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Endologix, Inc. (ELGX)

Q2 2018 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Greetings and welcome to the Endologix Second Quarter 2018 Earnings Conference Call. At this time, all participants are in listen-only mode. A question-and-answer session will follow the formal presentation. As a reminder, this conference call is being recorded.

This conference call is also being broadcast live over the Internet at the Investors section of the company's website at www.endologix.com, and a webcast replay of the call will be available at the same site, approximately one hour after the end of the call.

Before we begin, I'd 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 known and unknown risks, uncertainties, and other factors that may cause the company's actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

For a discussion of risk factors, I encourage you to review the Endologix Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2018 and subsequent reports as filed by the company 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 conference and broadcast, August 9, 2018. Endologix undertakes no obligation to revise or update any statement to reflect the events or circumstances after the date of this call.

With that, I'd like to turn the call over to Mr. John Onopchenko, Endologix Chairman and Executive Officer. Mr. Onopchenko.

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, operator, and good afternoon, everyone, and welcome to our second quarter conference call. This afternoon I'll provide a brief overview of our second quarter results and then discuss some of the details of our new strategy and go-forward plan. I'll then turn the call over to our Chief Financial Officer, Vaseem Mahboob, who will review our second quarter financial results and our revised 2018 financial guidance. After that, we'll open up the call for questions. For context, our focus on today's call will be the second quarter and more importantly the remainder of 2018 while the October 2nd investor event that we announced earlier this afternoon in our earnings press release will be focused on initiatives that we are undertaking to improve the company's performance in 2019 and beyond. As a reminder, we have posted a supplemental slide deck on our Investor Relations website directly below the webcast link and plan to walk you through that presentation as part of today's discussion.

Since being appointed as the company's Chief Executive Officer at the beginning of May, the leadership team and I have been working hard on re-establishing Endologix's credibility and reputation with our physicians and customers and building a culture of accountability with the ultimate goal of delivering value to our stakeholders around the globe. As part of this work, we have completed a thorough evaluation of five key value drivers that have the greatest impact on our long-term plans, our culture, the markets we serve, our product portfolio, our clinical development, and our operating model.

As a result of this evaluation, we are making significant changes to our strategy. What remains intact,

However, is our strong belief that our well-differentiated product portfolio coupled with an expanding body of clinical evidence is compelling and saving lives. Further investment in product and clinical development coupled with improved execution and disciplined expense management will be rewarded by even more patients realizing long-term benefits, a growing and loyal customer base of physicians, and finally significant value creation.

As a result of this review, we have come to the conclusion that we are underperforming relative to our clinical evidence. And if we don't implement this strategic reset, our longer-term aspirations will remain elusive. This reset has precipitated the reduction in our financial guidance for fiscal year 2018 and I'd like to review some of the specific factors that drove this change.

Our total revenue for the second quarter decreased 7.9% year-over-year as strong growth of AFX in Japan and Ovation in the U.S. was more than offset by softness in AFX sales domestically, our Latin America business, and regulatory challenges that we faced in Asia Pacific. We continue to see sequential decline in sales of AFX in the U.S. market, however, our monthly trend data show a slowing decline and we anticipate that AFX STRATA-related customer losses to be behind us by the end of the first half of 2019. The declines in AFX combined with the ongoing weakness in our Latin America business drove the operational portion of the lower revenue guidance for the full year.

As you can see on slide 4, these two factors combined with a delay in regulatory approvals take our revenue guidance from the prior midpoint of $175 million to roughly $167 million. The remainder of the change in guidance that gets us to the range of $145 million to $155 million is driven by strategic changes to right size, redirect, and critically focus the business which I will now discuss in more detail. Our continuous improvement mandate coupled with related investments in our quality systems has recently resulted in the distribution of two field safety notifications after collaboration with the FDA.

