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CONTENTS

Endologix Inc. NasdaqGS:ELGX

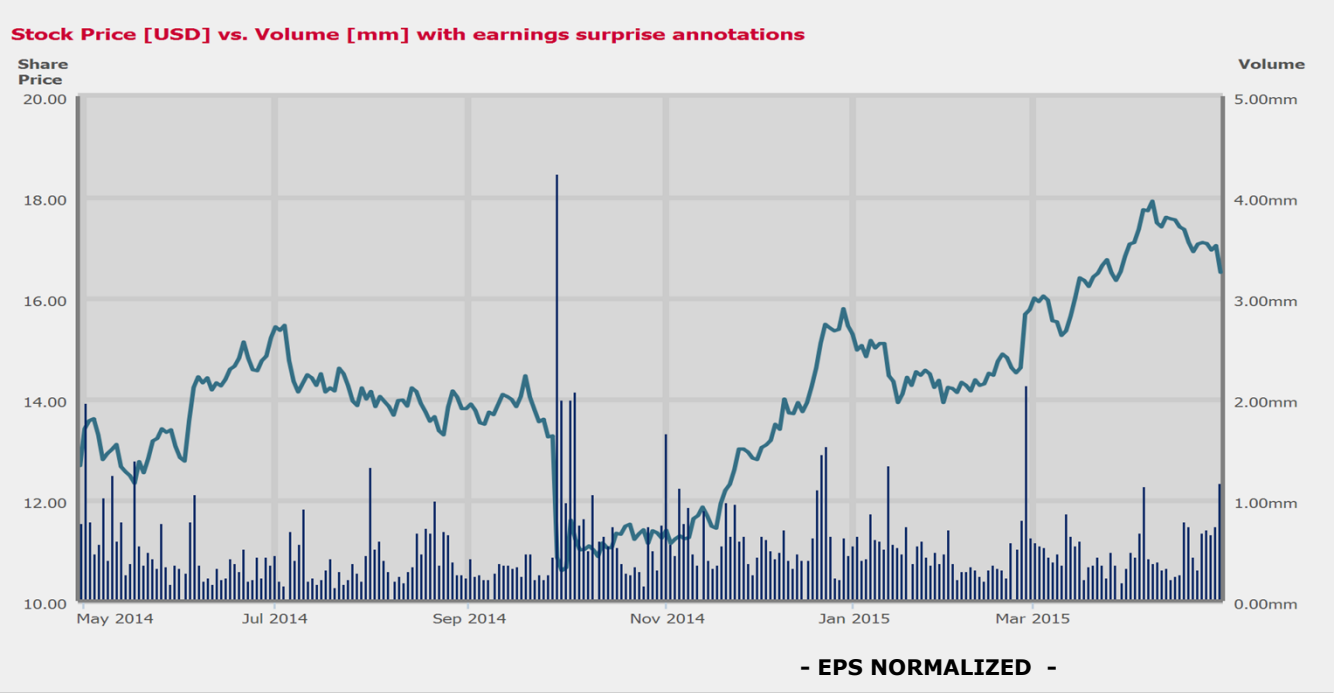
FQ2 2015 Earnings Call Transcripts

Monday, August 03, 2015 9:00 PM GMT

S&P Capital IQ Estimates

	-FQ2 2015-			-FQ3 2015-	-FY 2015-	-FY 2016-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	(0.13)	(0.18)	NM	(0.13)	(0.54)	(0.35)
Revenue (mm)	39.40	39.48	0.20	39.90	159.32	185.50

Currency: USD
Consensus as of Jul-16-2015 12:34 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ2 2014	(0.08)	(0.06)	NM
FQ3 2014	(0.13)	(0.13)	NM
FQ4 2014	(0.10)	(0.11)	NM
FQ1 2015	(0.13)	(0.14)	NM

Call Participants

EXECUTIVES

John McDermott
Chairman of the Board and Chief Executive Officer

Robert D. Mitchell
President

Zack Kubow
Senior Vice President

ANALYSTS

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Presentation

Operator

Greetings, and welcome to the Endologix Second Quarter 2015 Earnings Conference Call. [Operator Instructions] As a reminder, this conference is being recorded. I would now like to turn the conference over to your host, Mr. Zack Kubow of the Ruth Group. Thank you. Mr. Kubo, you may begin.

Zack Kubow
Senior Vice President

Thanks, operator, and thanks, everyone, for participating in today's call. Joining me from the company are John McDermott, Chief Executive Officer; and Bob Mitchell, President. 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 1 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, August 3, 2015. 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 McDermott
Chairman of the Board and Chief Executive Officer

Thanks, Zack, and good afternoon, everyone. Today, we'll have a slightly different format than in the past because Shelley Thunen, our CFO, is away on her honeymoon. I'll start with a brief overview of the highlights from the quarter, then Bob Mitchell will give an update on Nellix and our progress in Europe. After Bob, I'll come back on with the financial and guidance update and finish with our key objectives, then we'll open it up for questions.

So let's get started. For the second quarter 2015, we had total revenue of $39.5 million, an increase of 3% year-over-year or 8% on a constant currency basis. In the U.S., revenue increased by 3% year-over-year and 14% sequentially to $28.8 million. International revenue grew by 4% year-over-year or 20% in constant currency to $10.7 million. In Europe, constant currency revenue grew 23% year-over-year and 9% sequentially. This was a little less than we originally planned but mostly due to softer-than-expected AFX sales. For Nellix, our system sales in Europe were up 37% year-over-year and 22% sequentially, so we're very pleased with these results.

