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ELGX - Endologix Inc AFX Shipment Update Conference Call

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PRESENTATION

Operator

Welcome to the Endologix update conference call. Today's conference is being recorded. At this time, I would like to turn the conference over to Zack Kubow of The Ruth Group. Please go ahead, sir.

Zack Kubow *- The Ruth Group - IR*

Thanks, operator, and thanks everyone for participating in today's call. Joining me from the Company are John McDermott, Chief Executive Officer; Vaseem Mahboob, Chief Financial Officer; and Dr. Matt Thompson, Chief Medical Officer. This call is also being broadcast live over the Internet at www.endologix.com and a replay of the call will be available on the Company's website for one year.

Before we begin, I would like to caution listeners that comments made by management during this conference call will include forward-looking statements within the meaning of federal securities laws. These forward-looking statements involve material risks and uncertainties.

For a discussion of risk factors, I encourage you to review the Endologix Annual Report on Form 10-K and subsequent reports as filed with the Securities and Exchange Commission. Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, December 30, 2016.

Endologix undertakes no obligation to revise or update any statement to reflect events or circumstances after the date of this call. With that said, I'd like to turn the call over to John.

John McDermott *- Endologix Inc - CEO*

Thanks, Zack, and good morning, everyone, and thank you for joining us this morning for a business update as we close out 2016. The last few months have been challenging but we've made significant progress to continue to see tremendous growth potential. Today, we'd like to share information on three important topics related to the AFX System and make sure everyone has a clear understanding of the issues and how we are addressing them.

First is the physician safety notice we are sending out today regarding Type III endoleaks. Second is the recent temporary hold on AFX and AFX2 and the subsequent partial release yesterday and third is the temporary suspension of our CE Mark for AFX and AFX2 in Europe. After we review these topics, Vaseem will share our current estimate of how these issues may impact the fourth-quarter revenue for 2016 and then we'll open up the call for questions.

Starting with the physician safety notice, this is a topic we've been discussing for a few years, including in 2014, when we introduced our DuraPly graft material on AFX. Over the years, we've had several physician communications, [eye] a few updates and product enhancements and as a result, we have experienced a significant reduction in Type III endoleaks with the latest versions of AFX.

The physician letter sent out today represents the culmination of these activities and provides physicians with all the latest available information on our progress in reducing Type III endoleaks with AFX. We are pleased to work with FDA on this letter and appreciate their guidance and collaboration. I'll now turn the call over to Dr. Thompson to provide more details about the letter and a physician's perspective. Matt?

Matt Thompson - ***Endologix Inc - Chief Medical Officer***

Thank you very much, John. So as many of you know, I joined Endologix as the Chief Medical Officer around four weeks ago and since that time, have been immersed in the AFX story. I thought it would be helpful if I gave you my perspective on the physician communication. This letter is available to read on the Company website and in my view, should be regarded as a positive communication.

The physician letter details a transparent process of how an endovascular product can be iterated as a consequence of listening to physician feedback, close post-market surveillance and putting patients in trust first. An overall summary of this communication, we've communicated the product iteration and changes to implant procedure of reduced endoleak rates and consequently, improved patient outcomes. We've also provided guidance for the management of patients who received the first generation of the AFX graft.

I'll now just briefly review the key points contained in the physician letter. AFX was introduced in 2011. Initially, the ePTFE component of the AFX graft was termed STRATA. After the introduction of this endograft, there were some reports of Type III endoleaks in line with published rates for EVAR, which were investigated and resulted in IFU and product iteration.

So broadly in clinical practice, there are two subclassifications of Type III endoleaks. Type IIIa involves component separation, usually between the main body of the bifurcated endograft and the proximal cuff. With AFX, IFU changes were instigated in 2013, along with a manufacturer of longer bifurcated grafts that appeared to have significantly reduce Type III endoleak rate for the AFX system by correcting sizing errors and ensuring longer overlap zones.

Type IIIb endoleaks are caused by fabric tears or suture holes. In 2014, Endologix introduced a new material processing technology to produce DuraPly, a high-strength PTFE which was incorporated into the AFX system. Since the adoption of DuraPly into the AFX system, the rates of Type IIIb endoleaks have appeared to have reduced considerably with a Type IIIb endoleak rate of 0.19 in over 17,000 implants.

The current iteration of the AFX system is AFX2, which incorporates thicker DuraPly material as well as delivery system improvements. As yet, there are no reports of Type IIIb endoleaks with AFX2 in over 4,000 implants and additionally, in the prospectively monitored LEOPARD study, which involves AFX with DuraPly and AFX2, there have been no reported Type III endoleaks reported to date.