We remain committed to timely reporting and communication of important technical and safety updates to our physicians. Let me now briefly discuss these two recent FSNs. The first is related to re-interventions through the AFX system, as well as an update on Type III endoleak rates for the AFX platform. The data in this update show that cumulative Type III endoleak rates remain extremely low for the currently marketed AFX2 system. The second notification communicated updated information regarding the migration and treatment of polymer leaks at the time of polymer fill with the Ovation platform.

The incidence rate of polymer leaks is less than 1%, 0.65%. Our recent investigations have suggested that some physicians have performed graft deployment steps out of the suggested sequence which had been positive for polymer leaks. We have also updated a recommendation for treating the effects of polymer leaks which need early and robust therapy. We believe the actions resulting from this update have the potential to reduce both the incidence and sequelae of polymer leaks.

We believe that the performance of our product portfolio should not be defined by the narrow issues addressed in the recent FSNs. Endograft performance needs to be described by broad patient outcomes. The LEOPARD study, the first and only randomized controlled trial to compare endografts, demonstrates excellent contemporary clinical performance of the AFX2 system whereas the ENCORE study reports superior short-term outcomes even considering polymer leaks with unmatched durability as related to the Ovation platform.

Looking at our commercial markets, one of the primary goals of our strategic reset is to lower our cost-to-serve which is a two-pronged effort in the U.S. and EU. In the U.S., we are rightsizing and investing in customer and market intelligence within our commercial organization while shifting our focus to serving higher volume accounts and away from lower volume accounts. To be clear, we value every customer and will optimize resources, costs, and incentives to ensure that we scale each product line appropriately in order to best serve our customer needs.

In the EU, we are lowering our cost-to-serve by prioritizing those geographies where we can be successful in high volume accounts and shrinking our overall footprint by exiting unprofitable and less scalable geographies. We have historically chased revenues without a rigorous regard to how margin contributions and the implications to cash flow. This will no longer be the case.

Having hopefully given you a better understanding of the changes to our revenue guidance, I will also point out that our expense base will be taking a meaningful step down as well, although at this point in time given the totality of the reset, we do not expect to realize cash independence in 2019 as has been previously communicated. Vaseem will walk you through that in more detail in a moment. Overall, a fresh look at the business drives this much needed reset of our strategy and plan, and it is a key step toward predictable and consistent long-term growth. Our path to being cash flow positive is an imperative and we are now on that path.

As I mentioned a few minutes ago, two of the five areas we evaluated were clinical development and our product portfolio, and I would like to provide important updates for each. In clinical development, we are updating our timeline to enroll the EVAS II study beyond year-end 2018 due to slower than anticipated site activation which slowed our overall enrollment ramp. The study is enrolling well now that more sites are activated, and we remain optimistic about its potential. Our product differentiation will be built on strong clinical evidence supported by thoughtful trial designs that we believe will lead to superior outcomes. We are actively evaluating approaches to strengthen the impact of our studies. We have an ongoing collaborative dialogue with the FDA over the trial design for the ChEVAS IDE study. This is an entirely new therapy where trial design needs particularly careful consideration. Given these realities, we are updating our timeline and now expect to be able to enroll the first patient in this study in the first half of 2019.

Within the product portfolio, we have taken steps to prioritize and fully resource next-generation EVAS. This is an important decision towards securing our long-term category leadership. We continue to believe that our products change lives as evidenced by the unique EVAS mortality data we presented to Charing Cross in April and the long-term results from ENCORE, which were presented at the same meeting. We will provide a more in-depth look at our long-term pipeline during our investor event.

We strongly believe that Ovation, Alto, Nellix, next generation EVAS and ChEVAS are the future of endovascular aortic repair. Traditional EVAR has reached the limits of its potential. Our portfolio offers the only set of differentiated solutions that address the unmet needs that have persisted over the 30 years of EVAR.