During the second quarter, we sold a total of 720 Nellix systems worldwide compared to 560 in the first quarter. This represents a 40% increase over the second quarter of last year and a 29% sequential increase over the first quarter. Included in the 720 global systems were 44 systems implanted in the U.S. Continued Access Protocol for the IDE. We continue to enroll patients in the CAP and have requested approval for more patients from the FDA. Recently, FDA requested testing and data on the compatibility of Nellix with ancillary devices like stents before they will approve our request for additional increase in the number of patients in the CAP. We expected to potentially need this for the PMA submission, so we'll now accelerate this work and complete it within the next few months. While we are gathering this information for FDA, we will continue to enroll the remaining 25 patients in the CAP in the third quarter of 2015. We expect to obtain the CAP and IRB approvals by the end of the year, after which we should return to our normal enrollment rate. Despite this minor delay in the CAP, we do not expect it to impact our overall PMA approval time line, which is still forecasted by the end of 2016.

Turning now to inventory. You might remember in the fall of 2014, we initiated the transition to our new ePTFE graft material called DURAPLY. We have continued to see excellent results with DURAPLY and AFX and decided during the second quarter to accelerate the transition of all models to DURAPLY and to write off the remaining inventory of older ePTFE graft material. At the same time, we created a reserve for the current AFX product in anticipation of FDA approval of AFX2 by the end of this year.

Lastly, we recorded a reserve for older Nellix inventory to provide physicians with an enhanced version of the product that incorporates our latest manufacturing and quality process improvements. In total, these decisions resulted in a $4.3 million inventory reserve during the second quarter. We believe these moves position us nicely for the remainder of the year in 2016.

Also during the quarter, we had important clinical data presentations at the Charing Cross Meeting in London and the Society of Vascular Surgery Meeting in Chicago. At Charing Cross, the latest data from the 300-patient EVAS FORWARD - Global Registry was presented as well as several other presentations highlighting the broad anatomical capability of Nellix. The presentations were well attended and continued to demonstrate very good results with low rates of endoleaks, reinterventions and aneurysm-related mortality within a very complex patient population.

At the SVS, the 30-day results were presented from the Nellix, EVAS FORWARD-IDE. The 150-patient pivotal cohort demonstrated the lowest overall rate of endoleaks ever reported in an IDE clinical trial for the endovascular treatment of abdominal aortic aneurysms.

To provide more depth and information about Nellix and our plans, I'll now turn the call over to our President, Bob Mitchell. As a reminder, Bob was the CEO of Nellix when we acquired the company and technology back in 2010, and he also led the build-out of our direct sales and marketing team in Europe. Bob?

Robert D. Mitchell
President

Thanks, John, and good afternoon, everyone. As discussed, Nellix revenues continued to grow at a respectable pace, and we expect the current trajectory to continue. Today, we thought it would be helpful to provide a deeper dive on Nellix, especially now that we had -- we've treated around 3,000 patients and the base of evidence is building, thanks to the U.S. IDE, the Global Registry and more than 25 papers published to date. This growing body of clinical data supports our belief that Nellix represents a breakthrough technology. While the data is encouraging, it's important to remember that EVAS is a new treatment paradigm compared to conventional EVAR. There is no denying that we've come a long way in terms of training and system enhancements, but our goal remains to diligently capture, understand and innovate around all lessons learned. There's tremendous interest in Nellix, both for traditional and complex aneurysms. And we felt it important for physicians to gain experience with traditional anatomies before they take on more complex situations.

With this in mind, we continue to upgrade our training, certification and site -- and on our new site-selection processes. We believe this disciplined approach helps to ensure that we're able to achieve the maximum long-term potential for Nellix, not only in Europe, but also in the U.S. and other international markets. In order to give you a sense of this potential, I'd like to give you some -- I'd like to take some time to share some stories from several well-known thought leaders regarding their experience with Nellix and how it has impacted their aortic business and patient outcome.

Andrew Holden from Auckland City Hospital in New Zealand said, "Procedural predictability and simplicity are major attractions for Nellix, but most important is the high level of clinical success and very low intervention rates. Over time, our results have improved as we came to understand and optimize the procedure."

Michel Reijnen from Arnhem in the Netherlands mentioned that his results with Nellix have always been good, but they're also getting better with time. He stated, "We have an exceptionally low rate of reinterventions with Nellix. Patients get the concept, and the hospital staff view the procedure as very

intuitive when it comes to case planning and OR time efficiency." He further commented that Nellix has empowered his team to treat the majority of all patients they see at their institution.

Rudy Yacob [ph], a very busy vascular surgeon in Augsburg, Germany has witnessed the significant increase in his aortic aneurysms caseload, thanks to Nellix. He received multiple patient referrals, not only from surrounding hospitals, but also from individual patients who seek him out specifically because of his experience with Nellix.

Marwan Youssef from the University of Mainz in Germany, where their -- Nellix is their preferred device, and they're touting an overall endoleak rate less than 1% commented that, "Nellix is an essential tool for my practice. It has single-handedly expanded our capabilities to treat more patients."

Eric Zimmermann from Hamar Hospital in Norway has generated an extensive experience using Nellix for his patients. He stated, "Nellix has allowed us to treat more patients with an endovascular technique. In the last year, the number of cases we have treated has increased by 40%."

