transcript

EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

Event Date/Time: Apr. 20. 2006 / 2:00PM PT

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PRESENTATION

Operator

Greetings ladies and gentlemen, thank you for holding. Welcome to the Edwards Lifesciences first 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. [OPERATOR INSTRUCTIONS] 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 first quarter 2006 financial results.

During our call today, we will focus our prepared remarks on information that compliments the material included in the press release and financial 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 continued success of recently introduced heart valve therapy products and expected share gains, the uptake of FloTrac, LifeStent and other new products and their projected sales, the success of the RESILIENT clinical trial, the timing and success of our percutaneous clinical studies and the market opportunity for these technologies, 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 from the forward-looking statements.

Additional information concerning factors that could cause actual results to materially differ from those in the forward-looking statements may be found on 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...

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Thank you, David. We're very pleased to share with you our first quarter results, which were highlighted by strong underlying sales growth, and continued share gains in our heart valve franchise. Additionally, we continued to make important progress in new products that will drive our future growth. And, the growing clinical experience with our simplified percutaneous aortic valve procedure is driving improved patient outcomes.

On a reported basis, total sales for the quarter grew 3.1% to \$257 million, and grew 9.1% on an underlying basis. Performance was solid across all of our regions and franchises. Now I'll shift to a more detailed review of our product line sales, as well as provide an update on our future growth drivers, and then Tom Abate will discuss the financial results.

On a reported basis, sales of Heart Valve Therapy products grew 7.2% this quarter. Excluding a \$4 million negative impact from foreign exchange, underlying sales were up 11%, driven by double-digit growth in tissue and repair products across all regions. Based on their superior clinical performance, our PERIMOUNT valves continue to gain market share over competitors. Global sales of our market-leading PERIMOUNT valves grew nearly 13% in the quarter. Sales of our best-selling Magna Aortic valve continued to grow this quarter and today comprise half of our global aortic sales.

And, with the addition of our proprietary ThermaFix anti-calcification treatment, we expect this premium-priced valve to drive continued market penetration and share gains. Our new Magna Mitral valve is gaining traction in Europe, and we still hope to receive FDA approval in the U.S. later this year. Meanwhile, sales of our Theon mitral valve continue to be a growing contributor to our U.S. results.

Global heart valve repair sales demonstrated strong double-digit growth this quarter, driven by the 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 with the introduction of yet another new and innovative mitral repair system later this year. You'll recall our Ascendra minimal access, beating heart aortic valve program leverages the technology from our Cribier-Edwards percutaneous valve platform.

Successful cases in our feasibility study have been performed at multiple sites in Europe and Canada, and the early results are quite encouraging. Surgeon interest is very high and we are continuing to add study sites. We still anticipate completing our initial feasibility study this year and will determine the specifics of the pivotal trial design once our feasibility work is complete. Program updates will be provided at clinical meetings throughout the year starting with the PCR next month.

The global heart valve market is continuing to grow at about 5% annually, with tissue and repair products growing at twice that rate. We continue to believe that there is a substantial population of aortic valve disease patients who, today, are under-treated. Early demographic data suggests that for every severe and symptomatic patient who has their valve replaced, there is another who would benefit from a replacement, but doesn't receive one.

To quantify this market opportunity, we're sponsoring a number of retrospective studies to determine the precise reasons for under-treatment, and we expect early results later this year. To raise awareness of the clinical consequences of under-treatment, we plan to sponsor clinical education programs for surgeons and cardiologists.

Our Critical Care franchise, which is well positioned to become a faster growing and more profitable business for Edwards, saw reported sales growth of 1.5%. Excluding a \$3.2 million negative impact from foreign exchange, underlying sales growth was 5.7%. Growth this quarter was driven primarily by sales of pressure monitoring products, advanced technology catheters, and our recently launched FloTrac system. Partially offsetting the growth was the ongoing decline in base catheter sales.

The introduction of FloTrac is continuing in the U.S. and Europe. FloTrac's launch commenced in Japan earlier this month, and we are particularly optimistic about the potential in this market because of its less invasive nature and recent reimbursement approval. Globally, several studies to further evaluate the broad patient applicability and cost-effectiveness of FloTrac are underway, and results should be available beginning in late 2006 and continuing through 2007. We continue to expect worldwide FloTrac sales to ramp up to \$10 to \$20 million in 2006.

In our Cardiac Surgery Systems franchise, reported sales for the quarter declined 7.5%, due to the discontinuation of our Japan perfusion products business in 2005. Excluding the impact of the divested business and foreign exchange, underlying sales grew 8% driven, primarily by share gains in specialty cannula. Sales of our Optiwave 980 cardiac ablation system, launched earlier this quarter, were modest as we continued to ramp up our selling efforts. Early clinician feedback is positive for this unique technology, and for 2006 we continue to project Optiwave sales of \$3 to \$5 million.

