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Endologix, Inc. (ELGX)

Q3 2014 Earnings Call

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Chief Financial Officer and Secretary

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MANAGEMENT DISCUSSION SECTION

Operator: Greetings, ladies and gentlemen, and welcome to Endologix third quarter 2014 earnings conference call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. [Operator Instructions] As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Mr. Zack Kubow of The Ruth Group. Please go ahead, sir.

Zack Kubow
Senior Vice President, The Ruth Group, Inc.

Thanks, operator, and thanks, everyone, for participating in today's call. Joining me from the company are John McDermott, Chief Executive Officer; and Shelley Thunen, Chief Financial 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 30 days.

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, October 30, 2014. Endologix undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this call.

With that said, I'd like to turn the call over to John McDermott.

John D. McDermott
Chairman & Chief Executive Officer

Thanks, Zack.

We've made good progress with several strategic initiatives during the quarter, including first, completion of enrollment in the 300-patient Nellix Global Registry. Second, we remain on track with enrollment in the Nellix U.S. IDE clinical trial. We also introduced our new DURAPLY ePTFE Graft Material, and lastly announced the LEOPARD study, the first ever head-to-head clinical trial comparing commercially available EVAR devices. We believe these initiatives together with the ongoing launch of Nellix in Europe, the continued expansion of our sales force, and new product initiatives will be important growth drivers for our business.

On today's call I'll provide an update on these programs and also review some of the recently presented clinical data on AFX. Next, I'll turn the call over to our CFO, Shelley Thunen, who will provide a review of our third quarter financial performance and full-year guidance. After that, I'll come back on to review the key goals for the rest of the year and into 2015, and then we'll open it up for questions.

In the third quarter we achieved total revenue of $37 million, an increase of 12% year over year. International revenue grew 49% year over year, driven by strong adoption of Nellix in Europe, where sales grew 100% over Q3 last year. In the U.S., revenue grew 2% year over year, reflecting increased competitive activity.

Turning to our sales forces, in the U.S. we started the year with 85 sales reps and clinical specialists and expect to finish the year around 100, representing an increase of about 18% in 2014. In Europe we started the year with 25 reps and clinical specialists and are planning to get it up to around 32 by the end of this year, which represents an increase of 28%. This will give us a nice initial footprint in Europe that we will keep adding to in 2015 to support the high level of demand for Nellix.

In the U.S., very positive clinical results were presented on AFX last month at the Western Vascular Society Meeting. Specifically, an independent core lab evaluated 181 patients implanted with AFX and reported a zero percent Type Ia endoleak rate in standard on-label anatomies and the low 4% Type Ia endoleak rate in complex off-label anatomies. As a reminder, Type Ia endoleaks are leaks into the aneurysm sac due to the lack of seal at the top of the graft. To put these results into perspective, in the peer-reviewed literature the Type Ia endoleak rates for similar complex anatomies tend to range between 7% and 11% for other EVAR devices.

The independent core lab also evaluated Type II endoleaks, which are leaks into the aneurysm sac from side branches in the aorta. The core lab found that 5.5% of the patients with AFX had a Type II endoleak. This compares to reported rates between 17% and 34% with other devices, and highlights the unique design advantages of AFX.

These very low endoleak rates contribute to our confidence in running the LEOPARD clinical trial, the first ever randomized head-to-head EVAR study. The LEOPARD study is designed to enroll at least 600 patients at 60 leading centers throughout the United States. The centers will be a mix of current and new Endologix customers, with each site selecting one competitive device to randomize against AFX. The clinical endpoints of the trial are treatment success at one year, defined by acute procedural success and freedom from aneurysm rupture, conversion to open surgical repair, endoleaks, device migration, aneurysm enlargement, and secondary endovascular procedures. We expect to start enrolling LEOPARD in the first quarter of 2015, and we'll follow the patients for five years.

While we expect to achieve significant market adoption with Nellix, for those physicians who still prefer traditional EVAR, LEOPARD will provide important information about device selection and overall costs. Based upon our historical experience with anatomical fixation together with the recently presented clinical results, we think AFX will compare favorably to the other commercially available devices.