Overall then, these are positive results when taken in the low overall endoleak rate achieved with the AFX system and show the continued improvements in patient outcomes that can be achieved through close post-market surveillance, product iteration, and IFU changes.

Finally, I just wanted to say a word about the patients who have received the first generation AFX system with the STRATA material. The Company is responsive to the needs of this patient population and has suggested a surveillance regime in the physician communication and in addition, we'll be working with a group of experienced AFX users to provide guidance regarding management of this patient group. I'll now turn the call back to John.

John McDermott - ***Endologix Inc - CEO***

Thanks, Matt. Now I'd like to discuss our second topic, the temporary hold we put on AFX and AFX2 earlier this week. We discovered the issue during routine internal testing just before last weekend and couldn't complete the root cause analysis and testing before Tuesday. So we chose to put the products on a temporary hold.

To minimize the impact to physicians and patients, our team worked around-the-clock to complete the investigation and we were able to release the hold yesterday on all sizes of AFX and about 40% of the sizes on AFX2. For the sizes we're not yet able to release, we are bringing them back in a voluntary recall and putting them through a secondary lot release protocol to get a portion of them back into the market as soon as possible.

As we suspected, our investigation confirmed that the issue is in our loading process for larger diameter devices which are historically the most challenging to load into the delivery system. We have isolated the issue and are actively making process improvements to prevent this from happening again. In the meantime, we can supply AFX devices, the smaller sizes of AFX2 and also conduct lot release testing on existing inventory of larger sizes of AFX2 to cover the demand.

We are also very fortunate to have the Ovation device, which already has the broadest indication of all infrarenal devices and has great clinical data that was just recently presented. So while we do expect some disruption in competitive counter-detailing, we should be able to take good care of our customers while we resolve this issue.

At this point, it's too early to provide a precise timeline of when we'll have 100% of the AFX2 sizes up and running but we should be able to give more details on our fourth-quarter call in February. Most importantly, our broad portfolio of devices will enable us to keep supporting physicians and treating patients with abdominal aortic aneurysms.

The third and final topic is the temporary suspension of our CE Mark for AFX and AFX2 that we announced on December 13. Based upon communications with our notified body, G-MED, they suspended our CE certificate due to reports of Type III endoleaks. We believe these reports are related to the first-generation AFX device with the STRATA graft material that was discontinued in 2014.

On December 20, we filed an appeal with G-MED and provided them with information to reconsider their decision. We've also been contacted by physicians throughout Europe who have sent letters to G-MED with their positive clinical results with AFX and AFX2 requesting that the CE certificate be reinstated.

Excuse me. We expect a decision on the appeal in the month of January 2017. If the appeal is not successful, the next step is to file for recertification in January and likely get a decision in April of 2017. Based upon the low rates of Type III endoleaks with the current versions of AFX and AFX2, as outlined by Matt and in the physician safety notice, we believe the CE Mark will be reinstated in January of 2017.

While AFX and AFX2 are temporarily unavailable in Europe, we will continue to provide Nellix and Ovation to physicians for the treatment of their patients with abdominal aortic aneurysms. I will now turn the call over to Vaseem to discuss our preliminary view of the fourth-quarter sales results.

Vaseem Mahboob - ***Endologix Inc - CFO***

Thank you, John, and good morning, everyone. We have done a lot of work and analysis to understand the impact of the CE Mark suspension and the shipment hold on our Q4 financials. We see four main sales impacts. First, the OUS loss cases, we expect that to be in the 60 to 70 case range, and these are cases that we were not able to perform as expected and represent loss of revenue for Q4 of about $1 million. Second, delayed shipments to distributors in our OUS markets. We had several orders of up to $2 million that we were unable to fulfill and ship due to the hold.

This is a timing issue and we expect to recover this revenue in 2017. Third, we also had to rework on the AFX2 revenue related to our OUS distributors since we could not swap and/or replace the recalled AFX2 sizes within the current quarter. Again, this is a timing issue as well and we believe that these are sales that we can recover when the shipment hold is lifted; hopefully, sometime in Q1.

Fourth, the CE suspension has primarily affected us in markets where we don't have Nellix or Ovation approved, like France and Belgium. We estimate that this impact could be in the $300,000 to $500,000 communicated in previous calls for the fourth quarter. Overall, the impact on Q4 sales is estimated to be approximately $4.5 million versus our guidance for the quarter.