On a reported basis, total sales of Vascular products grew 11.7% this quarter, but were up 15.8% on an underlying basis. Driving most of this growth was sales of LifeStent products, which were sequentially higher again this quarter to be slightly more than \$3 million dollars. Sales of base vascular products showed a modest increase. We remain on schedule to launch our new FlexStar delivery system in the second quarter. This system, which has already received positive feedback in marketing trials, is designed to insure the easy and accurate delivery of our uniquely flexible stent technology.

FlexStar's pending launch, combined with our sales momentum, reinforces our confidence that we will double our peripheral stent sales in 2006. Our RESILIENT trial remains on track, and we expect to complete enrollment of 225 patients in Phase II this quarter. Favorable 12-month Phase I data has been reported, and we expect 12-month data on Phase II patients to be presented in the first half of 2007. This keeps us on track for the receipt of an SFA indication by the end of 2007.

In our angiogenesis initiative, Phase I clinical trials are continuing at the NIH and Duke University, and we are adding additional sites. And, we still plan to initiate a Phase II clinical trial before year end. Other Distributed Product sales declined 18% on a reported basis this quarter. On an underlying basis, excluding discontinued products and foreign exchange, sales increased 6.4%. As we pass the anniversary of the pacemaker divestiture in Japan, reported sales next quarter will no longer reflect the impact of this transaction.

In summary, we're very pleased with our 9.1% underlying sales growth rate for the quarter. Based on current foreign exchange rates, we are maintaining our 2006 sales estimate of a billion thirty to a billion seventy, reflecting an underlying sales growth rate of 8 to 10%. This excludes an approximately 4% negative impact comprised of \$17 million of sales from discontinued businesses, and an estimated \$20 million negative impact from foreign exchange.

For the second quarter, we're projecting total reported sales of \$260 to \$270 million. For Heart Valve Therapy, as we previously discussed, we had an unusually strong results in the second quarter last year. As a result, we expect the underlying growth rate for the second quarter this year to be in the mid-single digits, although we expect sales dollars for the quarter to show a solid sequential increase.

For the year, we continue to expect total reported sales of \$505 to \$515 million. Excluding the impact of foreign exchange, underlying annual sales growth is estimated to be above 10%.

In Critical Care, we continue to project annual sales of \$335 to \$345 million, or 6% to 9% underlying growth. In Cardiac Surgery Systems, we project annual sales of \$90 to \$100 million, or 8% to 10% underlying growth. In Vascular, we project full year sales of \$70 to \$80 million, or more than 15% underlying growth. And lastly, we expect annual sales of Other Distributed Products to be approximately \$30 million. All of these projections assume foreign currency at current levels.

Now I would like to provide a brief update on our percutaneous valve programs. In our percutaneous aortic valve program, our U.S. clinical feasibility trial is progressing as expected. During the quarter we added a second clinical site, which has begun performing cases. Earlier this month, a third site received its approval and they expect to complete their first case shortly.

We expect to complete enrollment of this 20-patient trial during the second quarter and will work closely with the FDA to determine the next steps in the process. Outside the U.S., the multi-center CE mark study is ongoing in Europe and Canada. We are continuing to train physicians and add new sites, which should enable us to complete enrollment by early 2007. This continues to position us to receive a CE mark by the end of '07.

Overall, we are pleased with our progress and expect our investigators to report on their experience at upcoming clinical meetings. At the recent ACC, Dr. John Webb discussed his experience with nearly 50 patients who have received a Cribier-Edwards valve in Vancouver, and his results illustrate two important learnings. First, the 30-day survival of these high-risk patients was better than their predicted surgical risk. This experience suggests that for these types of patients, this percutaneous valve procedure may be safer than traditional valve surgery. Second, Dr. Webb's results suggest that with greater clinical experience, the procedure becomes more predictable and patient outcomes improve. We expect 2006 will be a year of important progress for Edwards in the development of this technology, and continue to believe percutaneous therapies will significantly transform the treatment of aortic valve disease.

In percutaneous repair, our feasibility work with the MOBIUS Leaflet Repair System is continuing in Europe and Canada. We've also made procedural and device enhancements, including a modified design to accommodate thicker mitral leaflets, thus enabling us to treat a broader group of patients. This will extend our feasibility study into the second half of this year.

Turning to the MONARC Annuloplasty System, our coronary sinus device, patient cases are continuing at multiple sites in Canada and Europe, and we continue to anticipate completing enrollment in these feasibility studies in the first half of this year. Following the completion of feasibility studies, we will determine pivotal trial plans. You can expect clinical updates and see case presentations on both our MONARC and MOBIUS systems at the upcoming PCR in May.

In summary, Edwards is continuing to lead the development of interventional therapies for treating valvular heart disease. We are the only company with three active clinical programs that include a broad base of patient experience and an extensive intellectual property portfolio. We intend to shape the evolution of these important emerging technologies for a growing and largely untreated patient population.

Given the recent interest in Medicare reimbursement, I'd like to offer a few comments on the subject before we move to a discussion of our financial results. We are closely monitoring CMS's proposed changes to inpatient reimbursement rates, and heart valve surgery in particular.