Now turning to Nellix, we started to gradually make Nellix available to more and more physicians in Q4 and are pleased with the initial feedback. As discussed during our last call, for all the physicians using Nellix in Europe, we currently have about 25% of their business. For those physicians who have had access to Nellix for a year or longer, we are above 50% of their case volumes. We think this is a good indication of the market potential for EVAS.

On the clinical side, in September we announced the completion of enrollment in the EVAS FORWARD Global Registry. This 300-patient prospective multi-center study is designed to capture real-world clinical results with the Nellix device. Clinical data from the global registry is expected to be presented at the VEITH Symposium on November 20.

For the EVAS FORWARD IDE, we currently have 165 patients enrolled and expect to complete enrollment of all 180 patients before the end of this year. The enthusiasm among U.S. investigators is very high, and we anticipate moving into our continued access phase of the study in 2015 while we work with the FDA on the PMA and potential approval by the end of 2016.

With that, I'd like to hand the call over the Shelley Thunen for her financial review. Shelley?

Shelley B. Thunen

Chief Financial Officer and Secretary

Good afternoon and thank you, John.

Today we are reporting our financial results and key metrics for the third quarter of 2014. Total revenue for the third quarter increased by 12% year over year to $37.2 million. for the nine months ended September 30, 2014, total revenue increased 12% to $108.7 million compared to $97.0 million for the nine months ended September 30, 2013.

Domestic revenue in the third quarter increased by 2% year over year to $27.1 million, reflecting increased competition in the quarter as compared to the third quarter of 2013, which was quite strong with little apparent seasonality. International revenue increased by 49% year over year in the third quarter to $10.1 million. In Europe, revenue increased to $6.9 million, up 100% year over year. The total international sales increase was primarily attributable to continued strong sales of Nellix in Europe, partially offset by softness in Japan.

Gross margin in the third quarter of 2014 was 63% compared to gross margin of 78% in the prior year. For the nine months ended September 30, 2014, gross margin was 70% as compared to gross margin of 76% for the nine months ended September 30, 2013.

The decrease in gross margin for the three and nine-month periods was due to a $4.7 million inventory write-off in the third quarter of 2014, primarily for product inventory that was replaced with the launch of DURAPLY material for our AFX system. The inventory write-off resulted in a reduction of 13 points of gross margin in the third quarter and five points of margin in the nine months ended September 30, 2014. In 2014, both for the

quarter and nine months, gross margin also decreased due to geography and product mix, with a greater percentage of our sales outside the U.S.

Operating expenses for the third quarter of 2014 were $32.5 million compared to $28.1 million in the same period last year. Operating expenses for the nine months ended September 30, 2014 were $94.4 million compared to $82.7 million for the nine months ended September 30, 2013. The increase in operating expenses was driven by research and development, sales and marketing, and general and administrative expenses.

Our GAAP net loss was $13.9 million or $0.21 per share in the third quarter of 2014 compared to a loss of $9 million or $0.14 per share for the third quarter of 2013. Our GAAP loss increase in the third quarter of 2014 is primarily due to lower gross margin due to the inventory write-off in the third quarter and increased investments for sales and marketing, primarily sales and clinical personnel in both the U.S. and Europe, general and administrative expenses to support the sales growth, and research and development expenses and clinical expenses, along with a $0.06 non-cash expense for foreign currency balance sheet remeasurement due to the weakening euro as compared to the U.S. dollar, as we have payables from our European subsidiary denominated in U.S. dollars. At September 30, the euro spot rate was $1.27 as compared to an average rate of $1.36 during the first nine months of 2014 and 2013 average of $1.33.

For the nine months ended at September 30, 2014, we reported a net loss of $17.6 million or $0.28 per share compared to a net loss of $12.7 million or $0.20 per share for the nine months ended September 30, 2013.

On an adjusted EBITDA basis, a non-GAAP measure of income or loss adding back the Nellix contingent consideration, stock-based compensation expense, depreciation, amortization, interest expense, business development, tax, and foreign currency remeasurement gains and losses, our net loss in the third quarter of 2014 was $6.3 million or $0.10 loss per share compared to income of $1.9 million or $0.03 per share in the third quarter of 2013. For the nine months ended September 30, 2014, the adjusted EBITDA loss was $10.3 million or $0.50 per share compared to income of $1.8 million or $0.03 per share in the prior period.