Regarding inventory, we estimate that we have about $3.6 million of AFX2 inventory that will need to be lot tested, reworked or at some point, scrapped. We have already started the process to return this inventory and will provide the actual P&L impact by our Q4 earnings call. All three parts are currently performing well and the core business is intact.

While recent events have impacted our top line for Q4, we feel we can recover some of the sales in 2017. At this point, we also believe that these events will not have a material impact on our liquidity and cash position in 2017. We think we can manage our costs and cash burn to offset this, and continue to invest in the growth of the Company.

Last, in terms of the 2017 outlook, we plan to provide formal full-year guidance on our Q4 call. At this point, we should have improved visibility on the status of the CE Mark and our progress in lifting the shipment hold on the remaining sizes of AFX2. With that, I'll hand it back to John. John?

John McDermott - ***Endologix Inc - CEO***

Thanks, Vaseem. Before we open up the call for questions, I'd like to emphasize a few things to make sure everyone is clear on the issues, how they are being addressed, and our perspective on the impact to the business. First, is the physician safety letter; this is a voluntary communication and collaboration with the FDA. We see this as a positive culmination of our efforts over the past few years to dramatically reduce the rates of Type III endoleaks seen with our earlier generation device.

Second, the voluntary manufacturing hold on some sizes of AFX2 is based upon internal testing results and our desire to only deliver to the market the absolute highest quality products. We'll get back on the market soon with remaining sizes of AFX2 and in the meantime, have other excellent devices to continue supporting physicians.

Third, the temporary CE Mark suspension on AFX and AFX2 is clearly based upon events from the first-generation device that was discontinued in 2014. We have compelling evidence that the newer generation AFX and AFX2 devices provide excellent clinical outcomes and the CE Mark should be reinstated soon. In the meantime, we will continue to sell Nellix and Ovation in Europe to support our customers.

While these have been challenging issues for us over the past few months, I'm proud of the way our team has responded and our continued focus on quality and patient safety. We continue to see significant growth potential at Endologix and have several catalysts over the next six months to grow our business and increase shareholder value. With that, we'll now open up the call for questions. Operator?

QUESTION AND ANSWER

Operator

(Operator Instructions)

We will take our first question from Brooks West from Piper Jaffray.

Brooks West - ***Piper Jaffray & Co. - Analyst***

Good morning, can you hear me?

John McDermott - ***Endologix Inc - CEO***

Yes, good morning, Brooks.

Brooks West - ***Piper Jaffray & Co. - Analyst***

Thanks for taking the question. A couple for me. John, you said you were able to release, if I heard you correctly, 40% of AFX2 SKUs. Is that representative of about 40% of the case mix or is it higher or lower?

John McDermott - ***Endologix Inc - CEO***

It's the same.

Brooks West - ***Piper Jaffray & Co. - Analyst***

It's the same. Okay. Do you have an estimate of patients who might have been implanted with the potential damage AFX2 system?

John McDermott - ***Endologix Inc - CEO***

Well, yes, we would have -- had we -- had many of those, Brooks, we would have gotten reports. As I said earlier, the -- this hold was not initiated by reports of Type IIIb endoleaks from the field. It was an internally detected manufacturing issue.

We haven't received reports of acute Type IIIb endoleaks, which is what you would see here if those products had made it to the field. Again, we see this really as an internally-driven activity just to be on the safe side.

Brooks West - ***Piper Jaffray & Co. - Analyst***

Okay. And then I would love to have Dr. Thompson just comment on -- I had a couple of questions on, if you did implant a graft that had a tear in the graft material, would you see that acutely or could that present over time? I'm just wondering how that works?

Matt Thompson - ***Endologix Inc - Chief Medical Officer***

I think, to be honest, Brooks that depends on the size of the hole. So if you had a fabric defect in either of the main body or limb of an AFX graft that was big enough to allow free passage of blood such that you would see it on an angiogram, then you would pretty much see it straightaway and be able to deal with it straightaway.

If the hole was much smaller, I think the likelihood is that, that wouldn't cause a problem because that would just [thrombose] at the time and would probably not present itself as a problem later on down the line.

We do know, of course, that if you look at any endoleak complication, that it would only get worse with time if you look at cumulative rates because they will go up year on year as more people get an endoleak. But I don't think we are looking at a smoking gun here at all.

I think with the holes that were [seen] in the internal process, it is likely that, that would cause no problem at all. You would see them at the time intubating. As John says, looking forward through the AFX2 data there being absolutely no reports at all in 4,000 implants of the Type IIIb and even in the prospects of the monitored LEOPARD study, we have not seen any.