Heart valves are among the most highly differentiated medical implants and their performance is critical to patient outcomes. Additionally, heart valves represent a relatively small percentage of the DRG. Therefore, we believe Edwards will be less affected by these proposed changes. Obviously, we will stay actively engaged during the comment period.

And now I'll turn the call over to Tom Abate. Tom...

Tom Abate - Edwards Lifesciences - CFO, Treasurer

Thank you, Mike. As Mike previously mentioned we had a very strong first quarter.

Our gross margin was strong once again, and our operating margin excluding special items showed healthy year-over-year improvement. As we go through the results by line item, I'll be detailing the impact from FAS 123. To assist you with modeling, we've provide an updated table detailing quarterly stock option expenses, for 2006, on our Investor Relations website.

This quarter our gross profit margin improved to 63.7%, which was up more than 200 basis points over last year. The impact of stock option expense on this line was approximately \$700,000, or 30 basis points. The improvement over last year resulted from a favorable foreign exchange impact and a more profitable product mix, led by the strength of our heart valve franchise and last year's divestiture of our low margin perfusion business in Japan. We now expect a gross profit margin for the full year of 64% including option expense.

On a reported basis, first quarter SG&A expenses were \$92.2 million, or 35.9% of sales, which included a \$3 million dollar, or 1.2%, impact from stock option expense. Excluding the stock option impact, SG&A was \$3.6 million higher than the year ago quarter, primarily due to higher

expenses related to our Heart Valve Therapy franchise and new products. The increased spending in these programs was partially offset by foreign exchange. For 2006, we expect SG&A as a percentage of sales to be between 36% and 37% including option expense.

R&D investments grew to approximately \$27 million this quarter, or 10.6% of sales. Excluding option expense of \$800,000, R&D was \$1.4 million higher than last year, reflecting additional spending in our percutaneous valve programs. For 2006, we expect R&D investments to be approximately 11% of sales including option expense.

Net interest expense of \$900,000 was approximately \$2 million lower than the same quarter last year, as result of the recent earnings repatriation. Higher interest income earned on our U.S. cash balances is offsetting a greater proportion of the debt in our foreign subsidiaries. For 2006, we continue to expect net interest expense to be less than \$1 million per quarter.

During the quarter, we reported special items that resulted in a net \$23.8 million pretax benefit consisting of the following components: a \$20.2 million gain from the Medtronic patent settlement in January, the receipt of a \$5.7 million earn-out payment from last year's sale of our perfusion business, and a \$2.1 million charge related to the closing of a Japan manufacturing facility. These items are included in the net income reconciliation table that accompanies the press release.

For the first quarter, our reported tax rate was 30.9%. Excluding special items, our tax rate was approximately 26%, and we expect our effective tax rate to remain at this level for 2006, including the effect of stock options. When compared to the same quarter last year, foreign exchange rates negatively impacted first quarter reported sales by about \$9 million, or 3.6%. Our currency hedging program, combined with our natural hedges, enabled us to substantially offset the bottom line impact. Using current foreign exchange rates, we estimate that full year sales will be negatively impacted by \$20 million, or 2%.

During the first quarter, we repurchased 687,000 shares of common stock for about \$29 million. We continue to find our shares an attractive investment and remain committed to share repurchase. Free cash flow generated during the quarter was \$29.2 million dollars, which we define as cash flow from operating activities of \$66.7 million, minus capex of \$8 million, and the receipt of both the patent settlement of \$23.8 million, and the \$5.7 million earn-out payment. For 2006, we continue to estimate free cash flow of \$140 to \$150 million dollars.

Turning to the Balance Sheet, long-term debt at March 31st was \$289 million, resulting in a debt-to-cap ratio of 28.5%. Net debt at the end of the quarter was \$100 million, a decrease of \$38 million from the fourth quarter. Including receivables in our asset backed securitization programs, Days Sales Outstanding for the quarter improved by almost 2 days to 67 days. Inventories increased by \$3.5 million dollars from the prior quarter.

As I mentioned earlier, we began expensing stock options this quarter and the impact on net income was \$3.3 million, or \$0.05 per share. In connection with our annual equity grants in May, FAS 123 will require us to accelerate expense recognition for retirement-eligible employees. As a result, in the second quarter we expect our stock option expense to increase to approximately \$0.08 per share.

In the second half, the quarterly expense returns to between \$0.05 and \$0.06 per share. For total 2006, we expect our cost to be \$0.24 per share, consistent with our previous estimate.

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

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Thanks Tom. Based on our results this quarter, and our continued progress on growth initiatives, we expect another year of strong performance in 2006, and remain confident in our ability to achieve our previously stated financial goals. These include 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.

Based on current foreign exchange rates, we are maintaining our 2006 sales estimate of 1.30 billion to 1.70 billion, which we increased last quarter. We remain comfortable with our previous guidance for full year EPS of \$2.16 to \$2.26, excluding special items and stock option expense, and \$1.92 to \$2.02 including stock option expense. Additionally, we expect second quarter EPS of \$0.48 to \$0.50, including approximately \$0.08 per share of stock option expense.