Matt Thompson and Ian Loftus from St. Georges in the U.K., and they're known globally for treating some of the most challenging aortic anatomy asserted that Nellix is not only potentially suited for these complex cases, but it's becoming more interesting for more common anatomies, including those questionable aneurysms typically treated off label by convention endografts. Included in this population are conical necks, short renal bifurcation, tight aortic bifurcation, short common iliacs and disease in the proximal neck. They believe that these anatomies represent between 50% and 60% of the current EVAR patients, where results could definitely improve.

Please note that we maintain a rigid policy to train within the IFU and discourage utilization behind these -- beyond these guidelines. That said, physicians see -- quickly see that the potential for Nellix to treat more patients and expand their endovascular aneurysm practice. All physicians mentioned remain hopeful that Nellix will offer a novel solution for patients with more complex anatomy. Professor Thompson commented, "This is a large underserved need where patients left untreated do badly with a 50% mortality at 2 years." As a company, we're dedicated to continually test, understand and validate all potential clinical applications for Nellix.

Over time, Nellix has evolved to be the preferred device for the physicians mentioned, and we're witnessing similar trends of adoption with several experienced centers throughout Europe. I often get asked if the results in Europe will be indicative of what to expect when we launch in the U.S. Ultimately, of course, time will tell, but we're very encouraged with the results from our experienced physician base. They view Nellix and EVAS as the most promising future for aneurysm therapy, and based upon their high adoption rate, we're very optimistic with our continued growth prospects. Please note, however, that we are planning a controlled rollout in the United States similar to Europe to ensure there is a full appreciation, training and understanding of the Nellix EVAS technology. We believe this will put us in the best position to achieve Nellix's long-term market leadership potential.

I'll now turn the call back to John.

John McDermott
Chairman of the Board and Chief Executive Officer

Thanks, Bob. As you can see, this isn't just another aneurysm device. Nellix clearly has the potential to be the market leader, significantly expanding and improving the current treatment options for physicians and patients.

Now let's switch gears into our financial results and updated guidance. As mentioned previously, global revenue was $39.5 million in the second quarter of 2015. In constant currency, this represents year-over-year growth of 3% in the U.S., 23% in Europe and 13% in other international markets. Gross margin in the second quarter of 2015 was 61% compared to gross margin of 74% in the second quarter of last year. The decrease was driven by the $4.3 million inventory reserve that I discussed earlier. Moving forward, we expect gross margins to normalize around 70%.

Operating expenses for the second quarter of 2015 were $36.3 million compared to $32.3 million in the prior year period and slightly down from Q1. These increases were attributable to continuing R&D, clinical and marketing investments in anticipation of further Nellix commercialization and somewhat higher legal and professional costs between quarters.

We reported a net loss of $13 million or $0.19 per share in the second quarter of 2015, which compares to a loss of $9 million or $0.14 per share in the prior period. On an adjusted EBITDA basis, our net loss in the second quarter of 2015 was $8.1 million or $0.12 per share compared to a loss of $1 million or $0.02 per share in the second quarter of 2014.

Now turning to the balance sheet. We ended the second quarter with cash and cash equivalents of $70.5 million compared to $73.7 million at the end of the first quarter of 2015. Inventory turnover increased to 1.9 turns at the end of the second quarter of 2015 from 1.2 turns at the end of the first quarter of 2015 because of the previously mentioned inventory reserves. Accounts receivable outstanding was 67 days at the end of the second quarter of 2015 compared to 66 days at the end of the first quarter and 63 days at the end of the second quarter of 2014.

Now turning to guidance. Based upon our results through the first 6 months and our outlook for the rest of 2015, we are revising our global revenue guidance to be in the range of $154 million to $157 million, which is down from the previous guidance of $159 million at the low end of the range up to $165 million. This updated revenue guidance equates to a range of $160 million to $163 million in constant currency, which is a growth of 8% to 10% over 2014. The reduction in full year guidance represents approximately $3.5 million from the low end of our previous range to the midpoint of our new range. This change consists of an estimated $1.5 million from the CAP in the U.S., an estimated $1 million from Europe as we systematically train and certify new physician users on Nellix and another $1 million estimated reduction from our other international markets.

Full year revenue guidance in the U.S. is now estimated between $107 million and $108 million, which represents growth of 2% to 3% from 2014 and equates to about 2% growth in the second half consistent with the market growth.

For Europe, we estimate revenues in the range of $32 million to $33 million for 2015. On a constant currency basis, this represents full year growth of 29% to 33% and equates to growth in the second half of the year above 30%.

For our other international markets, we are estimating revenues in the range of $15 million to $16 million for 2015. This represents growth in the second half of 2015 of around 20%. Consistent with prior years, we expect to see procedural seasonality in the third quarter as physicians take vacation and patients defer procedures when possible.

Now turning to our gross margin guidance. Due to the second quarter inventory reserve, we expect gross margin to be about 68% for the full year 2015, down from our previous guidance of 70%. In 2016 and beyond, we expect gross margin to normalize back to around 70%. We're updating our GAAP loss per share guidance to a range of $0.72 to $0.77 and an adjusted non-GAAP loss per share range of $0.59 to $0.64. These adjustments are result of the estimated revenue reduction and increase reserve for product inventory.

For cash, we now expect to end 2015 with approximately $60 million to $65 million, which does not include any potential business development or unplanned legal expenses. We expect our forecasted cash together with our $20 million unused line of credit to provide adequate resources to execute our strategic initiatives.