Brooks West - ***Piper Jaffray & Co. - Analyst***

Okay. That's very helpful. I guess just last one for me for John or Vaseem, I know you don't want to update 2017 guidance but just broadly speaking, 2017 is going to be a re-basing year for you guys. Do you think the business can grow on a reported bases year over year in 2017 or should we think about it as kind of flat to down overall?

Vaseem Mahboob - ***Endologix Inc - CFO***

Brooks, that's a great question and we've had a lot of discussion internally about that and the real one card here is the CE Mark certification. I think we remain very optimistic that, that -- it's going to be reinstated here soon and as I said hopefully, we will have good clarity on that before the earnings call in February.

Based on internal discussions with our sales teams, we feel very comfortable that we can still hold to that mid-single digit guidance that we had given out back in yesterday, but again, we just have to monitor the situation and see how this evolving, and also the CE Mark.

Brooks West - ***Piper Jaffray & Co. - Analyst***

Great. Thanks for taking the questions.

Operator

We would take our next question from Rick Wise from Stifel.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Good morning. It is Matt Blackman in for Rick. How are you, John, Vaseem, Dr. Thompson? Just a couple questions, just curious.

So what's left to be done with the remaining sizes of AFX? What is the testing that needs to be done and it is sort of a matter of weeks or is it like more of matter of months for you to work through whatever needs to be done to get those lots -- or those sizes back on the market?

John McDermott - *Endologix Inc - CEO*

Well, there's a few activities, Matt. One of the activities that's already underway is that with our existing inventories of AFX2, we can put them through additional lot release testing. Take testing samples from established loss under statistical testing methodologies and if those units pass, we can release those to the market.

Those activities have started; in fact, we released product yesterday. That will be an ongoing way to get product to market although there is clearly a cost because we have to do deployments and destructive testing to those.

We will do that same thing with the AFX2 devices that we bring back from the market. We will get those in, we will batch them into lots. We will test them and release as many as we can. That will be happening concurrently while we make additional process improvements on the line. That's why it's a little difficult to predict with those moving parts exactly what the flow of AFX2 products will be for those remaining sizes.

But again, the good news is with all of the AFX codes available and Ovation, now that all the reps are trained and certified, we have still got plenty of great products and opportunities to treat the patients. So we should be able to provide a good update on the exact status for the remaining AFX2 codes on the Q4 call in February.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Okay, John, that was very helpful. That dovetails into my next question.

I'm guessing we will more likely to hear on the AFX and AFX2 progress as well as the European suspension on the Q4 call rather than in the upcoming conferences you may be presenting. Is that the right way to think about the timing of updates?

John McDermott - *Endologix Inc - CEO*

Yes. Actually, I expect to hear about the CE Mark suspension in January. So if the G-MED holds to their timing, we would know that before the end of the month in January. I don't think we will know that by JPMorgan.

Maybe we will get lucky and find out by then but more likely, it would be in the middle to second half of January. We will obviously release that as soon as we find out and then we'll be able to provide some more color on the AFX2 device availability for the remaining codes on the Q4 call as well as the guidance and everything else.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Okay. And then just one last question. I've sort of skimmed through the physician letter and I was hoping maybe Dr. Thompson could add his thoughts here. But is there anything in the updated IFU, either with the procedure or the follow-up that makes implanting AFX or AFX2 more cumbersome, or the follow-up more cumbersome than that perhaps competitive devices?

And then a couple of follow-ons, just again, looking at some of the tables that were in there. It looks like that the curves for the Type III leak rate really started to inflect in year two-plus. And although the curves have separated a little bit and haven't seen that inflection in AFX, with DuraPly right next, too, it seems like these next couple of years, we could still see that pop up.

So just how do we think about -- are you through the woods yet, really, is the way I'm thinking about it? I know we don't have reports of leaks yet but do we still have to wait another 12 or 24 months before we can fully put this behind us?

Matt Thompson - ***Endologix Inc - Chief Medical Officer***

Thanks Matt. So a couple of things there. With surveillance, I think the recommendations on the IFU don't differ significantly from all other IFU recommendations and indeed, what the societies are recommending. I think at the moment, particularly for patients with the STRATA grafts and we are recommending [CT] as opposed to any other form of surveillance as long as people have the renal function, the comorbidities to withstand that. But in reality, I don't think that differs from any of the competitive devices or really, any of the other devices in the Endologix portfolio.

With regard to the endoleak rates, I think your interpretation is spot on. We -- with all these cumulative curves and survivor analyses, you see rates sort of going -- getting worse, two, three or four years after implementation.

