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Transcript

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

Good morning. And welcome to our analyst meeting at 2006 ACC. During the presentations today, there ll be a number of forward-looking statements and so our before I go on with anything else, our Safe Harbor clause does apply and as we get more complex in the world it now takes two slides. So you can read both slides at your leisure. Welcome to the to this meeting analyst update for those on the webcast, you will be able to ask questions during the Q-and-A session and we welcome your participation.

Today s update at ACC is quite simple. We re going to spend a little time talking about the regulatory issues, giving you an update on that Paul will do his best to give you an update on how things are going across the board on the regulatory side. Because there s been some recent developments over the past month or so on that. We ll then ask Joerg Koglin to come up and talk a little bit about the clinical updates here at the ACC. And give you a perspective our perspective on how well our TAXUS program is evolving and continuing to evolve. Then we ll ask Paul LaViolette to come back up and Paul will spend some time giving you a good update on the state of the union at the cardiovascular business. And then we ll open it up for any questions you might have Paul, myself and Joerg will be up here.

We ll also be glad to answer any questions you might have with regards to the status of the Guidant transaction. We are closing in on that hopefully with a closing sometime in first week in April. So we re excited about everything that s going on there. Things are going so far very smooth and according to plan. So we might be able to say and basically do what we said we could do back in January. More to come on that.

So with that brief introduction, let me turn it over to Paul LaViolette to give you a bit of an update on the regulatory matters. Paul?

Paul LaViolette - ***Boston Scientific Corporation - COO***

Thank you, Larry. And good morning all. As Larry described, I ll basically divide my comments into two sections. First give you a general overview of things, excuse me, and then in particular drive in on the regulatory status and then I ll yield the stage to Dr. Koglin for his update. And then I ll give you a broader business review. Let me just describe what we ll be covering today and what the key themes and key takeaways are for the status of the business as we stand today. Most importantly you re all focused on particularly given the American College of Cardiology the status of our drug-eluting stents portfolio.

And I think it s very safe to say that our overall, worldwide leadership position, of course excluding Japan where we do not yet compete, is very stable and relative to our next competitor, strengthening overall. I ll describe our U.S. position in a little bit more detail, but we clearly have a very stable market share position today and of course that s going to be reinforced in the next several quarters by the launch of the first second-generation stent platform in the United States, the TAXUS Liberté.

Internationally which we see I think as a very strong bellweather of the United States activity still to come, is doing extremely well, once again, very stable market shares in the face of increasing competitive activity driven by TAXUS Liberté which of course is already available and strengthening because of our investment in pipeline, TAXUS Liberté will see an upgrade in the next year and of course we now have the ability to merge overall technology platforms between the Xience program and TAXUS Liberté. We re also seeing very clear evidence so far that Endeavor is performing modestly well. That in our view their overall penetration has peaked and that the vast majority of their market share has come from the less deliverable platform offered by Johnson&Johnson. So our international position is very strong.

Our domestic position is also very strong. We have a compelling pipeline, which I ll articulate in more detail as we go along, driven by stent platforms, stent innovation, delivery system changes and second-generation drug programs. And you ll hear from Dr. Koglin that our clinical program is by far the most comprehensive and complex in the field. And of course, that s been highlighted at this meeting in particular by instant restenosis data from the TAXUS V study. If we look at our overall status and I ll immediately migrate into the warning letter status you ll see that we re making very solid, measured progress on that just as we had expected.

Larry has already described our overall status with regard to Guidant, and we will answer questions on that, but clearly our focus in the past weeks has been on clearing or clearly defining the separation strategy, moving forward on the vascular intervention divestiture, moving toward the close of the deal in that first week of April and then moving toward a more comprehensive integration and growth strategy focusing on the key drivers of the value of that transaction including, of course, most importantly, diversification of Boston Scientific and an acceleration of our overall growth platform. And the bottom line is as of today, Boston Scientific year to date performance continues to be very strong. And I ll give you indications of that certainly as it relates to cardiovascular and stent business activity in particular.

So let s spend a minute just talking about warning letter status. I think you re all familiar with what we were cited for. We have a series of systems issues that we are addressing and I think it s imperative to once again reinforce that these are not product safety issues DRQs are not product manufacturing and process control issues. These are quality systems issues that we are very capable of addressing and we are and will continue to address them. We have a series of comprehensive, cross-functional changes underway and in some cases already in place that will in our view comprehensively address the warning letter issues.

We have a three-staged approach that really focuses immediately on remediation, moves us to a much stronger position of compliance excellence within the near term and then of course we re building on that platform with a continuous improvement program that will assure that we can turn quality into a competitive advantage over time. So we are making very solid progress. We have responded to the FDA warning letter with a an outline a programmatic approach that they have received and they are currently reviewing. We are going to be in interaction with FDA routinely from this point forward including face to face meetings, including monthly updates and we expect to have that interaction fed back into our own programs and to fine tune our remediation plans going forward. We are making very clear and measured progress.

This is a matter of weeks now that we have been working on this but it s imperative to understand we were working on many of these things in advance of the receipt of the corporate warning letter and we believe that our remediation actions the change in focus, the intensity with which we re pursuing these efforts inside the company will clearly address these points to the satisfaction of the FDA and to the timelines that we ve articulated previously.

With that, I m going to end my preliminary comments and introduce Dr. Koglin who along with Dr. Russell has been leading our cardiovascular clinical sciences effort for the past number of years and he s going to give you an update on our current, newly released data and some broader perspective on the TAXUS clinical program.

Joerg Koglin ***- Boston Scientific Corporation - Senior Medical Director, Vice President, Cardiovascular Clinical Sciences***

Thank you Paul. Good morning, ladies and gentlemen. Thanks for being here this morning. My name is Joerg Koglin. I m the Senior Medical Director for Boston Scientific. That means together with a team of physicians and scientists I m responsible for the medical aspects of our clinical research program. Besides that I got assigned a room with a very aggressive air conditioning system. Typically my voice is much crisper. I hope you are able to excuse that.

So what do I want to do this morning? First of all I want to quickly talk about where we are where do we see us right now with our clinical research program. I want to then move on and talk about how I want to talk about the new data which we released here at the ACC and on a sneak preview into what data will be available pretty soon within the TAXUS program.

Moving into ACC, one of the news headlines was the DES war continues. I think this headline was also in reference to the fact that a lot of different programs released data here at ACC. So what do we think about this? If you look across programs, and here I just outlined TAXUS and Cypher programs the Endeavor programs, the Conor program, I have ZoMaxx on here and Xience, this is obviously not a battle between equals. If we just look at the sheer size of the program, it s very obvious that many of those programs are still in the early feasibility stage.

So if you look down here at the Xience, ZoMaxx or Conor program you are looking at really small sample sizes and I think those, we as well as Cordis, have learned how many hurdles have to be taken before you really can talk about a proof of principle for your data. Both Cordis and we have worked now for more than four years to establish that and so it is going to be a long path for those smaller programs. If you now just pay attention to the programs which already have presented [inaudible] data within the U.S. and with these Endeavor programs together with Cordis and then our program I think it s obvious that the Endeavor program might still be considered to be in its early adolescence.

They ve presented reasonable one-year data but I think we have to wait for two and three year data before we can assess the durability of the clinical results and most importantly before we can really look into the long-term safety profile. For example, with respect to late stem thrombosis, it is certainly not good enough to just have a large program with a long-term follow up. At the end of the day, the success of a drug-eluting stent program might depend on its ability to expand proof of principle from simple work-horse lesions into more complex patients and lesion populations. This is a slide template which I borrowed from our friends at Cordis. Here, they depict the increasing complexity as a so-called stairway to evidence-based medicine.