Turning now to our growth drivers. Following are the key initiatives over the next 6 to 12 months to increase shareholder value: First is to continue building clinical evidence for Nellix. We expect to resume enrollment in the continued access phase of the IDE later this year, and we'll likely start Phase II of the Global Registry in the first quarter of 2016. Second is to continue gradually expanding our global Nellix customer base while providing a high level of training and clinical support. As Bob mentioned, Nellix is proving to be a very powerful technology for physicians treating patients with aortic aneurysms. We plan

to continue our methodical rollout internationally while we prepare for the U.S. introduction. Third is to file modules 2, 3 and 4 of the Nellix PMA between now and the end of the first quarter of 2016, positioning us for potential U.S. approval before the end of next year. And forth is to continue driving our AFX business. We expect regulatory approval in Japan in the third quarter, continued enrollment in the LEOPARD clinical study and the anticipated U.S. approval of AFX2 in the fourth quarter of this year.

Together, these initiatives represent a good mix of short and long-term growth opportunities and position Endologix as the leading innovator in the treatment of abdominal aortic aneurysms. We look forward to keeping you posted on our progress and are planning to participate in the Canaccord Growth Conference in August and the Crédit Suisse and Morgan Stanley health care conferences in September.
With that, we'll open it up for questions. Operator?

Question and Answer

Operator

[Operator Instructions] Our first question comes from the line of Rick Wise from Stifel.

Frederick A. Wise
Stifel, Nicolaus & Company, Incorporated, Research Division

A couple of questions. Maybe just starting with the AFX performance in Europe, less than planned. I mean, clearly, Nellix is going great guns. Help us think it through. Is this simply -- is this a logistical challenge and you need more sales folks to focus on both products? Is it -- is Nellix going to be less incremental from a share perspective? Are people waiting for AFX2? Just any clarity will be welcome.

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. Rick, I don't think there's anything special to it other than our team was primarily focused on Nellix and just didn't put the same amount of energy into AFX. I don't -- as we dug into it, we don't see any particular trend or any issues evolving. In fact, there's -- actually, in many accounts, they use both products. So I wouldn't read too much into it. For the quarter, it was just a little less than we expected, but I don't think it's necessarily a trend or anything to worry about moving forward.

Frederick A. Wise
Stifel, Nicolaus & Company, Incorporated, Research Division

Okay. And related to that, but you can broaden that as well to the U.S., your rep headcount, I think you were talking about in the press release expanding on the number of reps. Maybe I missed it, but can you update us on your numbers? And maybe more broadly talk about the European footprint. If you're adding now, do you have a large enough EU footprint to begin targeting the whatever 600 or 700 potential accounts that you could have for Nellix or...

Robert D. Mitchell
President

So Rick, this is Bob. Let me jump in on this one. I think in the United States, we're up about 6% versus last year. So we're currently at about 99 reps with clinicals, which was up from 93 last year. I think the rep -- at the end of the year, John, we're planning to be -- what are we forecasting by number of reps?

John McDermott
Chairman of the Board and Chief Executive Officer

99, 100. We're very close.

Robert D. Mitchell
President

We're right about there.

John McDermott
Chairman of the Board and Chief Executive Officer

Yes.

Robert D. Mitchell
President

Okay. So interesting to note about the United States before we jump to your question on Europe, we -- the rep productivity was 9 cases per month, which is a new all-time high for us. So we're getting -- actually, those were in former quarters. We've talked about rep productivity and new reps. We're starting

to get some traction from some of the newer reps as well. Now as it relates to Europe, we're currently at 41 reps. Clinicals -- that includes reps, clinicals and agents. And we expect to add a few more by the end of '15 but not many. Last year, at this time, we had 28. So we're really up about 46% year-over-year, but it's important to note that it's still kind of too early, because a large percentage of those are still kind of through the process of training and getting certified for -- to support cases.

Frederick A. Wise
Stifel, Nicolaus & Company, Incorporated, Research Division

Okay. And just last for me, if I add back to the reserves in the quarter, your gross margin seems to have been pretty strong, approaching 72%. I'm not sure I'm understanding the -- I understand the 68% includes it. But it's still -- when you think about '16 and beyond, it would seem like low 70s, particularly in the new facility and with the new products rolling out and with the write-offs behind you. I mean, 70% just seems awfully conservative. Am I missing something or not thinking about it correctly?

John McDermott
Chairman of the Board and Chief Executive Officer

No. Rick, I think the only other issue to consider with the margin is the sales mix and generally lower ASPs OUS. So as Nellix continues to have a full another year of revenue generation OUS and more sales and share capture that just puts a little bit more downward pressure on the margins. We certainly aspire to be higher than 70%, but we want to set and manage appropriate expectations.

Operator

Our next question comes from the line of Brooks West from Piper Jaffray.

Brooks E. West
Piper Jaffray Companies, Research Division

John, I wanted to start with -- I just want to make sure I've got the right base for how I'm thinking about the Nellix number. So I had you in Q1 at about $4.3 million commercial revenue for Nellix plus about $360,000 in the CAP for a total of about $4.7 million. Is that right? And then am I multiplying the $4.3 million commercial by 29% to get to my Nellix number for Q2? Or am I doing the whole thing with the CAP?

John McDermott
Chairman of the Board and Chief Executive Officer

I don't have each of those individual numbers at my fingertips.

Brooks E. West
Piper Jaffray Companies, Research Division

Let me ask it a different way, John. Am I -- should I be at $5.5 million for Nellix for Q2 or something more like $6 million?