The comfort that I take from the curves is particularly in that last curve in the physician letter where we have amalgamated all of the Type III leaks together so the IIIa's and the IIIb's to try and give a bigger sum of size. And actually, I think that curve, in particular, is pretty encouraging the way the three lines are separating.

So you're quite right. We will see further endoleaks later on down the line because that is the nature of the difficult space that we work in. But I think those curves are separating pretty quickly and I think if we were going to have a significant IIIb rate or IIIa rate, you would start to see an increased incidence of those by two years and we are really not seeing hardly any at all. So I think we can take comfort from that.

I'm sure we are going to continue to look at those curves and be able to provide you with those data in due course. But it looks to me pretty encouraging at the moment, as we've learned with Nellix, you can never say never. But I think once we have got out to two years, which we have here, and you are still seeing good separation of the lines, I would take that to mean that the current generation of devices is a significant improvement in terms of Type III endoleak rates off the previous one.

Matt Blackman - ***Stifel Nicolaus & Company - Analyst***

Thank you very much. Very helpful.

John McDermott - ***Endologix Inc - CEO***

Matt, let me just both maps. I will just add one note to Dr. Thompson's comments. Specific to IIIa. If you look at that curve, you will see that it really increases with the older material out to five years for IIIa. That's really a function of the early implant algorithm. So if you look at the -- that rate is higher out five years, what it doesn't consider is all of the IFU updates and the training that went into the overlap over the recent years.

I would expect, and the reason I think you're starting to see divergence in the curves for IIIa is because of the effectiveness of the overlap training. It is very straightforward.

The other difference that's worth noting for IIIb is obviously, the acute difference between the materials, STRATA and DuraPly, are obvious. But there is also a longer-term benefit in that we know that stronger material with DuraPly, we don't get whole propagation that we did see with STRATA.

So that also speaks to what should be a sustainable long-term benefit. And I think those curves are -- as you are starting to see they are diverging. And we believe that divergence will continue based upon those factors.

Matt Blackman - ***Stifel Nicolaus & Company - Analyst***

Okay, thanks. Thanks, everyone.

Operator

We will take our next question from Chris Pasquale from Guggenheim.

Chris Pasquale - ***Guggenheim Securities - Analyst***

Thanks. Vaseem, I just want to make sure I understand the financial commentary correctly. So you're talking about a $4.5 million impact in the fourth quarter, but roughly $3 million of that is primarily a timing issue and should be made up in the first quarter? Is that the right way to think about it?

Vaseem Mahboob - ***Endologix Inc - CFO***

That's correct, yes. So the $2 million of the OUS shipments from this quarter and $1 million revenues to us that we had to take because we could not swap or replace the AFX2 inventory that was already out there.

Chris Pasquale - ***Guggenheim Securities - Analyst***

Right. And then as we think about the pieces that could spill over into 1Q, do you have an estimate at this point what it would mean for the business if AFX is off the market in Europe for all of January?

Vaseem Mahboob - ***Endologix Inc - CFO***

We have done some scenarios, Chris, but I think it's too early and premature to share that with you guys. But like I said, we will share that with you on the next earnings call when we give out the guidance for 2017.

Chris Pasquale - ***Guggenheim Securities - Analyst***

Okay. Then the last component I would think could be some ongoing supply constraints as you work through this stepped-up product testing regimen. Should we expect that to lead to loss cases or do you think you can basically cover demand and the real impact we're going to see is going to be more on the margin front?

John McDermott - ***Endologix Inc - CEO***

I can take that, Chris. I think with the broad portfolio, we've got the right level of coverage. But I still think that we should expect some level of impact. It's difficult to put a number on it right now but I think until we are back to 100% velocity, with all sizes of AFX2, we will see a little bit of slippage. But clearly, we've got the tools to mitigate it and seeing -- we've actually already seen a pretty nice jump in the Ovation case schedule.

So the team is pivoting very nicely as we would expect them to do but I don't want to say, there will be no impact. I think that we will have some and we will be able to characterize it better for you on our Q2 call (multiple speakers) on our Q4 call. Excuse me.

Vaseem Mahboob - ***Endologix Inc - CFO***

I think just to add to that, Chris, I think we will see some margin compression with this lot testing algorithms here in Q1 if we still figure out the long-term solution for the AFX hold. But I think to John's point, let's revisit this Q1 forecast and the impact on topline and the mix of the products and then also the impact on the margins based on the lots testing.

John McDermott - ***Endologix Inc - CEO***

I think the thing that's most important for me is that this is a Q1 thing and this shall be behind us here before we know it.

Chris Pasquale - ***Guggenheim Securities - Analyst***

Okay, thanks. That's helpful.