So TAXUS program as you all know has been specifically designed to systematically address each of these steps with dedicated trial programs. If you look into the Cordis material, you find similar trials covering most of those steps in the Cordis program. However, at the end of the day if you want to establish new evidence-based data, you are obviously limited to trials which meets the highest quality standards. That means in the end,

ACC/AHA guidelines or ESC guidelines will only be influenced by trials which are done in multiple centers, not only one or two. And trials which are done with independent core labs and trials which are done with independent clinical event [inaudible]. So if you subtract trials which you don t meet those quality standards, then you will get this landscape. And if you look at this landscape I think the Cordis and the TAXUS program have now successfully taken the first five hurdles. If you are looking forward and if you look into the remaining clinical needs, we actually believe we within Boston Scientific through our SYNTAX program are uniquely positioned to address those remaining clinical needs.

So I want to spend just a few minutes to talk about the SYNTAX program. SYNTAX as you know is a program which was specifically designed to address left main and/or three vessel disease. It is a pretty unique program in the way that it really doesn t have any in or exclusion criteria; its a real world, clinical trial assessment. That means inclusion or exclusion of the patient that is [in the end just] decided by the local physician team of a cardiothoracic surgeon and an interventional cardiologist. If the patient is deemed eligible for both treatment options, the patient gets randomized into our randomized arm comparing 900 patients in CABG versus 900 patients in TAXUS. If the patient is only eligible for one of those treatment options, she or he will be followed in our registry arm which will help us to characterize those patient populations who don t qualify for both treatment options.

We are very proud to report that we are on track to address the remaining needs here. As of the end of last week we have enrolled 1,100 patients that is more than 60% of our enrollment goal and in addition to that we have now almost 900 patient in the registry arm. This by just looking at the site report it s specifics of those patients will really help us learn more about expanding procedural complexity. So as reported by the site, these patients have in average, more than four lesions, up to 12 lesions per patient. These patients in average at this point of time have received almost five stents. And a third of those patients have received more than more than 10 centimeters of total stented lengths.

By just looking at the type of lesions enrolled in this trial, the left main enrollment has by far surpassed our expectations with more than 1,000 patients enrolled we have more than 5 400 [listenings] enrolled at this point of time. We have a fairly large diabetic patient population, as expected with three vessel disease a quarter of all patients are diabetics. More than 50% of all patients received overlapping stents. We have a huge dataset on bifurcations and trifurcations already at this point of time, more than 700 patients with lesions of this type. And we will learn a lot about chronic total occlusions, more than 300 patients.

So to put this into perspective, the SYNTAX trial is only paralleled by Freedom right now that s a trial which is now in its final stage predominantly using the Cypher stent. Those trials have a lot of similarities and there are a few differences. The Freedom trial which focuses on two and three vessel disease in diabetics excludes left main. It is designed as a superiority trial they have power to help with the 2,300 patients. They have a five-year MACCE endpoint compared to our one-year MACCE endpoint.

Nevertheless those trials started enrollment roughly at the same time period a year ago and, as just mentioned, we are very proud about our enrollment accomplishment already at this point of time. We have enrolled more than 60% of our patients and the Freedom investigators just have announced last week the enrollment of their 100th patient. So that means we will report our primary endpoint presumably before they even finish enrollment. And we will finish our long-term, five-year follow-up before they reach the primary endpoint.

With that going back, I want to now talk a little bit about what we report here at TCT. TCT for us ACC, I m sorry. ACC for us is first of all about TAXUS V ISR. Here at ACC we believe that we ve mastered another one of those steps in the evidence-based approach to increasing complexity. As evidenced through the simultaneous release of the data, both from the podium as a featured late-breaking trial presentation yesterday by [Greg Stone] as well as the simultaneous online publication in the prestigious Journal of the American Medical Association, we believe that with TAXUS V ISR, our TAXUS continues to change the way how patients are treated. So you might ask, why are you still interested in in-stent restenosis here at the beginning of 2006. I think there are three convincing reasons why in-stent restenosis hasn t lost any of its relevance.

First of all, it continues to be an unsolved clinical problem. Yes, through drug-eluting stents we were able to substantially reduce the need for revascularization. And even with drug-eluting stent, large registries still report a need for revascularization in 3 to 5% of all patients.

More importantly, however, in-stent restenosis is a substantial problem in bare metal stents. So in the U.S. in 2005, to our estimates still 12% of the market is covered by bare metal stents. So that if you roughly 150,000 stents used last year and outside of the U.S. the number is somewhere around 50% or 1 million bare metal stents used in 2005. So in-stent restenosis is still an unsolved clinical problem. Beyond that in-stent restenosis in the clinical environment is considered to be an excellent surrogate for lesion complexity. There is this clinical notion if you have a technology which works well in in-stent restenosis, you might have a technology which works well in all [my] lesions.

And finally more than many of those other lesion complexities, it really represents a very well defined restinotic challenge model which allows technology comparisons, for example, between vascular brachytherapy and drug-eluting stents. Or comparisons between different drug-eluting stent programs.

So this year on the last case in-stent restenosis. This is a patient who received the past two stents into his [circumplex] and this is the result with which the patient came back. This would be considered to be a proliferative in-stent restenosis. Physicians classify it in-stent restenosis depending on length and position. So less than 10 millimeters would be a focal in-stent restenosis more than 10 millimeters would be a diffuse restenosis. If it expands beyond the margins of a stent, it s considered to be a proliferative restenosis. And then there are total occlusions. This patient has a proliferative in-stent restenosis. For this patient, a reintervention with another PCI procedure which would come with a risk of 50% that this would not be successful.

So roughly 6 years ago, this led to the introduction of vascular brachytherapy as a new textbook-based gold standard. And yes, in fact, vascular brachytherapy has helped to reduce those rates so this patient with vascular brachytherapy for trial results would only have a risk of 30%. So the problem is not solved. More importantly vascular brachytherapy as you all know is not a trivial procedure. It involves the use of radio-isotopes. You need radiation permits. You need involvement of radiation experts and it involves the use of a fairly large machinery. This is what happened to this patient in TAXUS V ISR This patient was randomized to the TAXUS arm by QCAs his lesion was measured at 39 millimeters in length. The basal diameter was measured 2.5 millimeter, percent diameter of stenosis was measured by the [inaudible] at 77%. The patient received two types of stents altogether stent at lengths are at total stent length 56 millimeter and this is the result of 9 months. While the picture quality could be better I think it s obvious to see that this here is a marvelous result for an in-stent restenosis.

So this is TAXUS V ISR. It was a trial designed for patients with in-stent restenosis in previously implanted bare metal stents and we focused this trial on native coronary arteries. We allowed the inclusion of fairly long lesions up to 46 millimeters and we allowed the inclusion of [inaudible], essentially across the entire typical vessel site matrix. The patients were randomized one to one into either brachytherapy or TAXUS. The primary endpoint was a 9-month TVR or the target vessel revascularization rate. The statistical design was kind of unique. It was first of all powered as a non-inferiority trial, so it was a goal of ours to prove that TAXUS would not be inferior to vascular brachytherapy and only if that goal was reached, we were trying to also prove superiority.

Before going into the trial results I just have two pictures which talk about the different approaches for in-stent restenosis, so if you have an old stent, if you pretend for a second that you would have an in-stent restenosis within the stent, using TAXUS, would include just implanting a new TAXUS stent inside of the old stent. This would create a new in-stent segment. The area which would be covered by the balloon would be labeled as an injury segment and if you add 5 millimeters to both ends of the in-stent segment, you would have the analysis segment. If you would use vascular brachytherapy to treat this patient, this would be the approach.