In conclusion, we are continuing to deliver on our commitment of transforming Edwards into a faster growing, more profitable and innovative company, and we look forward to sharing our continued progress with you. With that Tom and I are ready to answer your questions.

QUESTION AND ANSWER

Operator

Thank you. Ladies and gentlemen, at this time we will be conducting the question and answer session. [OPERATOR INSTRUCTIONS] First question, Tim Nelson, Piper Jaffray.

Tim Nelson - Piper Jaffray & Co. - Analyst

Mike, can you comment some more on the valve market under-penetration issue, you've have talked about in the past, seem to be settling on this 50% on the penetrated rate, you're doing some studies, you talk about some market development activities you may initiated in terms of education, what kinds of things are you doing, when are you going to do them, and what do you think it will take to really get at that opportunity, over what period of time.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, we have begun at this point with retrospective studies. I think we have about five of these going at this point. And we have more that are planned. These studies include taking a look at echoes, and then as you evaluate those echoes finding patients that have symptoms and are demonstrating severe aortic stenosis, and tracking how many of those actually go to surgery.

The preliminary data suggests just what I have said during the prepared remarks, which is for every patient that goes to surgery there appears that there's another patient that is symptomatic and severe that doesn't go to surgery, and so we will try and validate that with these numbers. You should in the future, see more of this that gets published, and ultimately turn into education programs, that cardiologists and surgeons can do to educate their referring base.

Tim Nelson - Piper Jaffray & Co. - Analyst

This was, you know, a pretty hot topic at ACC this year. Are you doing any of these education programs this year, or are you going to wait until these studies are done and target them for next year?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, we will begin work in the second half of the year. I think you're also aware Tim, that we would expect heart valve guidelines to become available I think in June of this year. And that may be another catalyst for some more communication on the subject.

Tim Nelson - Piper Jaffray & Co. - Analyst

Great. On the Magna mitral, you mentioned later this year, are the filings done, the data collected, can you give us a little update on the progress there?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Sure, we're hopeful before the end of the year. We can't be certain. We have submitted everything that we think is necessary Tim, we have received questions from the FDA and answered those questions, what remains to be seen is whether there are going to be additional questions from the FDA. That we can't predict, we're continuing to be hopeful that it gets approved this year.

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

Tim Nelson - Piper Jaffray & Co. - Analyst

It's not in the guidance is it?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

No.

Tim Nelson - Piper Jaffray & Co. - Analyst

Okay. Question on the LifeStent results for the quarter, 3 million in sales. Can you tell us how much of that was the balloon-expandable versus the self-expanding?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, you know, I don't know that number off the top of my head. I would say that the self expanding stent must account for between 60 and 70% of the sales.

Tim Nelson - Piper Jaffray & Co. - Analyst

Okay. Great. That's all I have, thanks a lot.

Operator

Our next question comes from Dhulsini de Zoysa, SG Cowen.

Dhulsini de Zoysa - SG Cowen - Analyst

Good afternoon. Mike, I wanted to pick up on your comments on the CMS proposed rate changes. It looks like CMS really has spared valve replacement procedures, and I think you're right that the device price is really a fairly small component of the overall procedure. Would you happen to know what the cost to charge ratio is on average, just ballpark number?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

You know, I'm sorry, I don't know that number on average. We're in the process actually of doing some homework with our customers now, and so we really don't have anything at this point. We know that there's substantial variability across our customers, and we just don't have an average number.

Dhulsini de Zoysa - SG Cowen - Analyst

Okay. Just doing some rough calculations of the potential impact, I came up with something less than about a two penny hit to EPS. If the changes are implemented as proposed, and that assumes that you grant some sort of concession to your customers. Are you in fact already, are you hearing any chatter from hospital customers about the rate changes? Or is it too early for all that?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, it is early, and I would be speculating. We are doing homework at this point trying to understand customers' reaction. We have gotten at least some anecdotal data.

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

We have been somewhat interested to find some large academic medical centers actually think the DRG changes could be favorable to their centers, or slightly favorable at least. So we're really uncertain on what it means. As I indicated just because of the fact that the heart valves are so highly differentiated, and their performance is so critical to patients, and the fact it is such a small percentage, we just are not modeling that we're going to have any impacts of these changes. We think we will be far less affected than many others.

Dhulsini de Zoysa - SG Cowen - Analyst

I think that's probably a safe assumption. Then on the percutaneous feasibility trial, I think you said you expect to complete 20 patients in the current quarter. Will you let us know when that's done?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

You know what, we haven't decided specifically what kind of communication that we are going to do around that. We feel confident that we will complete those 20 patients, but I'm not sure what we would communicate, other than say that there was 20 done. We have been trying to think about something that's meaningful to communicate, and I guess when there's clarity on the regulatory pathway, you can be sure that there will be increased communication.

Dhulsini de Zoysa - SG Cowen - Analyst

So that would be maybe three or four months.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, I really don't know. And again, I would expect that, you know, in upcoming meetings, like the PCR, you would see some update of what's going on outside the U.S. as well. So that would I think be of some interest.