Operator

We will take our next question from Joanne Wuensch from BMO Capital Markets.

Joanne Wuensch - ***BMO Capital Markets - Analyst***

Good morning, can you hear me okay?

John McDermott - ***Endologix Inc - CEO***

Yes, good morning, Joanne.

Joanne Wuensch - ***BMO Capital Markets - Analyst***

A couple questions. We've been talking a lot about impact to revenue; have you quantified the expenses that are associated with this process -- these processes?

Vaseem Mahboob - ***Endologix Inc - CFO***

Sorry, Joanne, can you speak up? I didn't pick up the question.

Joanne Wuensch - ***BMO Capital Markets - Analyst***

Sure. I'll try again. We've been talking a lot about revenue; have you quantified the expenses that are associated with these processes?

Vaseem Mahboob - ***Endologix Inc - CFO***

Yes, as I said on -- to Chris's follow-up there, the big expense that we see here in Q1 and the impact that it will have on margins primarily is on the lot testing. As an example, if we go over the lot testing methodology of three and 30, which means that we will test at least three -- or we'll do non-disruptive testing on three units out of 30, that is a 10% margin compression on that lot of revenue.

So we are still trying to figure out what that lot testing regimen is going to look like and then as I said, we'll give you the impact of the margin compression that we'll see in Q1. But to John's point, it is only a Q1 phenomenon because we think that the long-term solution will be in place over the quarter.

Joanne Wuensch - ***BMO Capital Markets - Analyst***

But there are no one-time expenses related to recalls or anything else or physician communications?

Vaseem Mahboob - ***Endologix Inc - CFO***

There's not much cost related to the recall but there is an impact on the inventory. As I said, there's about $3.6 million of inventory that's out in the field related to AFX2 sizes that are still on hold and as that inventory comes back, we will have to go through the same process, Joanne, which is apply a secondary lot testing algorithm to that inventory and then depending on the re-work costs associated with that, it will kind of have to determine what happens to that $3.6 million. Worst case, you have a write-off a $3.6 million and then the best case would be that there is a big portion of that we can actually preserve and return back to the field.

Joanne Wuensch - ***BMO Capital Markets - Analyst***

Okay. I know we've been focused on this, so forgive me for bringing this moment up. Is there anything new on Nellix in the US that we should be aware of?

John McDermott - ***Endologix Inc - CEO***

No, nothing different. No surprises.

Joanne Wuensch - ***BMO Capital Markets - Analyst***

Thank you very much.

John McDermott - ***Endologix Inc - CEO***

Thanks, Joanne.

Operator

We will take the next question from Mike Weinstein from JPMorgan.

Andrew Hanover - ***JPMorgan - Analyst***

Hey guys, this is actually Andrew Hanover in for Mike. Thanks for taking the question.

John, I wanted to just dig in a little bit on the Dear Doctor letter for a second and just understand your relationship with the FDA. So given a lot of the issues that were laid out in the letter are old issues, one, that I think a lot of people have known about for some time, I want to go back to the question why now? The language in this letter? That's question one.

Also in the Dear Doctor letter, it was pointed out you didn't identify the changes to address Type III endoleaks. Will this letter and your quick actions taken on Tuesday, are these steps to help, whatever -- amend any relationship issue, if there is an issue with the FDA to expedite anything moving forward?

John McDermott - ***Endologix Inc - CEO***

Let me start at the end of that question, Andrew, and work back. I think one question you had there was about the types, the improvements and their relationship to endoleaks. I think there is a sentence in the letter that talks about the improvements that were made were not necessarily submitted as corrective actions. That's true.

Actually, at the time of the submission, for example, for some of the IFU updates and even the new DuraPly material, the rates were so low, the reported rates of Type III endoleaks were so low they weren't done as corrective actions. They couldn't even be characterized as corrective actions at the time because the rates were so low so those were filed and approved as process improvements.

That's a different type of submission and we discussed that with FDA at the time and again, at the time the rates were so low, it made sense to put them as process improvements. So this has been collaborative with the agency from the beginning and I would say through, there has been a lot of collaboration with the letter. We have been talking with them about the letter for several weeks.

We actually had a good meeting with them in the summertime, reviewed all of the updated information. We've been talking with them about updating our IFU to provide more specific instructions to physicians if they have a Type IIIb endoleak and how to treat it. In those discussions this summer, reached an agreement it was a good time and appropriate to provide another updated communication.