Again, pretend for a second please that the stent has an in-stent restenosis first thing which you would do is you would use a balloon and redilate this lesion. Use of additional stent is not a routine part of vascular brachytherapy actually in our vascular brachytherapy in only 11% of all patients receive an additional stent. After dilating the segments, the next step would be the insertion of a radiation source. This would create a so-called radiation segment and again by adding 5 millimeters on both ends you would end up with an analysis segment.

So this trial as I mentioned, randomized 900, err 396 patients. They were randomized one to one into brachytherapy and TAXUS. For the primary endpoint the patients were followed up to 9 months. As in all our trials, we will continue to follow up with those patients for a total of 5 years. In recent years, while vascular brachytherapy is still considered to be the textbook gold standard for treatment of these lesions, clinicians acceptance of this technology based on all the hassle have rapidly declined. And especially the introduction of drug-eluting stents worldwide has shifted clinical practice and the absence of any data already away from vascular brachytherapy to drug-eluting stents.

So for all trials randomizing against vascular brachytherapy this resulted in a substantial problem in getting patients enrolled, recognizing this fact, after having enrolled 200 patients into brachytherapy arm, the FDA agreed to stopping enrollment into the vascular brachytherapy arm and so we just continued to enroll additional patients in a single arm TAXUS registry. For scientific purposes, the results reported here at ACC are just based on the randomized portion, however if you include those 25 patients you get absolutely the same results. So these are the results.

We anticipated based on literature data that the TVR vascular brachytherapy would be around 20%. Actually in our trials the group did fairly well with a TVR rate of 17.5%. However the TAXUS group did not only do as good as they ended up with a TVR rate of 10.5% which is significantly better than the brachytherapy arm. That means our primary superiority endpoint was met. The need for revascularization in the same vessel but outside of the target lesion which we call TVR remote, was well matched in both groups. That means this difference was exclusively driven by a reduction in TLR target lesion revascularization. A reduction from 13.9% to only 6.3% in those highly complex restenotic lesions.

As we look at the cumulative TVR rate there are perhaps 2 or 3 remarkable points to take out of this. First of all, just to remind you again, this was initially designed as a non-inferiority trial. Nevertheless those curves separate early on. They actually already start to separate around 120 days. That is earlier than in most of those trials where we ve compared in the past bare metal stents to drug-eluting stents.

So that means we already have a highly significant difference between both groups, before reaching the angiographic follow-up window. This slide looks at the other components of what we call MACE, a composite endpoint. And bottom line is that all the other components are well matched between both groups that s true for cardiac deaths, for Q-Wave MI and non-Q-Wave MI. That means the significant difference in MACE was exclusively driven through a reduction in TVR.

As I already mentioned that before vascular brachytherapy does not routinely involve the implantation of a new stent. Stent thrombosis is not a good parameter in this trial. With vascular brachytherapy, target vessel thrombosis is typically used as a parameter. In this patient population if you use vascular brachytherapy it s considered to be a high risk patient population for this. In our trial, the vascular brachytherapy arm had an incident of target vessel thrombosis of 2.6%. So if you still have a very acceptable number for this high risk patient population, compared to that of TAXUS number was 1.6%. It s considered to be a very good result. And when I want to go now into the angiographic data, I need the methodology slide here. Why is that? Typically, before we start to look at statistical data the first thing which we do is we assess the distribution of data most biologic parameters that you know are normally distributed. That means if you plot them in a frequency distribution plot you get a bell shaped curve, which is pretty symmetric. Results are recorded as mean plus/minus standard deviation and in order to compare two groups, typically a parametric comparison can be used which takes very efficient advantage of the distribution type.

During the analysis process, and especially during the scientific publication process with JAMA we realized that a few of the angiographic parameters actually are not normally distributing. This is something which we published in the past for late loss which has a fairly skewed distribution, that is something that has been published by others using different stent platforms, for example with the Cypher platform. Along these lines, in order to meet highest statistical standards, the right approach would be to use a median. So a median is used whenever you have a non-normal distribution which is skewed or asymmetric. Typically the median is recorded with interquarter ranges, so this would be the 25th and the 75th percentile of the frequency distribution. Non-parametric comparison is used to compare two groups which essentially ranks each individual observation and therefore might be considered to be less efficient. For you in this presentation I will report both. I will report the mean so that you are able to cross-compare with the results of previous trials previous TAXUS trials and trials with other technologies. And we will use the median and the relevant statistical comparison test to actually analyze the continuous angiographic parameters.

So these are the results here. As it was a randomized trial, as expected, the distribution for the minimum lumen diameter before the procedure was similar. It is well known that vascular brachytherapy results in less acute gain, therefore there is already this trend towards a less pronounced increase in minimum lumen diameter. At 9 months we see a highly statistical difference in minimum lumen diameter both if you would use a comparison of the mean as well as the median.

Late loss, here we see the numbers for the median. Again, most patients with vascular brachytherapy don t get a stent therefore we don t have an instant late loss in that group. The median late loss for TAXUS in-stent was 0.25 and in segment was 1.3. On the same slide, I also plotted the mean late loss. So we come up with an in-stent late loss of 0.38 which it s just remarkably consistent with the results which we ve seen in all our previous trials. If you go back to TAXUS IV, TAXUS V, TAXUS VI and now TAXUS V ISR. So I think it is adequate to conclude that by using the TAXUS technology to get the same angiographic result independent of lesion complexity. So your analysis segment late loss shows the same consistency as the results here in the TAXUS arm are 0.29 for the analysis segment late loss.

Finally binary restenosis. I would like to guide you through that slide in the following way. Please pay first attention to the in-stent segment, we have binary restenosis rate of 7.0, which we consider remarkable. In the injury segment we are highly significantly superior to vascular brachytherapy 21, err 20.1 to 7.0%, there were no differences in edge binary restenosis, that means the overall binary restenosis in the analysis

segment is highly significantly reduced from 31.2% to 14.5%.

And finally, aneurysms even in the vascular brachytherapy arm, we have very good results for aneurysms measured post-procedure as well as nine months. And if you do a paired analysis we have very acceptable results for a results persistent and late acquired aneurysms the aneurysm profile in the TAXUS group is even better with very low rates three aneurysms post procedure two at 9 months, one result, one persistent, one late acquired.

So in summary for TAXUS V ISR, we have proven superiority in a non-inferiority trial. The use of TAXUS Express for treatment of in-stent restenosis in this trial has been shown to be safe there s a low rate for target vessel thrombosis, myocardial infarction, late acquired aneurysms and it has been shown to be effective with a TLR rate of only 6.3%, and an angiographic restenosis rate in-stent of only 7%. So effective when compared to vascular brachytherapy as the pre-existing gold standard. How does this compare to other results with other drug-eluting stents? So

in order to put this into perspective I would like to compare just briefly with the SISR trial that is a trial which was presented by David [Holmes] at TCT last year as you know. And these trials are pretty comparable. They both compare a drug-eluting stent platform versus brachytherapy . They are fairly similar in size, so this is a trial that you see here, randomized two to one whereas we randomize one to one. Unfortunately this is a trial used already a 6-month angiographic follow-up where we used a 9-month angiographic follow-up and a clinical follow-up was both at 9 months are indeed pretty well matched. We allowed inclusion of lesions which were a little bit longer and as in all our trials in order to resemble a more real world scenario we also allow additional PCI in non-target vessels something which you don t find in any other DES program.