Now turning to the balance sheet, accounts receivable days outstanding were 64 days at the end of the third quarter of 2014 compared to 65 days at the end of 2013 and 63 days at the end of June 2014. DSOs have remained excellent and consistent, but we continue to expect DSOs to increase over time as the percentage of revenue from Europe increases as a percent of our total revenue.

Inventory turnover was 1.9 turns at quarter end compared to 1.5 turns at the end of June, as inventories went down from the second quarter due to the $4.7 million inventory write-off in the third quarter of 2014. We still expect inventory turnover to normalize to closer to 1.5 turns in future periods.

We ended the quarter with cash and cash equivalents and investments of $100.5 million as compared to $110.8 million in cash and cash equivalents at the end of the second quarter. The principal use of cash in the third quarter was payment for capital expenditures of approximately $8 million out of a total of $11 million for our new facility.

In the fourth quarter, we signed a restructured agreement with our Japanese distributor that now includes a provision to acquire the IntuiTrak Shonin and the future AFX Shonin approvals. We expect to pay a total of $4.5 million in cash, of which $3.5 million is expected to be paid in 2014, with the remainder paid in 2015. Of this, our estimation is that approximately $2.5 million is expected to be 2014 expense and the balance 2015 expense. The restructured agreement also increases the minimum purchase levels in 2015 as compared to 2014.

Now turning to guidance, we are reiterating our full-year revenue, adjusted EPS, and adjusted EBITDA guidance, with adjustments to EPS for non-recurring items. We continue to expect revenue in the range of $145 million to

$148 million, a 10% to 12% increase over 2013, with U.S. revenue growth of 1% to 3% and international revenue growth of 40% to 42%. This annual revenue guidance equates to fourth quarter 2014 U.S. revenue of approximately $25 million to $27 million, international revenue of $11 million to $12 million, for the fourth quarter revenue total of $36 million to $39 million. We continue to expect 2014 gross margin to be approximately 72%.

On the bottom line, we now expect 2014 GAAP net loss of $0.44 to $0.50 per share as compared to previous guidance of $0.34 to $0.40 loss per share. The $0.10 reduction in our GAAP EPS guidance reflects the third quarter non-cash $0.06 loss for the foreign currency balance sheet remeasurement due to the weakening of the euro at the end of September. In addition, we expect an approximate $0.04 loss associated with the partial payment to our Japanese distributor to acquire our Shonin approvals.

On a non-GAAP basis, we continue to expect an adjusted net loss per share of $0.37 to $0.43 per share for the year. Adjusted net loss again excludes the Nellix contingent consideration, business development expenses for the Japanese Shonin acquisition, foreign currency remeasurement, and convertible debt expense.

On an adjusted EBITDA basis, we continue to expect a $0.20 to $0.26 loss per share for the year. Adjusted EBITDA loss excludes Nellix contingent consideration, interest expense, non-cash expenses such as depreciation and stock-based compensation, along with the foreign currency remeasurement and Japanese Shonin business development expenses I just discussed. Not included in this loss per share guidance, however, are potential adverse litigation outcomes and the effects of possible additions to business development expenses.

We are also adjusting our cash expectations to include the $3.5 million payment to our Japanese distributor in the fourth quarter of 2014 for the Shonin approvals, as discussed. Therefore, we expect to end 2014 with approximately $95 million to $97 million in cash, using between $29 million to $31 million in 2014. With the remaining cash of close to $100 million at year end, we believe we have sufficient cash resources to continue to fund the business in future years.

I will now turn the call back to John.

John D. McDermott
Chairman & Chief Executive Officer

Thanks, Shelley.

We continue to make good progress with our strategic initiatives and remain confident in the growth potential of the business. The following are our key goals and priorities for the rest of Q4 and into 2015. First is to complete enrollment in the Nellix IDE and submit the PMA. Second is the successful continued rollout of Nellix in Europe and move gradually into other international markets. And third is to drive growth in the U.S.