So that's really what triggered this but it has been, as I said, collaborative and they've provided some good guidance and we feel good about the letter and the information in the letter. And we think physicians will respond positively. Nothing -- I don't think there is any big new information in the letter because we have been communicating pretty actively on this topic for a while but it's a good overview with a lot of good current information.

Andrew Hanover - ***JPMorgan - Analyst***

Right, and then I want to go to just some Nellix things, too, which is I think you, in a previous question, you were talking about the AFX rates, pre-changes to the IFU and post the changes to the IFU and we know that you've made similar types of changes different but for Nellix, right? So do you think the FDA is going to require you to make a cut of the AFX data to date to help with the Nellix stuff to give them some comfort that on a longer-term basis, we might not see some issues longer term, past the two-plus years?

John McDermott - ***Endologix Inc - CEO***

Andrew, I'm not sure I understand that question. The question is about AFX or Nellix?

Andrew Hanover - ***JPMorgan - Analyst***

I'm just -- yes, well, it's a combination, right? I'm just trying to understand -- I'm going back to a relationship with the FDA and it sounds like there is a lot more collaboration, which is good. But in order for Nellix to get through which I think is -- other than the base business staying stable, is understanding how the relationship with Endologix and the FDA continues to build positively.

So I'm just wondering, can you can take some of the AFX data that -- and make some type of cut of the data two-plus years with the new IFU and parlay that into -- what you should -- it's different with Nellix, obviously. But try to build relationship and more data for the FDA to feel more comfortable with the device on a longer-term basis?

John McDermott - ***Endologix Inc - CEO***

I think the agency is probably looking at the devices independently because their designs are so unique and we have a long, long legacy also with AFX and these more recent reported complaint data are so positive, I think that it stands on its own.

For Nellix, the decision to want to review two-year data, as we talked about before, I completely accept and understand why they would want to see that because we saw a signal as we've talked about in some of those patients out to two years. It's a very reasonable request and I believe that with the proposed IFU updates, we will see very good results for the patients that are ideally treated with Nellix.

So I think the relationship is collaborative and I don't know that there is anything coming out of the AFX situation that will impact Nellix at all but I would just -- I would say that we talk to the FDA a lot. We've got a lot of projects going, with the Nellix, with this. We just got approval for the Ovation Alto IVE. We have a lot of interaction there and we're -- it's a good relationship and we are pleased with the collaboration.

I also -- if I can add just one comment as it relates to the FDA. We see the letter as positive also in the context of the CE certification. Clearly, the agency as we've worked with them on this updated physician communication, and we are hopeful that their desire to continue to have a product in the marketplace and provide this communication, provide some additional comfort and evidence for our notified body to reinstate the CE Mark.

Operator

We will take our next question from Chris Cooley from Stephens Investments.

Chris Cooley - ***Stephens Inc. - Analyst***

Thank you. Good morning. Thanks for taking the questions. Maybe just two quick ones for me. John or Vaseem, could you just clarify for us, you mentioned in your prepared remarks that you would know definitively in January now regarding recertification, if you will, from G-MED on the CE Mark? Originally, when you communicated to the Street, regarding that event, you indicated you would have clarity prior to calendar year-end.

And pardon me for parsing just a couple weeks here, but could you maybe just elaborate for us, is that a function of just the time it took the Company to prepare its response? Or should we assume that the current actions, obviously with AFX and AFX2, have made this a little more of a protracted process. I just want to make sure I fully understand what is pushing that out a couple of weeks? And then I have just one quick follow-up as well.

John McDermott - ***Endologix Inc - CEO***

Chris, I don't think the timeline has changed at all. I think when we communicated the CE certification issue, what we communicated was that the feedback we got from G-MED was that they would process an appeal within 10 to 15 days of receiving the appeal. I gave you the date in the prepared remarks for that, I think, was December 20 so that still pushes us into January.

And I think our communication from the beginning is that we would know in January. So nothing has changed. We turned around the appeal right on the schedule that we anticipated and at this point, we haven't -- we don't have any reason to believe that G-MED isn't going to also keep their timeline. So it has been January from the beginning.

Chris Cooley - ***Stephens Inc. - Analyst***

All right. Maybe I will follow-up with you offline. And then just lastly, and I appreciate the color, Vaseem, in terms of the four components and where you're trying to parse out the $4.5 million impact to the fourth quarter.

But on the second item on delayed shipments abroad, the $2 million, any reason why that should not come back in theory, if you are seeing a reduction maybe in end market demand? If there's any noise? I'm just trying to make sure I think about what does definitively come back into 1Q.