Now let me briefly discuss our updated credit facility that we recently closed with Deerfield management. As you may recall, we entered into our original financing agreement with Deerfield in April 2017. Since being appointed CEO earlier this year, it became clear early on in my review process that the meaningful strategic changes that we need to implement in order to transform into a company with predictable profitable growth would not be possible under the covenants of the prior financing agreement. As a result, we decided that we needed a deal that reflected the new reality that we present to you today. While it's a more expensive financing transaction, we have a different risk profile today than we did in early 2017, and we believe that this financing better suits our current capital needs and our goal of building a more sustainable company. I am proud of this accomplishment, as well as the much stronger relationship we've established with Deerfield, which is one based on mutual trust and confidence in Endologix's success. Vaseem will provide you more details on the financing in a few minutes.

Finally, I want to say a word about leadership of the company. One of my primary goal since becoming CEO has been to strengthen our leadership team, and we have taken some important first steps in this regard. For example, I'd like to welcome Jeffrey Fecho who joined us at the end of June as our Chief Quality Officer. Jeff is a highly experienced leader with a history of leading large quality organizations in the cardiovascular industry and he will be invaluable in advancing product safety and achieving sustained quality excellence especially during this critical time when we are resetting Endologix for long-term success. Jeff is the first of several announcements that we plan to make over the coming months as we continue to build a world class leadership team anchored by Vaseem Mahboob, Dave Jennings, Dr. Matt Thompson, Dr. Michael Chobotov, Jeremy Hayden, and now Jeff Fecho.

Overall, the actions I've just outlined represent a much needed reset. We now have a well-defined plan in place underpinned by highly differentiated products and a rational strategy to profitably grow the business while reducing our expenses. Transformations of this nature are not without struggle, but struggle perceived success in the dictionary as it does in life. We are already seeing early evidence of our new approach taking hold, and I look forward to sharing a more complete update during the investor event in October.

And now I would like to turn the call over to Vaseem to discuss the second quarter financial results and provide you with details on our updated guidance. Vaseem?

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Thank you, John, and good afternoon, everyone. Total revenue for the second quarter of 2018 was $44.7 million, a 7.9% decrease from $48.6 million in the second quarter of 2017. As John already mentioned, during the quarter, strong growth in AFX in Japan and of Ovation in the U.S. was more than offset by softness and domestic AFX sales, as well as our Latin America business and by regulatory challenges that we faced in the Asia Pacific market.

U.S. revenue for the second quarter of 2018 decreased 6% to $30 million, compared to $31.9 million a year ago as the decline in our AFX business was partially offset by continued growth in our Ovation business.

Our AFX business is still being impacted by slower than expected U.S. sales recapture attributed to the reputational challenges associated with the STRATA-specific Type IIIb endoleaks, and we expect AFX II sales to flatten out in 2019.

As we grow Ovation sales and penetrate high volume centers, we expect Ovation sales growth to outpace AFX growth. Our focus will be on consolidated sequential revenue growth moving into 2019, even as the mix may shift between product lines and customer segments. Continuing with second quarter results, international revenue decreased 11.4% on a reported basis to $14.8 million, compared to $16.7 million a year ago. On a constant currency basis, our second quarter 2018 international revenue decreased 14.1%. As I already mentioned during the quarter, we saw strong growth in AFX in Japan which was more than offset by declines across our product lines in the rest of our international markets, most notably Argentina and Brazil. Just a reminder, we had onetime distributor restocking shipments in the second quarter last year on account of the product issues we had faced in the prior quarter. Excluding those shipments, our international business was flat in the second quarter year-over-year.

Our second quarter gross margin was 66.2%, which is 20 basis points lower than last year. We have done a great job managing our cost amid declining volumes by adjusting our direct labor spend and managing our overhead pool. The softness this quarter was primarily driven by region mix offset by some favorability in our excess and obsolete inventory reserves. As we had mentioned on our last call, we have restructured our Irvine operations to reflect lower AFX volumes in 2018, but expect to see gross margin headwinds for the rest of the year, due to anticipated lower volumes in Irvine and our initiatives to reduce global inventories to improve our cash performance.