Our growth plans in the U.S. include promotion of the new AFX clinical evidence, an 18% increase in the number of reps and clinical specialists by the end of this year, continuation of our successful PEVAR physician training program, running the LEOPARD clinical study, and introducing AFX3 in the second half of next year. We also expect to provide continued access to our U.S. Nellix IDE investigators in 2015. The combination of these initiatives should enable us to grow at or above market rates in the U.S. while we prepare for the launch of Nellix in 2016.

Internationally, we expect to see very good growth next year in Europe as we continue adding to our sales and clinical team, plus we will also begin introducing Nellix into Latin America and some countries in Asia. We also

expect to see improvement in Japan next year with the introduction of AFX. So our global growth prospects for next year look very promising.

To provide regular updates on our progress, we are planning to participate in the Stephens Fall Investor Conference, the Stifel Healthcare Conference, and the Canaccord Medtech Conference in November. In December we are attending the Piper Jaffray Healthcare Conference and the Oppenheimer Healthcare Conference. In addition, we plan to host an Investor Meeting in conjunction with the VEITH symposium in New York on November 20.

With that, I'd like to open it up for questions. Operator?

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] Our first question comes from the line of Rick Wise with Stifel. Please proceed with your question.

Frederick A. Wise
Stifel, Nicolaus & Co., Inc.

Q

Good afternoon to you both. John, here we are one month into the fourth quarter, and you're clearly reiterating your guidance for the year. I feel slightly embarrassed asking but I'm still going to ask. In the past you've given us sequential commentary. What more have you learned about the nature of the competitive U.S. headwinds and the "increased competition"? And can you help us understand any better or any more clearly what's going on as pricing – just what's happening and is it getting worse or better or where you expected?

John D. McDermott
Chairman & Chief Executive Officer

A

Rick, I haven't seen any real change in behavior or what I would characterize as competitive intensity in the past since we had our last call. What I can tell you is that our October was spot on plan. So at this point, we're where we thought we'd be at this point in the quarter and for the full year. We anticipate the competitive environment to continue to be rigorous. But as we go through all of the different initiatives we've got planned, we feel confident about being able to grow at least at market if not above market. So I think it's mostly just a function of a lot more reps out there standing in doctors' doorways with an EVAR alternative.

Frederick A. Wise
Stifel, Nicolaus & Co., Inc.

Q

Right, and any more thoughts on market growth based on your last comments as well?

John D. McDermott
Chairman & Chief Executive Officer

A

Nothing refreshed. In terms of unit growth, we've still got it around 3%. We are updating those numbers as we speak. So I would say at this point in time we don't have any reason to adjust it down from 18%. Pricing is a little bit difficult to forecast with precision, as you know. As we look out, we forecast over the next five years a little more pricing pressure, as hospitals look for ways to save money. But at this point, we've got the U.S. market at about 3%.

Frederick A. Wise
Stifel, Nicolaus & Co., Inc.

Q

That's right. And on the Nellix supply side, just where are we with supply? Is your planned – your new facility fully up and running? It sounds like you're seeing some benefit. And maybe just help us understand where you are with that process and what kind of output you're getting and how we're going to think about the impact on sales as a result.

John D. McDermott
Chairman & Chief Executive Officer

A

So operationally, manufacturing is really not in the way or it's not any restriction on our volume or sales capacity. The biggest issue for Nellix is really just not having enough people hired, trained, and fully certified on the ground to support the demand. We're working hard on that and we've actually been bringing on some great new people recently and have plans to continue to build the team throughout the course of next year, so that looks good. In terms of operational detail, we have already been through our facility inspections and expect to complete the transition of all the manufacturing lines this quarter, as we had previously anticipated. So everything is moving ahead as planned.

Frederick A. Wise
Stifel, Nicolaus & Co., Inc.

Q

Just a last quick one for me. On this Japan distributor transition, is this in effect saying you're going direct? And when you think about it, does that mean that it helps offset some of the pressures you've seen that you've highlighted with the – so we feel therefore incrementally better about 2015 in Japan? Thanks, John.