The baseline lesion characteristics were very well matched and there were only 2 exceptions. Number one, the TAXUS V ISR our trial had roughly double percentage of insulin-treated diabetics. Number two, the TAXUS V ISR trial, because we allowed the enrollment of longer lesions ended up with 8 longer lesion lengths with increase of 1.3 millimeters. It s clinically considered to be quite relevant. Unfortunately the RVD and the B2/C lesions were not included in the SISR data release at TCT last year. So, if there is a bias against one or the other trial it is clearly a bias against the TAXUS trial. The TAXUS patient population comes with a higher perceived risk of restenosis in this trial. If we look at the data, and I just want to put the numbers side by side because you obviously are not able to make statistical comparison from here. The TLR rate of 6.3 in TAXUS V ISR as just presented compares to a TLR rate of 8.5. Please keep in mind we had more insulin-treated diabetics and we had longer lesions. The TVR, TVF, Q-Wave MI and non-Q-Wave MI rate s pretty comparable. The stent thrombosis rate is pretty comparable. Out of those 3 patients which we recorded with stent thrombosis, 1 patient would not have qualified under the Cypher criteria. I think you are learning again here during ACC that stent thrombosis assessment between programs is quite complex because there are just multiple stent thrombosis definitions.

If we now look at the angiographic data, unfortunately the in-stent numbers were not reported from Cypher in the in-stent segment so we are just limited here to the analysis and numbers. Our analysis segment late loss of 0.29 measured at 9 months compared to a late loss of 0.27 already measured at 6 months. Our binary restenosis rate in the analysis segment assessed at 9 months, 14.5 compares to a binary restenosis rate already at 6 months of 19.8 in the SISR trial.

So, with TAXUS V ISR, we have closed a development cycle from simple to complex lesions. With SYNTAX, we are attempting to address the remaining clinical needs out there. As a team, we are very proud about the fact that we are the first clinical team actually already working on the first second-generation drug-eluting stent. With TAXUS ATLAS, combining the proven drug and polymer combination with an even more deliverable stent, we believe that we have a unique chance to expand our clinical leadership position. We have TAXUS ATLAS de novo that is our workhorse pivotal trial. Those results will be presented at EuroPCR in 2 months from now. With ATLAS Direct we want to test the robustness of our stent technology by using direct stenting. We will try to report the results the 30-day results also at EuroPCR and we will show the primary endpoint which is a 9-month endpoint at TCT. And finally we have ATLAS small vessel and ALTAS long lesion ATLAS long lesion assesses the effectiveness of the 38-milimeter drug-eluting stent on a Liberté platform, so that is absolutely a new and we are only lacking another 2 patients as of today to finish the enrollment here. We are very excited about our enrollment progress there. And with vascular ATLAS small vessel we assess the effectiveness and the safety profile of a 2.25 millimeter stent and we are only waiting for the last 18 patients to finish enrollment there.

Thank you for your attention and I think it goes back to Paul here.

Paul LaViolette ***- Boston Scientific Corporation - COO***

Thank you, Joerg, and I hope everyone understands that the reason we spend a little time at each of these meetings going through data is to really describe the depth and the rigor of our work, the strength of the results, obviously the coherence of those results across trial after trial across complexity and then importantly in comparison to competitive data. So once again, in my view, shows the strength of TAXUS, the strength of

TAXUS in a clinical trial strategy, the strength of our data and the fact that we really do not have any weaknesses in the clinical trial set. And what I want to then do is parlay that into how that is working from a business perspective. So I d like to focus now on Liberte and then I ll expand from there.

First of all as you re aware, Liberté has been launched in the international markets for some number of months now. I think it s imperative to understand that Liberté is a fundamentally different platform. It is not a small modification to the Express platform. It is a significant stride forward and we re starting to see that in the impact it s having on our business. And I ll describe that in a little bit more detail. We re clearly entering accounts and converting accounts that we would not have had access to previously and we re seeing measurable results in the major markets where it s launched and we still have a number of markets based on the array of or continuum of regulatory approvals where we have yet to launch Liberté and where we still hold considerable upside. And importantly, in the face of new product launches from major competitors,

we have held share, and we ve also seen some price increase on the Liberté platform versus the Express platform. If you take a step back and assess the overall competitive environment, within the circle there really are only two major players obviously, we are upgrading from TAXUS Express to TAXUS Liberté and then of course Cypher is the remaining major platform. I think it s key to recognize that Cypher has lost share in the last several months in the face of both the Liberté and Endeavor launches. We are obviously aware that the J&J pipeline does not hold the same promise and I think importantly the marketplace is aware of that. And it s important to recognize that Cypher is really being selected in the marketplace, generally speaking, for simple lesions and the TAXUS platform is generally being selected for the more complex lesions.

If you then look outside the circle at the incremental dynamic in the marketplace, it is now about secondary players, about smaller companies that don t offer much in the form of clinical data, much in the form of clinical credibility and anything in the form of innovation. So while they will have internationally a small peripheral effect on the marketplace as has been the case with balloons or stents or any other technology platform in cardiology, we don t expect them to emerge with any significance over time. Endeavor of course has been launched and has in our view generally been perceived by the marketplace as not equivalent to Driver. There are deliverability drop offs between Endeavor and Driver and there is growing doubt about the clinical data performance because of the drug delivery issues from the Endeavor platform.

And I just want to spend one minute talking to you about Conor because there s a lot of buzz about Conor. There s a lot of promise associated with the hype frankly about combination drug delivery, about a stent that has a wow factor because it does offer some technology that other stents don t offer. But I would encourage you to spend a minute and actually think about Conor, actually segregate the input from the marketplace that is coming from those physicians that have a financial interest versus those that do not. I would encourage you to look at whether or not any significant data has actually been presented. I would encourage you to look at the mechanics of the stent and the fact that it is dramatically inferior on deliverability and conformability in comparison to all other leading stent platforms. That it has other mechanical limitations like in all likelihood, stent embolization as a function of very low stent retention forces. And just basically not get caught up in the hype of a new platform that has scant evidence and frank limitations.

With that in mind if you look at how Liberté is performing, we see dramatic growth in our actual sales and you see on this chart a depiction of both dramatic increase in sales, a conversion of our overall platform to 65% Liberté now, despite the fact that it s not launched in all markets. You see based on the height of the total graphs that our business in the last two quarters has actually grown over the business in aggregate in the three quarters prior despite the launch of the competitive platforms that we just talked about. And as I previously mentioned, average selling prices on the Liberté platform have increased on average over Express. Further to that if you look at our share performance in particular, despite again, multiple product launches in this time frame, we have less than 1% market share variation across three different quarters and we re continuing to see market penetration increase and now reaching 50% outside of the United States. Again as I had previously cited, in our view based on the stability of our market share, and some entree by Endeavor it s very clear and measurable that the market share conversion the market share dynamic has taken place almost exclusively between the Cypher platform and the Endeavor platform.

If you look at the status of the Liberté launch we have currently seen material change between 15 and 20% growth in the pre-launch to post-launch sales in those countries where we have launched it. And obviously, Germany, Spain, Italy, the U.K. are the best large-scale environments or markets to take that assessment. And importantly we have received approval only in the last 6 weeks or so in France and Belgium and if you take that same growth that we ve seen in the other major countries and extrapolate it to France you would expect to see somewhere between 5 and 10 market share points gains in that region.

So we have room to grow in Europe with the Liberté platform, outside Europe in our intercontentental region we still have five major countries where we have yet to launch Liberté, including the biggest countries of all in our region which are Australia, Korea, Canada and then China. So we have a lot of room to grow this platform and we expect that the 65% ratio of Liberté to Express is just going to continue to grow in the coming months. And I ll talk about how we moved forward beyond Liberté in a few moments.

If you look at why this is working, I m not going to go into the mechanics of Liberté, but I do want to simply emphasize the fact that it is a superior stent platform to Express and we believe to all other competitors today. It s because of the engineering and the geometry. It s because of the conformability and deliverability. It s because of the side-branch access. There are real mechanical reasons why physicians are choosing this platform over other platforms. Importantly as you re aware we have had complaints about the balloon withdrawal resistance although more from the United States than outside the United States, based on technique and perceptions. But nevertheless if you measure the both the perceived improvements based on physician feedback as well as the mechanical and bench-derived data on overall performance, TAXUS Liberté balloon withdrawal resistance is equivalent to bare metal Express. So we ve seen significant improvement there and I want to now just switch momentarily to talk about Liberté there in the United States to build a case for how Liberté TAXUS is likely to perform.