Dhulsini de Zoysa - SG Cowen - Analyst

Okay. Last one, at the Thoracic surgeons meeting in a couple weeks, is there anything we should be particularly keeping our eyes open for?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

I think that, I don't know that there's going to be anything that is going to be highly unusual. We continue to see very strong demand for our PERIMOUNT products, our Magna products, and our ThermoFix, a lot of interest in repair. So I think those are going to be the highlights of the program, and I'm not aware of anything else that is really going to take center stage.

Dhulsini de Zoysa - SG Cowen - Analyst

Okay, thanks Mike.

Operator

Our next question comes from Paul Choi with Merrill Lynch.

Paul Choi - Merrill Lynch - Analyst

Hi, thank you. If you guys could give us a sense of what you're feeling from St. Jude's recent launch of their Biocor valve, and any sort of recognizable or measurable competitive impact at this point?

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, we do see some trialing of the Biocor valve in the U.S., I think that's what you are referring to. That has had some impact. It's tough to say if it wasn't in the marketplace we think we might have generated another couple million dollars worth of sales in the quarter, but again that's just an estimate on our part. You see that we posted an underlying sales growth of 11%, and the U.S. I think was pretty close to that.

So we're really not seeing this to be something that we expect to have a sustainable impact on us.

Paul Choi - Merrill Lynch - Analyst

Beyond the certain initial trialing here.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Right.

Paul Choi - Merrill Lynch - Analyst

Okay. And secondly, in terms of the critical care business, how much would you say the base catheter business has been recently affected, it sounded like you saw a little bit of slow down there, given some of the newer products. Are we seeing more cannibalization, or is it something else there?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

I'm sorry, I missed the first part of the question.

Paul Choi - Merrill Lynch - Analyst

I'm sorry. In the base catheter business, is it mostly cannibalization that you're experiencing in terms of the slow down you described, or is there something else going on?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, there's a couple things going on. One, we see the continual shift from base catheters to advanced technology catheters, that's the primary impact. There's a little bit of base catheter pricing that we're feeling in Japan, as that annualizes out, but those are the primary impacts that we see.

Paul Choi - Merrill Lynch - Analyst

Thank you. In terms of the percutaneous front, I think you mentioned the Mobius trial would extend a little into perhaps the second half of this year. Are you doing any sort of additional design modifications to accommodate the thicker leaflets, or is it just more getting patients?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

No, that's what I intended to communicate Paul. We actually, we are continuing to enhance that procedure. And we did make a device change as well, to be able to accommodate those larger leaflets. It's the combination of those and we're still making improvements to that procedure - that has extended that feasibility trial.

Paul Choi - Merrill Lynch - Analyst

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

Okay, thank you very much.

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

You're welcome.

Operator

Your next question comes from Larry Biegelsen with Prudential Securities.

Larry Biegelsen - *Prudential Securities - Analyst*

Hi. A couple of questions. Are we going to see the new percutaneous valve data at the upcoming Transcatheter Valve meeting in San Francisco next week?

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

Yes, you know, Larry, we would expect certainly because there's such a high level of interest, that there would be a lot of talk around that meeting.

From what I understand the more substantial communication is going to happen around the PCR, although we might see some of it come around the Transcatheter meeting as well.

Larry Biegelsen - *Prudential Securities - Analyst*

Okay. Of the 200 basis point improvement in gross margin year-over-year, what percent was FX, and what percent was the mix?

Tom Abate - *Edwards Lifesciences - CFO, Treasurer*

Larry, it's pretty much 50/50 split. It's about as close as you could get to half and half.

Larry Biegelsen - *Prudential Securities - Analyst*

Okay. Last question, \$0.03 per share of additional option expenses in the second quarter, I wasn't sure if that was a one-time event, or is that something we can expect in future years?

Tom Abate - *Edwards Lifesciences - CFO, Treasurer*

Yes, you know, each year probably in the second quarter you can expect the number will be the highest number for the year. But pretty much it's on the number that we expected, and that has to do with the fact that the program when it's initiated, there's an acceleration of expenses for retirement eligible individuals.

Larry Biegelsen - *Prudential Securities - Analyst*

Thank you.

Operator

Our next question comes from Amit Bhalla from Morgan Stanley.

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

Amit Bhalla - Morgan Stanley - Analyst

Hi, thanks for taking the question. First question just on St. Jude again, are you seeing any changes in the pricing dynamics in the U.S. tissue market since they have been on?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, as you know we're the leader in valves, so we're the ones that probably lead that, and we haven't changed our pricing practices. So we're continuing to see a nice price differences between Magna and PERIMOUNT valves, and continue to see differences between ThermaFix valves as well. So in general you see the Edwards technology command substantially higher prices than the pig valves.

Amit Bhalla - Morgan Stanley - Analyst

Okay. Just two more questions. Can you quantify the amount of spending you're going to do on these education programs for heart valves?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

You're talking about what we had planned, and the program we communicated earlier about expanding market size?