John D. McDermott
Chairman & Chief Executive Officer

A

Yes, you're welcome. Our distributor in Japan has historically done a very nice job. It's fallen behind the competition more recently because we still sell our older generation of device there called IntuiTrak. That being said, we've already submitted our request for AFX and had interaction with the regulatory agency there, and we remain optimistic that we'll get AFX approved in the second half of next year. So we do expect, unlike this year, we expect to see some growth out of Japan.

The decision to acquire the Shonin is really just an opportunity that gives us more long-term flexibility. So Japan is the second largest market in the world, and we think it's an important part of our future growth strategy, so it just gives us more flexibility.

Frederick A. Wise
Stifel, Nicolaus & Co., Inc.

Q

I appreciate that.

Operator: Thank you. Our next question comes from the line of Brooks West with Piper Jaffray. Please proceed with your question.

Brooks E. West
Piper Jaffray & Co (Broker)

Q

Hi, thanks for taking the question. John, I wanted to follow up on a couple of lines that Rick was pursuing. You ended up at $37.2 million for the quarter. The original consensus was $37.7 million. So it's still a miss, but really

not that bad, and I know you pre-released because of what you saw coming at you in Q4, so I guess two things. Can you remind us how much of the guide down was due to Japan and really the product cadence there? And how much was the U.S. again?

John D. McDermott
Chairman & Chief Executive Officer
A

Shelley, do you have those numbers?

Shelley B. Thunen
Chief Financial Officer and Secretary
A

Yes, I do. We're going to take Japan down about $1.5 million this year from 2013. I don't know that that was necessarily a guide down for fourth quarter as much, although we will be about $1 million lower in Japan in the fourth quarter. And then of course, in the U.S., what we're always cognizant of in the fourth quarter is fewer surgery days. And so the U.S. is something we can and should expect. Japan, of course, is a bit unusual.

Brooks E. West
Piper Jaffray & Co (Broker)
Q

So I guess asked another away, if you think about the guide down from Q3 to Q4, what exactly – I guess how do you weight what you're seeing in the U.S. versus what you're seeing in Japan versus – again, all in really missing your Q3 number by $0.5 million?

John D. McDermott
Chairman & Chief Executive Officer
A

So as Shelly pointed out, the year-over-year comp for Japan is off about $1 million. So if you took our Q4 estimated guidance ranges there, they get penalized a bit because of this transition to the new agreement in Japan, which in 2015 is year-over-year positive. The guide down in the U.S. was really just a lighter finish to the quarter.

And also the reason for the pre-announce was we had other information to announce, the completion of the registry enrollment as well as LEOPARD, so we had other news, and it just made sense that the end of that quarter was trending a little bit light. As I said, December has been a good month, right on plan. So we feel good going into the end of the year.

Brooks E. West
Piper Jaffray & Co (Broker)
Q

Okay, and then maybe two follow-ups. So on Japan you said that it's going to up year over year. But I think you also negotiated 2014 down. So can you give us a sense of really I guess the size of your Japan business this year and what we should look for from Japan in 2015?

And then, John, I know you spent a lot of time on VEITH, and we've also got VIVA coming up next week and Monday is a AAA symposium, which they've never done before. I know we're going to see some Nellix case discussion there. Can you give us a little preview of what we might see at VIVA next week?

John D. McDermott
Chairman & Chief Executive Officer
A

Specific back to Japan, this year Japan represents just under $5 million. I can't give you the detailed number for next year. I can tell that it's double-digit growth. So we're going in the right direction with Japan and have a good arrangement there for the next few years as well as the flexibility to do what we need to do.

As it relates to VIVA next year, we don't control that program, but we have heard that there are plans for a live Nellix procedure, so I would anticipate that. I think there's also a Nellix presentation, and my guess is Nellix will be referred to multiple times. So we expect it to be a good meeting for us.

Turning then to the VEITH meeting, that will be a very good meeting for us. We have 10 different presentations from the podium, a nice mix of Nellix talks as well as AFX. Some of this new clinical data that we've talked about, some of that is getting presented at VEITH, as well as the first early mid-term results on the 300-patient global registry. We won't have follow-up on all 300 patients, but I think they're planning to present on 250 patients. So the next few weeks will be busy and very positive for us from the perspective of the conferences.

Brooks E. West
Piper Jaffray & Co (Broker)

Q

Great. Thanks, John.