If we have seen dramatic shifts in our platform internationally, if we have seen market share growth in the face of new competition, if we have seen mechanical improvements balloon withdrawal resistance improvements in TAXUS Liberté in comparison to TAXUS Express. And if we

see now, 27% market share in TAXUS bare in the United States obviously the bare metal market is not that large any longer but this is the highest market share we ve had in the last half-decade. And it comes at a time when we re not really spending that much time trying to drive bare metal stent performance. So it just is further evidence that Liberté on its own merits just based on mechanical performance is capable of being the leading stent in the marketplace. Add to that our current position in TAXUS U.S. and I think it s very important to understand we recognized a year ago at the American College of Cardiology, we were hit with data out of the reality trials related to FAT s data that subsequently has been generally dismissed by the marketplace about a safety disparity between the two platforms. We know that we lost market share from March of 2005 through the middle of the summer and we expressed at that point a belief that we could stabilize share, that we would rebound in our marketing campaigns, that we would put our data programs together and basically combat the claims against us put forth by our competition.

And I think it this slide tells the tale of exactly what has happened in that 6 to 8 month intervening period. We have categorically stabilized market share, we are clearly not seeing any erosion whatsoever, that has happened across time in the face of increasing supply of Cypher from Johnson & Johnson. In the face of increasing intensity on campaigns attacking safety. In the face of publications of meta-analyses that came out in August. And you see a very transient, small drop in our market share at that point with immediate rebound and recovery and now a period of basically two quarters in a row where we ve had virtually no change in our market share position. And we think that is clear evidence that our business is stable our business is strong. We expect to then layer on additional marketing activity in the remainder of this year. You ve seen some data from Dr. Koglin that gives us additional talking points to continuously reinforce the strength of TAXUS in complexity. In the second quarter we ll announce the pivotal data from the ATLAS trial on Liberté which will go a long way toward reinforcing the coherence of our bridging strategy from stent platform to stent platform and the consistent results of TAXUS. We will also then move into the second half of the year and have the ability to talk about the launch of the Xience platform through the Boston Scientific International channel as well as expanded size matrix of the TAXUS Express platform in the United States. And then of course, we ll move into the fourth quarter where we at that point expect to launch TAXUS Liberté in the United States while continuing to expand on the compelling clinical dataset that we have that is clearly stronger, more comprehensive, larger than any dataset from any competitor. So we think we have a very stable business. We think we have a lot of reasons to feel very positively about the outlook from this point forward.

On a program basis, regulatory status very clear evidence of solid progress with TAXUS Liberté. As you saw earlier this quarter we have finalized our submission with the last module containing clinical data, that is now pending approval at FDA. As we clearly described previously we do expect the timeline for warning letter resolution and the timeline for the TAXUS Liberté PMA to not intersect. We expect to resolve our warning letter issues in time for this projected launch of TAXUS Liberté. We also have already received of course through Guidant the Xience CE mark and we expect to launch that product internationally as I mentioned on the last slide in the June/July time frame as we close the deal, produce some newly manufactured product with Boston Scientific labeling.

And then as previously described, our TAXUS Express filing is pending at PMDA in Japan and is likely to be approved and launched in the first quarter of next year. From there we continue to move the pipeline forward. We ve previously described the vast array of new technologies that go into the Apex platform which will have a significant effect not only on the balloon catheter, but on the way that total system performs. We know that it will improve overall Liberté deliverability by 15 to 20%. And it s extremely impressive in my view to look at the launch times for the first half of 2007. So 12 months from now we ll be gearing up to launch the next generation stent platform in Europe. And only 12 months after the TAXUS 12 to 14 months after the TAXUS Liberté launch in the U.S., we will be launching another platform yet again. And it s in that timeframe that we ll launch by then our third platform just around the time the first new platform from any other company would hit the market. TAXUS Barracuda, our next generation stent platform beyond TAXUS Liberté , which we ve previously described I won t go into the details but importantly it is improved geometry, it is improved deliverability and conformability and radiopacity. That program also on time. Also moving into design freeze. Also trailing the TAXUS Apex by only about 12 months, both in international and in the United States. So you see very clear, compelling progress on platforms that make material, measurable differences in performance. And we ve seen certainly with Liberté that that performance difference has translated directly into sales performance changes in the international market.

So we think we have a very strong pipeline of conventional technologies and we re of course merging that with substantial improvements on novel or breakthrough technologies. And this is evidence of the Petal stent that of course we acquired through [inaudible], very successfully integrated now fully staffed and functioning within our own R&D organization. Multiple programs on delivery systems, on the stent geometry and on drug delivery. What you re looking at is a drug coded Petal stent which is in long-term implants and pre-clinical models. And with tremendous progress on delivery system and on design, this is actually a stent that will be launched with the Petal system on the Barracuda

platform and on our most up-to-date delivery systems. We ve made tremendous progress on the overall mechanical performance of this device and we expect to move in a drug-coded configuration into our first in man studies by the end of this year.

So we re making very impressive progress on breakthrough technologies in addition to our conventional pipeline cadence. And what this adds up to, I believe, is the most attractive overall outlook for any drug-eluting stent program by far. In 2006, in the United States we expect to have a size matrix expansion in addition to the year-end launch of TAXUS Liberté. We then within 12 to 14 months expect Apex to launch. At that point we

expect to launch Xience through our supply agreement with Abbott. So you re looking at two important launches. One with paclitaxel, one with everolimus literally within the same time frame and only a year or so thereafter to then have both paclitaxel and everolimus upgraded on the Barracuda platform and then followed by the TAXUS Petal launch. I would ask you to find any pipeline that comes close to comparing to this, and I think it s safe to say that the answer to that is unequivocally that there is none.

If you look at that drug-eluting stent pipeline, complimented by the rest of our business you see upgrades revolutionary upgrades coming in vascular access systems, the Delta wire which integrates the precision vascular wire technology from our neurovascular business into coronaries. We think that will be a revolutionary improvement in overall guidewire performance. And believe me, physicians love to have better guidewires and I think that will be just yet another reason for us to have an entree into every lab on earth. We re continuously upgrading our leadership position in embolic protection with product line extensions of the filter wire and the Rubicon product the Rubicon product is in final market evaluations in Europe as we speak, going extremely well. We ll be scaled up for international launch later this year and we expect a U.S. version following the completion of our regulatory strategy to be available in 2008 in the U.S. We ve previously covered the Apex delivery system for TAXUS. It will be launched as a new balloon program a little bit later this year in 2006 and we think that will strengthen our historic leadership position in balloons. And IVUS is one of our larger franchises as we speak going through a technology upgrade to the iLab and iSight system and catheter programs. So although we are focusing on major programs, we are investing in TAXUS Liberté, TAXUS Barracuda, TAXUS Petal and next generation technologies beyond that. We still have the wherewithal to invest in comprehensive leadership programs in vascular access, in balloon catheters and in imaging.

The same outlook is available through the peripheral business where we are planning this year to launch multiple new platforms, including the first new balloon catheter in a number of years, a second-generation stent to our Sentinol self-expanding [inaudible] platform. A replacement product to the [inaudible] glide wire and a radical new vascular graft which we think can move market share in the vascular surgery area pretty impressively. That is done in concert with our investments in the carotid space where we have two programs pending and I think it s important to now differentiate between these two because we have the EndoTex platform which is moving, as you re aware, through a third-party through the EndoTex Company which we now expect will be FDA approved in the third quarter. We have responded to final questions there and we think that is on track for launch. And of course we are pending approval and we have received a conditional approval letter on the WallStent carotid system but we do expect that to be delayed as a result of the warning letter. So it is beneficial that we have two programs pending. One internal, one external. We still expect to have multiple carotid stent launches in 2006 in the United States.