Amit Bhalla - Morgan Stanley - Analyst

Right.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

You know, we projected at the beginning of the year we were probably going to spend something like a million dollars, that's what we budgeted for this year. We're certainly going to do that and potentially more. I don't know that I have anything more specific of an update at this point in time.

Amit Bhalla - Morgan Stanley - Analyst

And just a question on pipeline. Can you give us the sense of how many patients have been treated with the Ascendra system, and also how many patients have been enrolled in the BioPhysio trial so far?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

On Ascendra, I don't know the specific numbers. I think our intention was to have at least 20 patients done here in the first half of the year, I think we're well on track to be able to do that. If that answers that question. BioPhysio, I think our number must be over 100 at this point.

Amit Bhalla - Morgan Stanley - Analyst

Okay, thank you.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, thanks.

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

Operator

Our next question comes from Mike Weinstein with JP Morgan.

Chris Pasquale - JP Morgan - Analyst

This is Chris [Pasquale] for Mike.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Okay. Hi Chris.

Chris Pasquale - JP Morgan - Analyst

Mike, can you talk a little bit about your plans for the stent sales force. You said part of the build out there might be dependent on the data you saw.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, we have maintained the size of our stent selling organization where it is right now, and our intention is to hold at that number until we launch our FlexStar, until we come forward with our longer stents, until we have more RESILIENT data that's reinforcing. We really think that's an activity that the decision point will be in the second half of the year.

Chris Pasquale - JP Morgan - Analyst

Okay. So no plans to do that yet, that's something you will revisit later in the year.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

That's correct.

Chris Pasquale - JP Morgan - Analyst

Then on the Optiwave, it seems like you guys are pursuing a pretty gradual roll-out strategy there, is that related to physician training or is it a capacity issue, or what's happening there?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, that's probably a little bit more of a capacity issue. We think that we have got that behind us at this point, and we're able to ramp that up, but no, it's not a substantial training issue.

Chris Pasquale - JP Morgan - Analyst

Okay, thanks.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

You're welcome.

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

Operator

Our next question comes from Glenn Novarro with Banc of America.

Glenn Novarro - Banc of America Securities - Analyst

Hey, good afternoon guys. I just had a follow up on the LifeStent, because sales continue to ramp a little bit slower than we thought. And I guess to follow up on the previous question, Mike is it strictly a sales force issue, or is it a lack of an accompanying products that would fully get you into rotation of a cath lab, meaning you know, balloons, wires, etcetera, so maybe give us a few comments on that, and then on the acquisition front, have you looked at anything else in the peripheral space as a way to be beef up your presence, so that you can get into the rotation within the cath lab, thanks.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Sure. Thanks Glenn. Yes, as a matter of fact you will recall that we set an expectation for this year that we would double our LifeStent sales. As a matter of fact we feel very good about where we are right now.

So we don't feel like we're off-track at all, this is very consistent with our expectations, and if that wasn't clear, I apologize for the miscommunication. We believe in our product, we think it's highly differentiated, and we think it's something special. It sure gets easier to deliver and more repeatable with the FlexStar system.

Then we think the issue will switch to one that is sales force. I think you're right in asking that question.

In terms of looking at other additions to the product, we're always looking, and there are always interesting candidates there. We have disciplined ourselves to say that the centerpiece of the peripheral offering is the stent, and that that is the biggest device opportunity in the space, and that we are going to drive that to leadership in the SFA, and that was going to be our primary focus, and the rest would come as a secondary focus. So we put that off until a little later.

Glenn Novarro - Banc of America Securities - Analyst

Okay. I just think that, I mean our feedback when we check with clinicians is the LifeStent is a great stent, I just don't understand why you don't put more resources behind it today, since the feedback is so good in the physician world.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, well, we have several voices within Edwards that probably feel the same way. And so we're continuing to have that discussion internally.

Glenn Novarro - Banc of America Securities - Analyst

One last question. Can you remind us where you are, in terms of your share buyback, and where you think that the shares outstanding will fall at the end of the year, thanks.

Tom Abate - Edwards Lifesciences - CFO, Treasurer

Sure Glenn. So far in the first quarter we said 687,000 shares, that leaves us with presently slightly less than a million left on the third 2 million authorization.

Glenn Novarro - Banc of America Securities - Analyst

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

Okay. You expect to finish that this year.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, I would say we still find shares quite attractive and buyback quite attractive, so we would stay on we think a pretty aggressive track in this regard Glenn.

Glenn Novarro - Banc of America Securities - Analyst

Okay, great, thanks.

Operator

Our next question comes from Jason Mills with First Albany.

Jason Mills - First Albany - Analyst

Thanks for taking the question. Sorry if I missed it, you may have given an update on the timing from Magna with ThermaFix launch, if I missed it I'm sorry, but could you repeat it?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, sorry Jason. Are you referring to the Magna mitral valve?