Operator: Thank you. [Operator Instructions] Our next question comes from the line of Matt Keeler with Credit Suisse. Please proceed with your question.

Matthew J. Keeler
Credit Suisse Securities (USA) LLC (Broker)

Q

Hi, John. Hi, Shelley, thanks for taking the questions. First, given that you expect a more hands-on ramp of Nellix in Europe with a lot of rep interaction, do you see a lot of room for upside from where you are currently in terms of revenue per rep?

John D. McDermott
Chairman & Chief Executive Officer

A

We're already, Matt, above the productivity levels in the U.S. So Europe has already jumped ahead of the U.S. in terms of cases per month per rep. That being said, we do think there's upside still with those productivity numbers. So not only do we see productivity gain opportunities, we're going pretty hard at building out our team. So the combination of increased productivity, more feet on the ground starting over the next few months, and then building that out over the full course of next year together with the wide availability of product, we have pretty high expectations for Europe in 2015.

Matthew J. Keeler
Credit Suisse Securities (USA) LLC (Broker)

Q

Okay, thanks. And then I know it's early. But with DURAPLY out, have you had any feedback from AFX users on it and any feedback especially in those users who might have had experience with the Type IIIb leaks?

John D. McDermott
Chairman & Chief Executive Officer

A

So far, feedback has been very positive. It's early, and the doctors can't really tell the difference with the new material. Although for those who have really gotten into and understand the new technology, I would say that's been very positive for us. I think we've done just under 1,000 cases with DURAPLY so far. Feedback has been positive.

Matthew J. Keeler
Credit Suisse Securities (USA) LLC (Broker)

Q

Perfect, thanks for taking the questions.

John D. McDermott
Chairman & Chief Executive Officer

A

Sure.

Operator: Thank you. Our next question comes from line of Chris Pasquale with JPMorgan Chase. Please proceed with your question.

Christopher T. Pasquale
J.P. Morgan Securities LLC

Q

Thanks. John, if Nellix becomes a bigger part of your mix, how should we think about its profitability relative to AFX and the steps to closing any gap there? I know you've been focused on implementing tweaks as you identify areas for improvement in clinical performance. But are there things you can do to bring costs down? Is that a near-term focus or at least in the next 12 months focus?

John D. McDermott
Chairman & Chief Executive Officer

A

It's certainly a focus of ours. We're double-penalized right now with the increase of Nellix sales in Europe, which has a lower ASP; and the Nellix product, at least in its current configuration, has a higher average cost than AFX. So what we're doing to mitigate those variables is really we've got a next-generation design. That design is already frozen. We're well into that process and expect to introduce that into Europe before the end of next year. That same design will be the PMA product. So we've got – and it's got in addition to some nice user advantages, it's got multiple cost benefits. So that's going to be nice. Between now and the end of next year, we'll make some good progress on the cost.

The other thing that we're working hard on is transitioning on our polymer. So as you know, the Nellix system utilizes a biocompatible polymer. That's currently frozen. We have an active program to take that to room temperature, which reduces the costs both of the actual material as well as the logistics significantly. So those are two important margin enhancing initiatives for Nellix over the next 12 to 24 months.

Christopher T. Pasquale
J.P. Morgan Securities LLC

Q

So just to clarify, this reduced cost product is not part of the U.S. pivotal trial, but you think you'll be able to slide it into the PMA filing; you won't have to do any clinical work with it?

John D. McDermott
Chairman & Chief Executive Officer

A

That's right. We will transition it into the continued access, but the enhancements are really primarily to the delivery system. There are a few minor implant modifications, but they're really small. So our read on it is that it doesn't require any kind of reset there. So that's right, we think that version of the product will be the PMA - approved product.

Christopher T. Pasquale
J.P. Morgan Securities LLC

Q

Okay. And could you just give us the sales rep counts as of the end of the third quarter, where you exited for U.S. and Europe?

John D. McDermott
Chairman & Chief Executive Officer

A

So what I would say is we're trending right on track is what we talked about, getting to 32 in Europe by the end of this year and 100 in the U.S. And what we'll do, Chris, is when we go to give next year's guidance, we'll provide new targeted numbers for 2015. I don't expect to add much in the U.S. next year at all. But we'll add more next year in Europe than we added in Europe this year, just based upon the growing demand for Nellix.