Our operating expenses increased 12.4% year-over-year to $45.1 million, compared to $40.1 million in the second quarter of 2017 driven by an increase in G&A expenses. Looking more closely at our second quarter operating expenses, marketing and sales expenses were down 11.2%. Offsetting that was a 77.4% increase in our general and administrative expenses, primarily driven by costs related to the CEO transition and legal fees related to the financing and some ongoing litigation.

Additionally, clinical and regulatory expenses increased 36.1%, primarily driven by our ongoing IDE trials and research and development expenses increased 8.9%, driven by a shift in our pipeline priorities. Net loss for the second quarter of 2018 was $23.9 million or $0.28 per share compared to an adjusted net loss of $16.3 million or $0.20 a share a year ago. Adjusted net loss totaled $15.6 million compared to an adjusted net loss of $8 million for the second quarter of 2017. Adjusted EBITDA totaled a loss of $9.3 million for the second quarter of 2018 compared to adjusted EBITDA of a loss of $2.3 million for the second quarter of 2017.

Moving to the balance sheet, our cash, cash equivalents, and restricted cash were $37.6 million as of June 30, 2018 compared to $50.1 million as of March 31, 2018. Our cash burn for the quarter was approximately $12.5 million. Today, we closed the credit facility with Deerfield. The key terms are outlined on slide 6 in our supplemental deck. As highlighted in the plan to fix the balance sheet issues, this new deal is the first important step to ensure liquidity and strengthen the balance sheet. The second step is underway as we restructure the business to lower our cash burn for the remainder of the year in 2019.

The third leg in this journey will be exchanging the now smaller 2020 debt maturities as we position the business for cash flow breakeven in 2020. We have negotiated covenants that will allow us to focus on improving our business under terms that are reflective of our current business as well as different risk profile than we had a year ago. We are pleased that the financing is done and that the cash is available.

Turning to guidance, due to the current business trends and the significant changes to the go forward strategy which John just discussed earlier in the call, we are reducing our previously issued full year guidance. We now anticipate 2018 revenue in the range of $145 million to $155 million compared to the previous range of $170 million to $180 million. We anticipate further reductions to our operating expenses to occur in 2019 and beyond, and we'll outline those in detail at the investor event.

We will be taking a restructuring charge in the second half of 2018 and as it stands today, we anticipate that the operating expenses in 2019 will likely end up in the range of $130 million to $140 million versus $160 million to $165 million in 2018. We now expect 2018 GAAP loss per share in the range of $1.04 to $1.12 compared to the previous range of $0.89 to $0.95.

These loss per share numbers contemplate the impact of the second half restructuring charge but exclude the impact of any financing-related accounting or adjustments. As John mentioned earlier, given this reset, which is undoubtedly the right path for the long-term success of the company, we now expect to achieve cash flow breakeven in 2020. We will provide greater detail on this in October, but rest assured while the model looks materially different both in terms of revenue and expenses going forward, we are positioning Endologix to be a profitable, consistent in achieving its commitments, and the company that's rewarded for innovation and growth.

With that, I'll hand it back to John for final comments. John?

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, Vaseem. I want to highlight and reinforce the changes we have conveyed today to ensure clarity and transparency. Our quality system improvements enabled a timely and comprehensive response to patient safety in the form of two recently issued field safety notices for both AFX innovation. Our patient safety vigilance and our LEOPARD trial data support our confidence that AFX2 is not only a safe and effective product, but also one that competes effectively worldwide.

While AFX declines in the U.S. have significantly tapered, we expect STRATA-related customer losses to be behind us by the end of the first half of 2019. Causes for Ovation polymer leaks are well-characterized and additional training is underway to ensure procedural standardization. Beyond core data and the rigor by which those data were created show best-in-category outcomes at five years, a key differentiator as we move to high volume centers.

EVAS II enrollment, given the site activation delays, will push beyond the end of 2018. Finalizing a ChEVAS trial design and the related interactions with the FDA [ph] gate (00:24:36) our ability to establish defensible time to U.S. clearance, but we will continue to keep you updated.