Jason Mills - First Albany - Analyst

Yes.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

What we suggested is that we're hopeful that we will receive that later this year. That we have done the submissions, we have answered a round of questions, and we're hoping that we have sufficiently answered those questions. There's always the possibility that we will get more, which is why there's a level of uncertainty about exactly when it happens, but our current belief is that we will have that approved for sale in the U.S. this year. Magna with ThermaFix is approved, and it's doing very well for us.

Jason Mills - First Albany - Analyst

Great. That's helpful. Then just to follow up on a previous question with respect to gross margins, I think you mentioned that 50% of the 260 basis point increase year-over-year was FX, but the 130 from mix, I suppose, you know, if you back out the stock based compensation expense from that, it looks to us like you may be tracking more towards the 200 basis point improvement potential for the year. Your cost of goods sold has declined two straight quarters. Could you just talk about where that could go, you know, longer term. It looks to us like that may be where you have the most leverage in the model.

Tom Abate - Edwards Lifesciences - CFO, Treasurer

Sure. You know, in fact if you notice what we gave was we said more like 64% for the full year including stock options, and that pretty much figures options to be about 30 basis points. So that would put the full year expectation pre-options at 64.3, which is a bit higher than we thought about last time.

Jason Mills - First Albany - Analyst

Okay. So when we look forward, I know you haven't given 2007 guidance, but just to push you a bit further, could we think about this type of expansion year-on-year for one, two, three years?

Tom Abate - Edwards Lifesciences - CFO, Treasurer

You know, typically we have looked at mix. As you saw this quarter it's about half of the improvement. So you could look at half being mix. Then when you look at FX, you have to figure it's going to depend on the rates. So we're thinking 50 to 100 basis points steadily year after year as a result of favorable mix.

Jason Mills - First Albany - Analyst

Okay. To what extent Mike, have you seen off-label use of LifeStent in the SFA anecdotally?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

You know what, I don't know specifically what the numbers look like. We think that LifeStent is getting used very often in the SFA right now. You know, pretty much all the peripheral stents that are sold in the marketplace don't have approved indications, and LifeStent is no different, but we think there's an awful lot of use of LifeStent in SFAs.

Jason Mills - First Albany - Analyst

Perfect. Thanks guys.

Operator

Our next question comes from Tim Lee with Kaufman Brothers.

Tim Lee - Kaufman Brothers - Analyst

Good afternoon. Thanks for taking the question. Just want to follow up on the question regarding the market expansion. I think at the Analyst Meeting you showed some data, in terms of improved outcomes in asymptomatic patients that get treatment. Are there any plans in terms of long range planning of looking at that potential patient population, particularly as you get your percutaneous valve available here in the next 18, 24 months?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Could you explain again which population you're talking about Tim.

Tim Lee - Kaufman Brothers - Analyst

The asymptomatic patients with aortic stenosis, these are the ones essentially walking around without symptoms, but could benefit from surgery. My question is, are there any long-term plans to look at, to really greatly expand the market. It seems like right now you're going after symptomatic patients that aren't being treated. At the Analyst Meeting, one of the clinicians showed a slide that said that if you had an asymptomatic patient population that did get treated, there's better outcomes.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

I think it's a great observation. I think it will be a step-wise process. Right now what we're indicating our early data suggests that symptomatic patients alone, if we just treated those that would double the number of patients treated. When you consider the device content of these devices, you know, that's pretty substantial market expansion.

If indeed it goes a step further, and the clinical community recognizes the advantage of treating patients that are symptomatic, of course the opportunities are even larger. But it's one of those things where, you know, the referral is right now, because the practices are all surgery those symptomatic, or asymptomatic referrals just don't happen. We don't know yet what the rest will be, but that's all upside for percutaneous procedures.

Tim Lee - Kaufman Brothers - Analyst

Thank you.

Operator

Our next question comes from Alex Arrow, Lazard Capital Markets.

Alex Arrow - Lazard Capital Markets - Analyst

Thanks, good afternoon. On the percentage split between Magna and PERIMOUNT, can you give us how much of PERIMOUNT has now been converted over to Magna?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

That's a good question. Let's see, we can talk about the aortic side where we said it's about a 50/50 split, Alex in terms of sales. It's very close to 50/50 right now.

Alex Arrow - Lazard Capital Markets - Analyst

That's by dollars or units.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

That's by dollars. Of course by comparison because Magna has a premium price of about 20% you can back into that.

Alex Arrow - Lazard Capital Markets - Analyst

Right, okay. And are you projecting, or would you advise us that's eventually going to get all the way to a 100%, or do you think there's an equilibrium it will reach, and where you will keep selling the regular PERIMOUNT?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

I think there will be some customers that choose standard PERIMOUNT Valves, for some reason, maybe primarily economic. We're not sure where that is, but we wouldn't be surprised if the majority of valves move to Magna.

As a matter of fact we're also seeing a very rapid movement of valves to ThermaFix. I think probably out of the Magna valves that are out there, we're probably getting close to a third of those valves that are already being purchased with ThermaFix treatment.