John McDermott
Chairman of the Board and Chief Executive Officer

Well, we haven't been splitting Nellix up on a by-product basis, so that -- and I don't really expect to do that. What we're -- the metrics we want to provide for Nellix moving forward is the systems. So as I mentioned, we did -- we shipped 720 systems, which is up 40% year-over-year and significantly sequentially. I did break out a number of units for the CAP just so you can get some visibility to how that would tail off until we got the CAP restarted later in the year. But our plan really for Nellix metrics is just to provide on a quarterly basis, the quarter-over-quarter systems numbers.

Brooks E. West
Piper Jaffray Companies, Research Division

Okay. So the 29% is a unit growth versus a dollar growth, is that the way to think about it?

John McDermott
Chairman of the Board and Chief Executive Officer

That's correct. Yes, yes. We don't -- yes, go ahead.

Brooks E. West
Piper Jaffray Companies, Research Division

Has anything changed with pricing? Or is pricing for Nellix kind of holding where it's been?

John McDermott
Chairman of the Board and Chief Executive Officer

It's been holding steady, yes. So we reported -- just to give you a little perspective, specific to Europe, we reported an increase of Nellix systems in Europe of 37% year-over-year. And in constant currency revenue, that was 34%. And there isn't -- I wouldn't read anything into that difference. Maybe we just had a few more systems shipped to dealers, but you can see it's pretty much a match.

Brooks E. West
Piper Jaffray Companies, Research Division

Okay, okay. So then I'm going now to the $3.5 million reduction in the guidance at the midpoint. So I understand the CAP -- the $1 million in Europe, is that just AFX in Europe? Or is it Nellix...

John McDermott
Chairman of the Board and Chief Executive Officer

Well, no, we just -- well, when we were looking at the CAP, we realized we were going to have to probably go back in and take a new look at the guidance overall, and it is a small adjustment. So we looked at Europe, and we thought they might be a little bit back-end loaded. We don't want to push these guys. We actually met in the middle of this past quarter internally. And we could have pressed for more cases with Nellix in Q2, but it takes us outside of our plan to just go methodically. So we just gave Q4 a little bit of a haircut, just to make sure we're not being overly aggressive with our how we're on-boarding and training new accounts. And then lastly, we took a little bit off of our -- the rest of our international business. Most of that's Latin America. We anticipated approval for Nellix in Brazil in the latter part of the year. We're still in a series of Q&A with the regulatory agencies there. So we thought we better pull that out and just be a little bit more cautious, so those are the nature of the adjustments.

Brooks E. West
Piper Jaffray Companies, Research Division

Okay. So for -- if -- and again, I'm just thinking about the European number. Maybe as we model it maybe a little bit later in Nellix and then the rest is AFX, that's the way to think about it?

John McDermott
Chairman of the Board and Chief Executive Officer

Yes, yes. So the Europe range in current currency is 32 to 33, that's constant currency growth of 30. But in the second half, we think those numbers are closer to year-over-year second half growth of 40. And that's driven largely by Nellix and also what Bob talked about, which is we've got about 46% larger sales force going into the second half of this year than we did last year. So we feel pretty good stepping into the second half. And we got 1 month under our belt, and we are right on plan. So it looks pretty good.

Brooks E. West
Piper Jaffray Companies, Research Division

Okay. I guess, just one more for me then. On the -- the reason you're pausing on the CAP is -- I want to make sure I have this clear. So your -- is FDA asking you to do some more testing around use of Nellix did you say with stents? And how do I -- how do we relate that, again, to the PMA submission? Is that ultimately going to be part of the PMA submission? Or any more detail there would be helpful.

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. So it's pretty common that ancillary devices like stents are used together with aortic stent grafts. So if a physician has -- puts in an aortic stent graft and wants to provide a smoother transition at the end -- at the distal end of the stent graft limb into the vessel, it's not uncommon that they'll add a stent or a covered stent or do some adjunctive procedure. In the -- in our case, it's less than 10% at a time in the IDE. But the agency's requested this compatibility testing, just because they are familiar with how it works with other stent grafts but Nellix is new. Again, this is something we expected to drop into the PMA, so it's not a surprise to us. We just didn't anticipate it for the CAP, so it's really no big deal. It's pretty straightforward testing. It's stuff we know how to do. We've got 3,000 cases worth of experience. So if there was a problem with compatibility with these devices, we'd already see it. So we don't anticipate any issues. We just got to move it up now and do it to get the CAP regoing.

Operator

Our next question comes from the line of Joanne Wuensch from BMO.

Joanne K. Wuensch
BMO Capital Markets Equity Research

Couple of questions. We've been hearing some pushbacks and concerns regarding the data that's being presented in the endoleak rate, despite it being particularly low in our view. Are you hearing -- or can you give me some anecdotal commentary regarding what you may or may not be hearing from the field?

Robert D. Mitchell
President

Well, I think if you look at a comparison, us versus the competitors, we're still sitting pretty good. Joanne, I think that we're -- we have a respectable endoleak rate compared to the -- the average is always in double digits. So it's interesting because Nellix is the -- it is -- as I tried to mention in my portion, it is -- it still remains a newer device, and we continue to learn as we grow. And it was interesting that some of the quotes that I noted is that the results for some of these institutions that have done many Nellix devices, their results improve over time as well. So I think there is an inherent learning curve associated with the numbers we're looking at, but overall, we still remain pretty encouraged with ours versus the rest of the competitors.