Any component of that, that could maybe see some -- or be subject to, let's just say, some refinement as we go into 2017? Obviously, the lost US cases are lost but I'm just trying to think about the delayed shipments and the rework?

Vaseem Mahboob - ***Endologix Inc - CFO***

So Chris, as I explained earlier, the impact on lost cases is essentially the cases we lost for the certification market impact on Europe and the AFX, and also the US loss cases. Obviously, there is a gone.

Now, the rest of which is about $ 3 million is what we expect to recover in Q1. So I do expect that all to be coming back now.

On the $2 million OUS shipments, it was more of a function of the mix and also for us, to make a little bit of a call on making sure we had enough AFX inventory here in the US to support the cases if we had an extended (inaudible) deploy FX, too, so on some of the larger sizes. So we chose to pull back on the inventory and wait for the (inaudible) root cause analysis to be completed and get more finality on that. Again, I do expect that the segregate to Chris' question, the $3 million of this $4.5 million is all coming back; it's not lost revenue.

Chris Cooley - ***Stephens Inc. - Analyst***

Understood. Thank you.

Operator

We would take the last question from Ravi Misra from Leerink Partners.

Ravi Misra - ***Leerink Partners - Analyst***

Hi, thanks for answering the questions. Just two questions for me on this end. Just on the AFX2 lot test, you said some of the larger sizes had been cleared; is that right? If so, how should we expect those working their way back to the market? Are they on their way, on the truck back or are you holding off once you do more lot testing on that?

Number two, I think you said something like 40% of the SKUs affected, about 40% of the addressable cases. So for the 60% of the sizes that are off the market, what portion can be addressed through Ovation or Nellix? Thanks, and Happy New Year.

John McDermott - ***Endologix Inc - CEO***

Let me take the last part of your question, Ravi. So for the sizes that are not available with AFX2, those are 100% covered by AFX. The size range for AFX and AFX2 is exactly the same so there is no loss of coverage. In addition to that, Ovation already has a broader IFU than AFX.

So in terms of overall anatomy coverage, there is no hiccup. What we have to do is just a little bit of a balancing act because our AFX inventories, as Vaseem pointed out a minute ago, have been reduced since we were shipping a lot more AFX2. So we will have to do a little bit of juggling, but in terms of ability to cover all of the anatomies, we are fine there.

Vaseem Mahboob - ***Endologix Inc - CFO***

On the lot testing, Ravi, we are still trying to finalize that methodology on how big and extensive it needs to be and balancing it with the risk of defects. And as John said, this was a proactive hold and we did that to make sure that we provided the best path, and the best clinical outcome for our patients and I think we will continue to monitor and manage that.

But at this point, I do expect by the earnings call, we will have a pretty good sense on what that looks like for the rest of the quarter and we're just very hopeful and very optimistic, we will be beyond lot testing at the end of Q1. So it's essentially a Q1 issue more than anything else.

John McDermott - ***Endologix Inc - CEO***

I know it is an anecdote but yesterday was their first full day of lot testing and the guys were pretty fired up with their early results. So we just need to give them a little bit more time and see what level of productivity comes out of that effort and how that fits into the overall supply chain. But so far, it looks encouraging.

Ravi Misra - ***Leerink Partners - Analyst***

Great, thanks. And then maybe if I could sneak one last one in. Would that mean that you're maybe increasing production of other sizes currently to offset this?

Vaseem Mahboob - ***Endologix Inc - CFO***

Yes. We have already started to fire up our AFX line for some of the larger sizes.

Ravi Misra - ***Leerink Partners - Analyst***

Great, thank you.

Operator

With no further questions in the queue, I would like to turn your call back over to your speakers today.

John McDermott - *Endologix Inc - CEO*

Okay, thanks, operator. Listen, before we wrap it up, I just want to touch on what I mentioned at the end of my prepared remarks, which are the catalysts. So here's how we see the next six months at Endologix.

We remain confident in our ability to get the CE certificate reinstated based on everything we talked about on the call today. We reviewed in detail the AFX2 situation, both the short-term and long-term plans for that and remain confident that we will get those larger sizes available soon.

We expect still, as we always have, to get CE Mark for the Ovation Alto device in the first half of the year. We think that is going to be a very nice new product for us and then following that, two-year clinical results from Nellix, which is expected in the second quarter.

So these activities are all going to be happening over the next few months and think -- represent a real opportunity to drive some shareholder value. So with that said, thanks, everyone, for joining us on the call this morning and your interest in Endologix. We will keep you posted on our developments Have a Happy New Year.

Operator

Ladies and gentlemen, that does conclude today's conference. Thank you for your participation. You may now disconnect.