Alex Arrow - Lazard Capital Markets - Analyst

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

I know you said Magna is in the 20% premium over a regular PERIMOUNT, have you said how much of a premium ThermaFix is over Magna?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

We haven't. We would say typically that it probably runs in the plus 5%. It's a more nominal change.

Alex Arrow - Lazard Capital Markets - Analyst

All right. On Ascendra, I know you had 20 patients to be done first half of this year, can you say anything about the eventual launch timeline of Ascendra?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

You know, I can't at this point. This will be largely driven by how well that initial feasibility trial goes Alex. As you might imagine, if it goes extremely well, then it becomes compelling for us and the regulators to move faster. If it still needs some more work, then of course that would slow things down. I think we, like you, will be anxiously awaiting the result of this initial clinical work.

Alex Arrow - Lazard Capital Markets - Analyst

If you hit your end points on the 20-patient study on Ascendra, and also on the PVT Cribier-Edwards, if they both hit their end points, which one do you think you would make first your lead product first?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

We're not sure that we would force one of these into the lead Alex. We think if both of them have successful feasibility trials, we will be going as fast as we can to move both of these to the marketplace.

Alex Arrow - Lazard Capital Markets - Analyst

On FloTrac, can you say who the main call point that's getting the traction, is it ICU docs, surgeons, ER docs, nurses, if we were going to interview people on FloTrac, where should we spend our time?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, it is all those to some extent Alex. If you're talking about where the lead is, certainly anesthesia has a substantial role, because the surgical use of this is one that we think will be quite prominent early on.

Alex Arrow - Lazard Capital Markets - Analyst

Okay. No one of those groups is sort of the main point.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Well, I would say anesthesia we have put in the lead.

Alex Arrow - Lazard Capital Markets - Analyst

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

All right. On Optiwave you said 3 to 5 million per quarter, can you say what the main challenge is with Optiwave and why is that, I mean the category seems to be doing well for AF treatment probes, is there something that still has to happen before Optiwave can take its seat at the table?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, just to clarify guidance, we said 3 to 5 million for the full year of 2006. We think that can ramp up. When we look at this one, we think it's primarily a leverage opportunity for our heart valve business, because there's such a substantial number of patients, particularly mitral valve patients, that have atrial fibrillation.

We're just being very thoughtful. We know there's already other treatment systems that are in the marketplace, and we need to displace them. We're not trying to be overly optimistic about the penetration.

Alex Arrow - Lazard Capital Markets - Analyst

Okay. Thanks. On the RESILIENT trial have you said what the threshold is that you need to meet, or what the end points are in order to get that end of '07 SFA indication that you're going for? I know you said what the timeline is, I'm wondering what it is that has to be proven in those patients.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

You know what it's being compared against which is the PTA balloons, Alex, so the comparison is going to be the restenosis rate between the balloons and the stents, and that's what will really drive the comparison. Is that answering your question, or is there something more specific I can help you with?

Alex Arrow - Lazard Capital Markets - Analyst

Basically it has to have a lower restenosis rate than the PTA balloons do for SFA?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes. Actually it's a re-intervention rate, but yes, that's what it is. It's a comparison of that.

Alex Arrow - Lazard Capital Markets - Analyst

At one year after intervention.

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

Yes, you know the FDA I think will look at both six month and one year data, it will be a combination of that that will drive this, that will ultimately power that study.

Alex Arrow - Lazard Capital Markets - Analyst

Is there a well accepted standard restenosis rate at 6 months or 1 year for PTA balloons that you and the FDA are referring to?

Mike Mussallem - Edwards Lifesciences - Chairman, CEO

No, not necessarily. I think that's why the randomized trial, that's why you will end up seeing two rates here, the haves and have nots.

Apr. 20. 2006 / 2:00PM PT, EW - Q1 2006 Edwards Lifesciences Earnings Conference Call

Alex Arrow - *Lazard Capital Markets - Analyst*

Thank you. If I can squeeze in one last question on the LifeStent. I know you have discontinued the LifePath AAA in the U.S., are you still selling that anywhere in the world? And is that still included in the \$3 million number that you gave for peripheral stents, or is that completely gone?

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

No, that's long gone. What we are doing in Europe, there might be some distribution of a competitive AAA device, but we discontinued LifeStent some time ago. So when we give you the more than \$3 million that's exclusively LifeStent.

Alex Arrow - *Lazard Capital Markets - Analyst*

Okay. I'm sorry, you're distributing someone else's AAA still?

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

Yes, I think in a couple countries, it's not very substantial Alex.

Operator

If there are any final questions or comments, please press star one now.

Mike Mussallem - *Edwards Lifesciences - Chairman, CEO*

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

David Erickson - *Edwards Lifesciences - VP, IR*

Thank 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 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, and use account number 2995, and conference number 198934. Let me repeat those numbers. Call 877-660-6853 or 201-612-7415, the account number is 2995, and the conference number is 198934. Alternatively, an audio replay will be archived on the Investor Relations section of our website. Thank you very much.

Operator

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

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