So when you add all of that up, what you end up with is a I think an amazing array of leadership franchises across the cath lab, a continuum of leading physicians at #1 or #2, whether it s from the largest market in drug-eluting stents down to the smallest markets in coronary or peripheral systems and a pipeline that is going to continuously replenish that position and reinforce it for the long-term. So let me summarize one final time, now that you ve seen our content, with a brief set of takeaways on the status of our business.

Our U.S. position is very strong. TAXUS has been remarkably stable in the last 6 months, consistently over 50%, no evidence of any change, no evidence of erosion despite increasing supply, despite all of the campaigns that we routinely hear about and that is bolstered by what TAXUS Liberte has done outside the United States which acts as an undeniable predicate for what s likely to happen in the United States when that technology is launched just a few months from now. We ve seen a pipeline of Liberte, Barracuda, Apex that is likely to reinforce that technology leadership and we see nothing from competition that would match that and of course we merged that pipeline with access to Xience, access to all of the technology bioerodable polymers, et cetera. And you look at a leadership position that is likely to be sustained long into the future. And that is continuously reinforced, day after day by TAXUS clinical data, whether it s in complexities, whether it s on new stent platforms or whether it s three, four and soon to be five year data on our earliest trials. I don t see a weakness in this outlook. That s complimented by the progress that we re making on our warning letter status which we again believe will be consistent, will be measurable and will be resolved in well in this year of 2006.

Our Guidant movement is on track. We have a very complex program separating the vascular business, divesting of that, moving toward a comprehensive integration of two very large companies, all in a very short amount of time. And we think we re making very impressive progress

on that again, moving toward a close April the week of April the 3rd. And then that is all happening while the business continues to be very, very strong in the worldwide marketplace.

And with that I ll close my comments and ask Larry to come on back up and lead us to the next section.

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

OK. Thanks for that complete update, Paul and also Joerg. Let s go into questions and answers session. We do have a couple of mikes floating around so if I could ask everyone to wait until you get a mike, and then identify yourself, ask your question, hopefully one, and then we ll go onto the next one. And if there s anyone on the webcast that would like to ask a question, just process it and we ll get it up to the podium. Why don t we if we could get a mike right down here now we have two mikes on one.

QUESTION AND ANSWER

Katherine Martinelli - ***Merrill Lynch - Analyst***

Katherine Martinelli with Merill Lynch. One was just a clarification on the Xience timing because I think the last comments from Guidant was that it was going to be a Q2 launch and it sounds like more like it ll be late Q2, Q3. Is that an inventory issue and then the second one is just in terms of Guidant s bioabsorbable program do you guys have rights to that? Does that go to Abbott? Thanks.

Paul LaViolette - ***Boston Scientific Corporation - COO***

Yes. OK. Katherine, you re right. There is probably a small difference in the launch timing. Guidant as a standalone company today has commenced manufacture of the Xience product for its planned launch based on recent CE mark approval and is I believe planning to launch in April sometime with limited volume. We re planning to launch a comparable version that does require some minor labeling changes so that we can differentiate product A from product B. And just based on production logistics, based on the need to include those labels in sterile packaging, we need to just basically start that from scratch which is going to occur immediately after the close of the deal. So it will take us a few months to build some inventory and then we will launch immediately thereafter. So we re targeting the end of Q2 or early into Q3. And we ll be I think we ll be very competitive with that. The bioerodable, bioabsorbable polymer technology is available to us, is covered in the technology sharing agreement devised by Larry and is something that we re looking forward to working with. So we will have access to that as well.

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

Right across the row right.

Mike Weinstein - ***J.P. Morgan - Analyst***

Thank you. Mike Weinstein, J.P. Morgan. Paul could I just first clarify that last piece on the bioabsorbable. You said it s available to you. Does that mean like with Xience, there s the same type of relationship where Abbott will develop the product, supply the product to you guys under co-branding relationship or when you say available do you mean the IP and the technology and then I have a follow-up.

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

I ll speak to that. First off we were pleased to hear that we have a bioabsorbable stent. We weren t as you know when we went into due diligence we were not allowed to do deep due diligence on the VI program. Abbott was. So we were not really aware what the maturity of it was at least I wasn t. So #1, we do have a rather mature program, in going into humans. We do have rights to it as Paul pointed out. But it is different than Xience, different in the following way. Xience which is a more mature platform for which there is an approval and clinical trials clinical regulatory blueprint that program we do have sharing all the way through the PMA, and a supply agreement and rights to all regulatory approvals, clinical data, et cetera. Once the PMA is established, then we only we must ourselves iterate off that PMA. If there are things in the pipeline at Guidant/Abbott that fall within the PMA as a PMA supplement we actually have rights to that also. Now, that s a much different phenomenon for the rest of the stuff, so to speak. This project that we re talking about I believe it was called Absorb at date of acquisition, we would have full rights to everything that exists on the program on that date. We re now talking in fact, Rick and I will be talking today and tomorrow about does that mean because there s a clinical trial underway, do we have the sharing of the clinical trial results. And that s what I m going to probably suggest. And then the question is, in the continuing clinical trials for the same technology, do we share that and continue that or do we have our separate trials. So there s question s a good one and we re going to put some clarity around that in the next several days. But generally speaking it s not in the same ballpark as with Xience.

Mike Weinstein - *J.P. Morgan - Analyst*

You d have to develop your own product?

Larry Best - *Boston Scientific Corporation - EVP and CFO*

I m sorry?

Mike Weinstein - *J.P. Morgan - Analyst*

You would have to you re saying you would have to develop your own product

Larry Best - *Boston Scientific Corporation - EVP and CFO*

Yes.

Mike Weinstein - *J.P. Morgan - Analyst*

if the question is

Larry Best - *Boston Scientific Corporation - EVP and CFO*

We would transfer the technology, know-how, everything having to do with IP disclosures, et cetera. And we would have to have our people begin to evolve the product and our own product. So it is different than the Xience. Xience is as I outlined.

Mike Weinstein - *J.P. Morgan - Analyst*

If I can ask just a second Guidant question, we talk a lot at this meeting and at TCT and prior meetings about how TAXUS is doing with stability of share. We re not at deal closing yet. Can you talk about how Guidant s CRM business is doing and the stability of that business share and then looking forward, the I haven t gotten the chance to ask this question on conference calls, but you ve talked about as you think about your own forecast and going out in the next five plus years about restoring that franchise and growing market share back north of 30% in high-powered devices. Can you elaborate on the plan to do that to the degree to which there is a plan at this point. Obviously, everything s happened so quickly and the confidence that you have and that maybe we should have that that s going to play out?

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

Yeah. I would say that at this point we re still in the confidentiality agreement with Guidant. It would be unfair for us to share publicly what we know about their CRM business. Secondly, we re going to wait for Jim and the team that was announced, I believe on Friday, to kind of get together and spend at least a couple weeks strategizing and getting to know each other and firming up what are the next steps for the CRM business. I could just say that we re extremely excited about the CRM opportunities. We actually think that the CRM business is going to rebound aggressively but the specifics behind our plan as a joint combined team still are evolving and will probably have something to say on that during our analyst meeting. I believe we re going to schedule one sometime in June, post-combination and Jim Tobin and the CRM team we ll have them up here and lay out what the future looks like, but goes without saying we re very excited.