John McDermott
Chairman of the Board and Chief Executive Officer

And Joanne, I can add to that. We may be a victim of setting the bar too high. I think there has been an expectation when people see how Nellix works that it will be 0 endoleaks. So when you put up low single-digit endoleaks, it becomes a disappointment, which is too bad. Maybe we should have done a better job of setting the bar in a reasonable place, but I'm not hearing much pushback from physicians on the concern over endoleaks.

Robert D. Mitchell
President

No, not at all.

John McDermott
Chairman of the Board and Chief Executive Officer

No.

Joanne K. Wuensch
BMO Capital Markets Equity Research

That's helpful. And as a follow-up, could you please give us an update on where you are with the CFO search?

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. We've got several good candidates right now. I'm actually very encouraged. We went through a little bit of a dry patch there a while back, but we've got a handful of what I think are very good candidates. We're deep into interviews and reference checks and other activities, and our hope is that we have the new CFO on board and participating in the next earnings call.

Joanne K. Wuensch
BMO Capital Markets Equity Research

And then just my last question is I have sort of a $7-million, maybe a little bit more, revenue run rate for Nellix in the second quarter. Do I take your comments from before that you would assume a similar type of ramp in the United States once it is approved? Or can we not extrapolate?

John McDermott
Chairman of the Board and Chief Executive Officer

Well, of course, when we get closer, we'll start to provide some guidance relative to the ramp. The big difference, of course, is that we've got a well-trained, seasoned sales force on the ground already in the U.S. versus building one from scratch like we're doing in Europe. So intuitively, I think we all believe we could put up bigger numbers faster. But based on our experience, what we want to do is just make sure we take it slow. Our goal really is to just gradually increase the number of customers and the number of procedures sequentially quarter-over-quarter. So I think you'd be safe if you apply the current trends to the U.S.

Operator

Our next question comes from the line of Jason Mills from Canaccord Genuity.

Jason R. Mills
Canaccord Genuity, Research Division

I want to follow up on Joanne's last question. Strategically, when we get to the point you're rolling out Nellix in the United States, could you talk about -- you mentioned that you'll ramp sequentially the number of centers that you give access to Nellix. How will you do that sort of juxtaposed to the AFX2 product that you're excited about as well? Will there be sort of carrot-and-stick model, for lack of a better way to put it, where a higher utilization of AFX2 will generate earlier access to Nellix? Could you just talk a little bit about, as much as you're willing to, I guess, of how you might strategically place 2 of those devices together in the next year?

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. I can start, and then Bob can jump in. AFX2 should be a very active force at the end of this year and all next year. So from a timing perspective, of course, we get, plus or minus, a full year benefit of AFX2 before we start transition into Nellix. And I do think they're -- I do think AFX2, although will certainly be a big improvement to the existing customers, it's going to have some nice features for new customers as well. But as it blends into the question about Nellix, we have to have some mechanisms to prioritize those people who get access to the Nellix training. And as we've talked about in the past, we're going to roll out Nellix to our existing customers first. And so I would imagine that on a regional and local basis, it will go to the most active customers first in terms of priority. That's how we're thinking about it. And we don't want to use that inappropriately, of course, but we just think that there ought to be some recognition of loyalty to our existing customer base.

Robert D. Mitchell
President

And Jason, this is Bob. One of the things we did learn in Europe, again, is focusing on building the physician experience. And the best way to do that is to think deep versus wide. And so our focus will be

on those large customers and to provide just the excellent clinical training and support to help them go deeper within the channel. So you'll probably see a similar launch as you've seen in Europe. We are going to be very methodical. We're going to be very thoughtful on the way that we launch Europe in the -- Nellix in the United States.

John McDermott
Chairman of the Board and Chief Executive Officer

Jason, sorry to interrupt. I'll add one more comment. Not to drag this out too much, but just to put it into clinical context, can these products live side by side or is it all cannibalization? I'm actually a bit surprised with how well the products complement each other. So Nellix can do a lot of things, but there still are some anatomies where AFX is a better choice. Specifically tight distal aorta, that's really a sweet spot. Any time a physician wants to preserve the bifurcation, only AFX can do that. So there are still some anatomies where AFX is -- really continues to be the best product, and the 2 products complement each other nicely.

Jason R. Mills
Canaccord Genuity, Research Division

Can -- Just to expand on that a bit, John and Bob, could you talk about the number of U.S. accounts that you're in today? What percentage of the total that makes up? And sort of how would you expect to grow, not only your total customer base, but how you would expect to roll it out in terms of maybe, generally, number of accounts per quarter -- or number of additional accounts per quarter as you roll through 2017? I realize I'm giving a couple of years out on you and sort of bypassing a lot of steps, including the important FDA approval. I think we're all focused on rollout of Nellix for obvious reasons, and it'd be helpful to understand how you sort of plan to do that, generally speaking, given that it does seem to be a product that can help you gain share, not only number of accounts, but as Bob mentioned, going deep with that account?

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. So right now in the U.S., we've got about 750 to 800 active accounts. And I don't -- we also -- for the quarter, we had the highest number of reported active physicians. So in the second quarter, we had an increase in active physicians as well as active accounts. That -- there's a total of 2,000 total EVAR hospitals in the U.S. that are doing -- or actually, there's a total of 4,000 physicians, but only about 1,200 that are key targets that do the volume. We're in, right now, Jason, approaching 40% of the EVAR accounts that are targeting. So -- and in those accounts, we tend to have about 1/3 overall of their share. So we still feel like we've got a lot of upside in the existing accounts as well as starting to broaden out beyond that third of the accounts that we're in. So we'll go deeper. The first play in terms of shares will be to go deeper in existing accounts. And then as we add new accounts, we'll do that with an eye to go deep in each of those as well.