Christopher T. Pasquale
J.P. Morgan Securities LLC

Q

Great, thank you.

Operator: Thank you. Our next question comes from the line of Joanne Wuensch with BMO Capital Markets. Please proceed with your question.

Joanne K. Wuensch
BMO Capital Markets (United States)

Q

Thank you very much for taking the question. I want to talk about gross margins just for a second. I'm going to assume that the 63.5% is the low point. But how should I think about that rebounding into the fourth quarter? And then, if you could, just give us some qualitative commentary of where that directionally may be heading in the next year or so.

Shelley B. Thunen
Chief Financial Officer and Secretary

A

You should see that rebound in the fourth quarter. If you look at just the 63% and add back the 13 points of gross margin, that put us on a comparable basis right around 76%. That's a bit high. Going forward, we do expect about 72% in the total gross margin for the year. I do think that as we get into 2015, while we're not yet giving guidance, as you can see, the gross margin has come down slightly as we've grown so quickly in Europe because the ASPs are lower in Europe and the Nellix product is more expensive. But we still expect that we will have gross margins in excess of 70%. I don't see them going beyond that, but about 72% for this year.

Joanne K. Wuensch
BMO Capital Markets (United States)

Q

And as a follow-up, it seems a significant reason for the pre-announcement had to do with the relaunch of AFX2 and the new material, I guess it's [ph] AVELA (36:43) and the new material. Could you just comment on how that's being perceived and how that's helping in the counter-detailing with the salespeople? Thank you.

John D. McDermott
Chairman & Chief Executive Officer

A

Joanne, the rollout of the DURAPLY, we actually pulled the sales team together and put them though all the details of the development of the new material and all the rigorous testing. It's by far the best graft material that we've ever developed. So the sales force feedback and the customer feedback so far has been very positive. So I

think that's put a nice bounce back in the step of our guys in the field. That combined with the newly presented clinical evidence that I talked about earlier has given the guys a nice lift, and they're doing a nice job.

Joanne K. Wuensch
BMO Capital Markets (United States)

Q

Thanks.

John D. McDermott
Chairman & Chief Executive Officer

A

You're welcome.

Operator: Thank you. Our next question comes from the line of Jason Mills with Canaccord Genuity. Please proceed with your questions.

Jeffrey Chu
Canaccord Genuity, Inc.

Q

Hi, this is actually Jeff filling in for Jason, two quick ones for me, I guess the first one on PEVAR. John, I was wondering if you could provide any additional updates on PEVAR training and then how that's going during the quarter.

John D. McDermott
Chairman & Chief Executive Officer

A

It's going well. We actually set a goal, Jeff, this year between when we started last year and the full year 2014 to try to train up to 500 doctors. We've already passed that or met that goal. So sitting here at the end of October, we've already trained 500. And based upon our results, which we go back and look at all 500 physicians that have been trained, on average our increase in case volumes with those physicians is over 30%. So there are still a lot of guys that are interested. We're still filling the courses. We plan to continue the PEVAR training initiative throughout 2015.

Jeffrey Chu
Canaccord Genuity, Inc.

Q

Great. And then in terms of the cap for Nellix, the Nellix IDE, is there any indication on the number of patients that will be part of this, like a supplement cohort?

John D. McDermott
Chairman & Chief Executive Officer

A

The submission is in, so we hope to get feedback from that here soon. I can't tell you the exact number. We're estimating around 200 procedures next year in the continued access protocol, but that's our best estimate right now.

Jeffrey Chu
Canaccord Genuity, Inc.

Q

All right, great. Thanks for taking the questions.

John D. McDermott
Chairman & Chief Executive Officer

A

You bet.

Operator: Thank you. Ladies and gentlemen, there are no further questions at this time. I would like to turn it back to management for closing comments.

John D. McDermott
Chairman & Chief Executive Officer

Okay. Thanks to everyone for joining the call today and for your interest in Endologix. We look forward to seeing you at the upcoming conferences and our investor meeting on November 20. Have a great afternoon and evening.

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