Rick Wise ***Bear Stearns - Analyst***

Rick Wise, Bear Stearns. Larry can you talk a little bit about the financial implications of selling the Xience stent? Is it successful, does it have an impact or do we think differently about gross margins? I assume it s going to be a less profitable product for you. Or is that the right way to think about it?

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

Yeah. For a period of time, we are you should view it as a distribution alliance with Abbott. Abbott is acquiring control of the business. We are we have with respect to the DES portfolio full access as though we were co-owner of that portfolio, but only because of the opportunity to commercialize do we have this interim supply agreement. And this interim supply agreement really is a very similar almost exactly as a distribution agreement with very specific terms and we will not be corroborating on how we market it together or anything. This is a separate program. We will have our marketing sales and marketing approach. They will have theirs. So we will be pretty independent companies other than I m sure we ll have many, many discussions about supply. We do have the right, if there s any supply constraints, to 50% of the production. So and I m sure there s going to be some supply constraint, and the other thing I just comment while we re on this topic, there will probably be a little bit of delay of us getting into the market versus Abbott. We do we re working on that right now. We do have to have our label on these products. It takes a little time to gear up the labels. I don t know if it s a month, two months, three months but there will be a little bit of an advantage to Abbott with regard to entering the market. But we ll be close behind and we do have the right to 50% of the production and I assume that there ll be supply constraints for some time.

Rick Wise - ***Bear Stearns - Analyst***

Just a follow-up separate follow-up for Paul

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

And when I say that, because of those ongoing clinical trials that ll be required around the world to gain the additional approvals.

Rick Wise ***Bear Stearns - Analyst***

So it s not manufacturing, as much as the clinical

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

Right.

Rick Wise - ***Bear Stearns - Analyst***

Just a follow-up for Paul, managing anti-platelet therapy seems to be one of the major concerns I ve read in the last few days from doctors. And looking at your staircase is there anything that you all are doing or can do specifically to help doctors figure out how long to keep patients on [inaudible] and clopidogrel? Are you doing anything specific? And last maybe you could talk about the logistical challenges of putting in place the post-FDA agreed upon solution? Is that going to be a hard process is that something we should be worried about? Thanks.

Paul LaViolette - *Boston Scientific Corporation - COO*

When you say the post-FDA agreed upon solution you re referring to what?

Rick Wise - *Bear Stearns - Analys*

I m sorry, the warning letter. On the

Paul LaViolette - *Boston Scientific Corporation - COO*

OK. Well, Dr. Koglin, please add anything as well to the anti-platelet question but you know, we re obviously within a 6 month labeling now. Based on the questions in the marketplace about late events, about delayed healing of stent platforms in general, we re not looking to shorten that

recommendation. Any change in that would be dependent upon new technology, new platforms, which would be beyond the scope of the three next generation stents that we re talking about. In other words, you d have a different drug or different healing properties before any change would be available. So I think the state of the state today for anti-platelet management is going to persist for some time. And it s going to be more about I mean, I think we clearly see that the majority of late events are related to interruptions in anti-platelet management often associated with colonoscopy or another surgical procedure or some form of trauma. So that is a risk in drug-eluting stents I think that s going to stay that way for some time and I think it s very clear that it s mirror image risk with both platforms. In terms of the warning letter remediation systems, I don t believe there will be any significant logistical problems inside the company. We re putting new systems in place. Some of those systems are going to enable us to manage the company with greater transparency, greater clarity, greater control and more efficiently. So across the systems, whether it be management control systems, complaint management systems, kappa systems, we re familiar with all the systems we re planning on using. Some of them are being implemented now. And I think they ll be managed well within the error bars of how we manage things today but we ll end up with greater control, greater decision traction, greater response times and I think we ll be much better off as a result.

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

One from the couple from the webcast. One is from Glenn Reicin. He s asking whether we are waiting, Paul, for any formal response from the FDA and I assume that s in response to the information we put into the FDA recently.

Paul LaViolette - ***Boston Scientific Corporation - COO***

We are waiting for a response. We believe we ll get that in the next few days. And as I alluded to on the slides, we will then begin working directly with FDA. We are scheduling a follow-up, face to face meeting and I think between the feedback we get, the subsequent face to face meetings, we ll then be on a very clear path toward our program in response to any refinements from FDA. And then we will just continue to implement, we ll continue to make measured progress and we will continue to update the FDA on that every 30 days thereafter.

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

Paul, we have another question from the webcast from gentleman from South [inaudible] Capital having to do with whether you have any comments regarding the competitiveness your views for the potential competitiveness of ZoMaxx based on what you know today.

Paul LaViolette - ***Boston Scientific Corporation - COO***

Well, we all saw very preliminary ZoMaxx data yesterday 40 patients, four months and it looked what I would describe as preliminarily competitive. You can draw any conclusion you want from a low late loss number and one follow-up event. In what is comparable to TAXUS I, TAXUS II type complexity. So it s a drug that should work. It s a company that has a great history in drug development. We expect it to be a competitive program and anything short of that, I think, would be a surprise.

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

Gentleman right here.

Glenn Novarro ***- Bank of America Securities - Analyst***

Thanks. Glenn Novarro with Bank of America. Question for Paul and then for Larry. Paul, it s impressive that you ve been able to maintain U.S. market share in the face of new capacity coming online from J&J. Can you tell us at least from what you understand, how many new lines J&J actually has brought on with respect to capacity. I know they were talking about up to three new lines this quarter. Then second question is in the fourth quarter, the U.S. [inaudible] stent market did not grow sequentially. Are you seeing growth so far through the first two months of this quarter? And then Larry if you could just elaborate a little bit on what the FTC issues were that forced you to refile? Thanks.

Paul LaViolette - ***Boston Scientific Corporation - COO***

I honestly don t know the details with Cypher manufacturing. I hear obviously everything you hear and maybe a little bit more, but I can t qualify it. Every time I m out to dinner with someone from Cordis I try to give them extra wine and it doesn t seem to work. So I don t know. I really don t know those details. In terms of the market, you re right. We have not seen sequential uptick in overall market volume yet, although our forecast continued to show that by the end of this year we expect the market to return to that full and conventional organic growth. Probably 5, probably 6%. It has taken longer based on penetration and based on the reduction in revascularization procedures. It has taken longer to earn off of that. But we our teams are forecasting that that will return between now and the end of the year.

Glenn Novarro - ***Bank of America Securities - Analyst***

On the we ve seen flat growth?

Paul LaViolette - ***Boston Scientific Corporation - COO***

It s you know, it s too early to say. What we generally do is take the J&J and Boston Scientific numbers, add them together and use that as a retrospective validation of market size so intraquarter, where we are today, it s too early to say what the first quarter is doing. We think we ll see sequential growth. We think our Q1 sales will grow slightly over Q3 and Q4 numbers. We don t know if that s an extra half a share point or a little bit of growth in the market. We won t know that until April.

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

On the FTC issue, Glen s referring to we filed an 8-K last week saying we refiled our paperwork for the FTC, they re and restarted a 30-day clock. The answer to that is it was expected, it was planned when we filed the definitive agreement around January 25th. Now when you do the math, we re going to come up short a little bit on the 30-day. And we felt that we had a pretty clean transaction and however, it was going to be a little bit tough to get the 30 days. So when we discussed it with the FTC, together we concluded that the best step is to refile, trigger another 30-day clock and hopefully within that time period, the early part of that time period, we get an approved transaction. So there was nothing to you should read into it. This was purely this was part of the design of the regulatory blueprint or the FTC blueprint.

We have time for three or four more questions, maybe. Right back here, Alice. I believe that s Larry.