Jason R. Mills
Canaccord Genuity, Research Division

That's helpful color. Last question for me. I know that you started in the first quarter to do some implants in Australia, some in Asia Pac and Latin America with Nellix. Out of the 720 that you did this quarter -- and you gave us the 44 or whatever it was in the United States, what was outside of Europe out of the remaining 680 or so?

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. Jason, we've talked about that internally. I don't think we want to start breaking the total number down too granular for competitive and other reasons. I mean, we want to be very transparent with you guys, but we don't want to be handing our daily sales report to the bad guys. So we're -- we'll give you the macro numbers, and we'll try to give you some geographic highlights. But after that, we'll probably stay with the more macro numbers.

Operator

Our next question comes from the line of Chris Cooley from Stephens.

Christopher Cook Cooley
Stephens Inc., Research Division

I just want to make sure I have the domestic sales growth guidance fully under wraps here. John, you grew just under 4% through the first half of the year domestically. And if my memory serves correct, you should have -- or you still expect a fairly nice increase from LEOPARD here through the second half of the year. I think you had 60 centers going through the IRB process at the end of the last quarter. I understand the reduction in the CAP numbers, but help me think about what else is employed there such that we get the roughly $1.5 million -- sorry, that's $1.5 million from CAP, but gets us back down to 2% growth in the back half of the year here in the U.S.? And I just have one other follow-up.

John McDermott
Chairman of the Board and Chief Executive Officer

Yes, nothing -- not one thing that I can point to, Chris. We just want to make sure we set these numbers in an appropriate place. So we've done a bottoms-up, top-down forecast, peeled out the CAP, looked at some anticipated seasonality in Q3. And that's how we get to those numbers of $107 million to $108 million total full year.

Christopher Cook Cooley
Stephens Inc., Research Division

Okay, okay. And then -- but for the CAP, just to be clear, do you still expect to get just under 200 patients through the CAP this year? Or help us kind of think about what that tail is into the 1Q? So I believe in the last call, it was roughly 200 incremental patients that you're expecting to be able to do as part of the CAP here in the back half.

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. We won't get those, so that's what...

Christopher Cook Cooley
Stephens Inc., Research Division

The $1.5 million.

John McDermott
Chairman of the Board and Chief Executive Officer

That's the $1.5 million of the $3.5 million reduction is. Now listen, we're going to push hard internally to turn this testing around and get the CAP we started as soon we can, but we thought we should be just a little bit cautious and assume that we don't get the CAP started until the very end of the year. So if we get the CAP started earlier, then that's a little bit of upside in the U.S. for us.

Christopher Cook Cooley
Stephens Inc., Research Division

Understood, just want to be clear there. And then could you help us, maybe just conceptually, when we think about the international opportunity, obviously, you're doing great there with Nellix. Is there an opportunity there to augment the efforts with more like a clinical specialist, such that you could drive deeper penetration with Nellix within the existing accounts but maybe not necessarily see the same degree of a taper on AFX? That number just looked a bit little weaker than what we were modeling for the quarter. Just want to make sure I get the full understanding of just kind of the bandwidth of the team as it stands today outside the U.S.

Robert D. Mitchell

President

Chris, as mentioned, we've added substantially year-over-year, and it's almost a capacity issue. We have a good number of people right now. We just need to get them geared up and trained and qualified to be able to support our product most efficiently. As it relates to the AFX being light, I mean, John, do you have any color on that?

John McDermott
Chairman of the Board and Chief Executive Officer

No. Like I said, there wasn't any one thing we could point to. Chris, if you're talking about the international, excluding Europe, specifically in the second half.

Christopher Cook Cooley
Stephens Inc., Research Division

Yes.

John McDermott
Chairman of the Board and Chief Executive Officer

Yes.

Christopher Cook Cooley
Stephens Inc., Research Division

I'm sorry.

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. So we do think that's going to grow more than it did in the first half because we anticipate the approval for AFX in Japan. So there, it represents some upside there. But we tried to soften that a little bit in the second half with Brazil, which has been one of our good historical rest of world markets. It's got some economic challenges as you know. So you've got a couple of ups and downs going on there. So we've just tried to exercise a little bit of conservatism in the second half for Latin America primarily, but there's actually probably some upside there. We'll just have to see as get deeper into the second half.

Operator

Our next question comes from the line of Matthew Keeler from Crédit Suisse.

Matthew J. Keeler
Crédit Suisse AG, Research Division

First, can you give us any color on U.S. pricing in the quarter? Then I have one follow-up.

Robert D. Mitchell
President

So the pricing, Matt, seems to be pretty stable in the United States. We haven't seen much price erosion at all here, and we don't anticipate that, that's going to happen in the foreseeable future. So in addition to that, we've had some -- actually some good news on some new codes that recently have been recategorized for EVAR. So that effectively could represent about an 11% increase for U.S. hospitals by recategorizing those 2 codes for reimbursement. So we feel pretty comfortable with the stabilization of the pricing in the United States.

Matthew J. Keeler
Crédit Suisse AG, Research Division

Okay. That's helpful. And then on your last call, you talked about some of the changes to be present in your updated version of Nellix, and one of the changes you mentioned was a different endobag

configuration distally. I'm wondering can you help us think about the benefit of that. Is it just easier to place? Or is there a potential functional benefit once it is placed?

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. It doesn't change the deployment of the device. What it changes is the precision of the endobag in relation to the end of the stent. So the stent is very visible during the procedure, but the endobag is not. So you could -- in the current version, the endobag can slide up and down, if you will, on the stent. And so you don't always get a precise landing of the bag. That's all changed with the new system. We've done a fair number of cases now with the new bag design, and the feedback's been extremely positive. So we think that's a nice upgrade for the new system.

Operator

Our next question comes from the line of Chris Pasquale from JPMorgan.

Christopher T. Pasquale
JP Morgan Chase & Co, Research Division

John and Bob, I think you both make comments about this gradual Nellix launch OUS. I just want to understand whether anything had changed with the pace of the rollout relative to what you're thinking at the start of the year. Are you still on track to expand to about 200 accounts by year-end?

Robert D. Mitchell
President

Yes. In fact, currently, in Europe, we have about 160 active accounts, and we still expect to finish around 200. And relative to the first part of your question, no. We've always kind of maintained a process -- a rigorous process to control the utilization of Nellix and its expansion in Europe, and we plan to continue to do that again as deep-versus-wide discussion.

Christopher T. Pasquale
JP Morgan Chase & Co, Research Division

And then I just want to understand a little bit more about the FDA request. Was that based on a concern that arose from some of the early trial data? And then what are you doing to address their questions? Does this involve actually pulling patient data from the clinical experience? Or is it just bench testing?

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. It's just bench testing -- bench durability testing and some metals compatibility. Sometimes they'll use a nitinol stent. Sometimes they'll use cobalt chromium stent. So we've done a lot of the blocking-and-tackling work already and have a little bit more testing to do. We just have to gather it all up and submit it to the agency. It was not a result of any patient outcomes or any issues in the study. It's just something that they wanted to see. As I mentioned in our case, it's -- less than 10% of the case is in the IDE. So again, this -- it's not a surprise that they would ask for it. We just expected to supply it as a part of the PMA. So we'll just pull it forward and do it now.

Christopher T. Pasquale
JP Morgan Chase & Co, Research Division

And then lastly for me, could you talk a little bit about LEOPARD and whether you're seeing any benefit yet or whether that's still on the come here as we get into back half of the year?

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. I think we're starting to see some benefit. We have -- 30 centers are active now, which is up from 10 last quarter. 40 more centers are in the contract phase and another 30 centers, on top of that, are in the

pipeline that are not yet in the contract. We've got 52 patients now randomized. It's starting to build some momentum. As physicians -- it's kind of a new concept, right? Nobody has ever done a head-to-head randomized trial with commercially available devices in EVAR. But as the physicians get into a flow, we're starting to see the case volumes pick up, and there continues to be good interest. And as we mentioned earlier, it's a good mix of existing and new customers, about 80-20. So I can't give you a number, Chris, in terms of the incremental impact in the U.S. But I can say overall it supports our efforts in the second half of this year and, I think, will be positive for us next year. So as we look out to next year in the U.S., we'll have full year AFX2. We'll have continued LEOPARD enrollment as well as the CAP development. And I'm sure there will also be some physicians who start to get aligned with us to get access to Nellix. So it looks like a pretty good setup.

Operator

[Operator Instructions] Our next question comes from the line of Steven Lichtman from Oppenheimer.

Steven M. Lichtman
Oppenheimer & Co. Inc., Research Division

Just in -- John, in terms of market growth, can you give us your latest thoughts in terms of where market's growing both in the U.S. and in Europe?

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. I -- it hasn't changed much, Steve. We've talked in the U.S. about 2% to 3% procedure growth. I think, as Bob pointed out, ASPs seemed to be stable. So we estimate this year about 44,000 in for renal procedures and, again, 2% to 3% growth. We update these numbers annually. We don't buy quarterly data, so we'll get another report probably. I'm not sure when the next one is due. In Europe, we estimated to be about 30,000 procedures, and again, kind of the same low single-digit procedure growth rate.

Steven M. Lichtman
Oppenheimer & Co. Inc., Research Division

Okay, great. And then just rest of world sequentially from 1Q, I think it -- just based on the numbers, it looked like it was down sequentially. Can you remind me, again, why that took a little bit of a step-down from 1Q?

John McDermott
Chairman of the Board and Chief Executive Officer

Let me check the numbers, Steve. I don't believe it was down sequentially. If it was, it's just dealer orders. I don't think there's anything unique to the -- I can do some digging on that. I don't have that at my fingertips. We do have forecasted for the second half of the year about 20% year-over-year growth in the second half. So actually, yes, I just got handed a note, Steve, sorry. We were down in the first half, but I think it's just ordering patterns. There's nothing going on there. A little bit of softness in Brazil as I pointed out earlier, but the second half looks better.

Steven M. Lichtman
Oppenheimer & Co. Inc., Research Division

Okay. And then just swinging back to the market growth, again, is the growth of the core market you continue to see is more flattish and the growth is being driven by complex. Is that right?

John McDermott
Chairman of the Board and Chief Executive Officer

Yes. I think that's the big growth opportunity in both the U.S. and in Europe and in other international markets. There's still a lot of patients that don't get an endovascular alternative, so we see that as a huge growth opportunity for us moving forward.

Operator

There are no further questions. I'd like to hand the call back over to John McDermott for closing comments.

John McDermott
Chairman of the Board and Chief Executive Officer

All right. Well, I'd like to thank everyone for joining the call and for your interest in Endologix. We look forward to seeing you at the upcoming conferences, and have a good evening.

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