Larry Keusch - ***Goldman Sachs - Analyst***

It s Larry Keusch from Goldman Sachs. Paul, I may have missed this but on the plans for Barracuda you talked about both paclitaxel and everolimus. In the IDE study that you re talking about beginning in the second half of this year, will that actually have an everolimus arm or how are you going to manage that process to move that drug onto the stent? And then secondly, I guess for Larry, when you think about the projections that you re making, is that Barracuda stent the first time that the profitability changes on that everolimus platform?

Paul LaViolette - ***Boston Scientific Corporation - COO***

Yes, we are we have yet obviously to integrate everolimus. So we have a team of folks that will be assimilating the everolimus technology immediately after the close and our plan is to take that technology, apply it to Barracuda. So that will be a new program, an incremental program to the one that we re referring to so all previous allusions to Barracuda are related to and continue to be related to the paclitaxel version and yes, that would be the first platform that would be vertically developed and manufactured by Boston Scientific and outside a supply agreement.

Larry Keusch - ***Goldman Sachs - Analyst***

So there s another clinical trial somewhere that we should look for?

Paul LaViolette - ***Boston Scientific Corporation - COO***

Yes, we would need to do some form of in all likelihood a single arm trial leveraging the existing Xience data at that point on a new platform, very similar to what we ve done migrating from Express to Liberté with TAXUS.

Larry Keusch - *Goldman Sachs - Analyst*

Thank you.

Larry Best - *Boston Scientific Corporation - EVP and CFO*

Right here there s a question right

Joanne Wuensch - *Harris Nesbitt - Analyst*

Thanks. Joanne Wuensch from Harris Nesbitt. Last year we heard a lot about new products such as Trivascular [inaudible] and Endovations and we also heard about investments in companies such as Aztec Medical and Cyberonics. Where do we stand now that you re integrating Guidant and some of those products appear to have slipped and or are delayed. Are you rechanging your focus, is it a clinical delay, should we look for you cashing out some of those investments? Thank you.

Larry Best - *Boston Scientific Corporation - EVP and CFO*

Let me try the first part of that and then turn it over to Paul. On the investment side we do own 14% or so in Cyberonics. Part of our neural stem strategy they re focusing on depression. We re a believer in depression. We re basically a passive shareholder but following their progress and we ll continue to do so. There s no decision or divestment plan at all. We re basically kind of this is part of knowing when to hold them and knowing when to fold them. Right now we have no intent of divesting that. Secondly Aztec Medical likewise, we love what they re doing. We own, I believe, 28 almost 29% of Aztec Medical. We re very excited about their progress in the depression market. So we plan on continuing to hold that investment. We re very happy investor there. With regards to some of these other platforms, and priority now with Guidant, let me turn it over to Paul, maybe you want to talk about Trivascular

Paul LaViolette - *Boston Scientific Corporation - COO*

Sure. Let s

Larry Best - *Boston Scientific Corporation - EVP and CFO*

In fact, there s one of the webcast questions was can you speak to the Endovations program, so maybe the Endovations, triple a and

Paul LaViolette - ***Boston Scientific Corporation - COO***

And

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

[inaudible - microphone inaccessible].

Paul LaViolette - ***Boston Scientific Corporation - COO***

Yeah, and [inaudible]. Larry s absolutely right. We have acquired growth with CRM so that is simply forcing that the internal hurdle rates be raised because we now have higher value growth nearer term. So we re absolutely going to, as a part of this deal, look at our portfolio, reprioritize, raise the bar and concentrate our resources on those that hold the highest potential in light of our new scale, in light of our new internal metrics. So the leading program in terms of timing and perhaps promise right now is endovations. That continues to be targeted for first human use next month. It s been a wonderful compilation of technologies and project management over the last couple of months to continue to

bring that forward. We continue to hold very high hopes for that as a revolutionary platform in endoscopy. So first human use next month, we ll update you at our spring analyst meeting on that progress and what we think our learnings from the clinical evaluations mean to the business model. We have mentioned previously that Trivascular has slipped because of a stent fracture discovery. And that team is long down the path to re-engineering the stent and once we have that finalized we ll re-look at the timelines associated with putting that back on the clinical pathway, but they ve done good engineering work there. As we discussed over the past several analyst meetings, the [inaudible] technology had difficulty basically staying simple, staying cost-effective and migrating through clinicals. So that has less promise for us now. Although we continue to be very interested in the [ceiling] space and we have new technologies that we re continuing to work on. And so I guess that s a summary of

Joerg Koglin - ***Boston Scientific Corporation - Senior Medical Director, Vice President, Cardiovascular Clinical Sciences***

Did you touch on Endovations?

Paul LaViolette - ***Boston Scientific Corporation - COO***

Yes, and I

Joerg Koglin - ***Boston Scientific Corporation - Senior Medical Director, Vice President, Cardiovascular Clinical Sciences***

OK.

Paul LaViolette - ***Boston Scientific Corporation - COO***

I spoke about Endovations, so Endovations and I would also say our program also includes bifurcation stents, carotid stents, next generation TAXUS so really in aggregate, the majority of our programs are making impressive progress. But we re going to raise the bar.

Larry Best - ***Boston Scientific Corporation - EVP and CFO***

OK. Let s have maybe one more question and by the way when we break for q-and-a, we do have in the back of the room our Chief Executive Officer, Jim Tobin, and we also have we re honored to have Pete Nicholas, our founder and Chairman of the Board. So feel free to take them aside and ask anything you d like. Any other one more question? Going, going, gone. All right. Thank you very much for joining us today. We ll probably be announcing an analyst meeting sometime in June where we ll update you further on the first half. We ll talk about the remainder of 06 and we ll also talk about maybe outlook for 07 on a combined basis. Thank you very much and thank you everyone on the webcast.

And thanks again for Jackie LoFuente for all the planning and support for this program.

Forward-Looking Statements

This presentation contains forward-looking statements, including, among other statements, statements regarding the proposed business combination between Boston Scientific Corporation and Guidant Corporation, and the anticipated consequences and benefits of such transaction. Statements made in the future tense, and words such as anticipate , expect , project , believe , plan , estimate , intend , will , may and s expressions are intended to identify forward-looking statements. These statements are based on current expectations, but are subject to certain risks and uncertainties, many of which are difficult to predict and are beyond the control of Boston Scientific or Guidant. Relevant risks and uncertainties include those referenced in Boston Scientific s and Guidant s filings with the Securities and Exchange Commission (SEC) (which can be obtained as described in Additional Information below), and include: general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. Risks and uncertainties relating to the proposed transaction include: required regulatory approvals will not be obtained in a timely manner, if at all; the proposed transaction will not be consummated; the anticipated benefits of the proposed transaction will not be realized; and the integration of Guidant s operations with Boston Scientific will be materially delayed or will be more costly or difficult than expected. These risks and uncertainties could cause actual results to differ materially from those expressed in or implied by the forward-looking statements, and therefore should be carefully considered. Neither Boston Scientific nor Guidant assumes any obligation to update any forward-looking statements as a result of new information or future events or developments.

Additional Information

Boston Scientific and Guidant have filed a definitive prospectus/joint proxy statement with the SEC in connection with the proposed transaction. The material contained herein is not a substitute for the definitive prospectus/joint proxy statement or any other documents that Boston Scientific and Guidant have filed or will file with the SEC. Investors and security holders are urged to read the definitive prospectus/joint proxy statement and any other relevant documents filed or to be filed by Boston Scientific or Guidant, because they contain or will contain important information about the proposed transaction. The definitive prospectus/joint proxy statement is, and other documents filed or to be filed by Boston Scientific and Guidant with the SEC are or will be, available free of charge at the SEC s website (www.sec.gov) or from Boston Scientific by directing a request to Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, Attention: Milan Kofol, Investor Relations, or from Guidant by directing a request to Guidant Corporation, 111 Monument Circle, 29th Floor, Indianapolis, Indiana 46204, Attention: Investor Relations.

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