Alto remains on track for a 2019 U.S. introduction. With AFX innovation in the near-term and Alto next year, we have a competitive and differentiated product lineup that only gets stronger as we generate additional data with ChEVAS and Nellix.

Finally, our next-generation EVAS platform is our primary development focus, staff to execute its mandate, that being establishing the highest performance and outcomes in aortic care. We made the difficult but correct decision to reduce our EU presence in order to focus on high volume geographies and accounts, and in concert, we rightsized our EU organization. We believe these changes will enable profitable growth.

In the U.S., we are addressing both productivity and cost to serve by modestly reducing head count, focusing on our clinical specialists to more frequently serve our base business accounts while our sales representatives shift to focus to high volume centers with Ovation and then Alto.

Currently, we are underperforming relative to our clinical evidence. Our revised strategy and plan does not support the previously stated goal of cash flow independence by year-end of 2019. Our strategy and plan for 2019 and beyond will be discussed at our investor event on October 2. We've strengthened our balance sheet with a new $50 million ABL and a revised set of terms on our $120 million term loan.

Importantly, we've strengthened our relationship with Deerfield, a valued partner in our journey. These changes reflect the hard work of our team and are intended to ensure all of you as well as the Endologix leadership team, employees on our board, that I have undertaken a comprehensive assessment of Endologix and decisively acted to improve the competitiveness and profitability of our business.

With that, we will now open the call for questions. Operator?

QUESTION AND ANSWER SECTION

Operator: Thank you. We will now be conducting a question-and-answer session. [Operator Instructions]

The first question is from Richard Newitter, [indiscernible] (00:27:41) Partners. Please go ahead, sir.

Q

Hi. This is [ph] Jamie (00:27:46) on for Rich. I guess a first question I have, you say the $3 million for the regulatory challenges for their guidance reduction. So, I'm just wondering is that $3 million associated with the challenges that you're seeing in Asia that you kind of cited or is it more so geared towards the Field Safety Notices that you cited for AFX innovation?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Well, thank you for the question. I think when you look at or when you heard John's comments, what he was walking you through and it's reflected on page 4 on the supplemental deck, the $175 million, which is kind of the midpoint of the guidance today to the $167 million is really those three buckets that we talked about, AFX $3 million, and we had said at the beginning of the year that the range $170 million to $180 million was predicated on how well the U.S. does when it came to AFX. And the rest of it was OUS.

But then you look at it on the chart, Latin America weakness was $3 million, which I mentioned primarily was driven by Brazil and Argentina and the softness in the business there; currency and some political pressures. The regulatory delays were OUS in our Asia-Pac markets where we were expecting some product approvals that

haven't come in yet. So, that's really what's driving us to the operational low end of the range from $170 million to $167 million.

Now, the $167 million to the $145 million and $155 million is really what we are talking about as kind of the second half reset drivers.

Q

Okay. All right. That's helpful. Thank you for the clarification there. And then I guess on the Nellix slide, so the EVAS II trial enrollment pushed out beyond 2018. What's your expectation for when you guys think now that you'll be able to complete this trial? And then, is it still fair to assume that you guys should likely be able to get that approval in 2020? I'm looking to get your thoughts there. Thank you very much.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Hi. It's Matt. So, thanks very much for the question. So as we said on the call, we're actually enrolling reasonably well in the Nellix trial once we got the sites activated. We were perhaps optimistic in how quickly we would get the previous EVAS I so it's activated and that's contributing to the overall slow enrollment.

So we would now anticipate finishing enrollment in the trial in the first half of 2019 and we're looking towards an approval date in the first half of 2021 – 2020.

Q

Okay. Thank you for taking my questions.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Thanks.

Operator: The next question is from Matthew O'Brien, Piper Jaffray. Please go ahead, sir.

Matt O'Brien
Analyst, Piper Jaffray & Co.

Q

Afternoon. Thanks for taking the question. Just quick – just a maybe quick housekeeping question. The OUS businesses that you're exiting, can you just quantify how much of that -- the $12 million to $22 million is in that piece of the business?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. It's about $4 million, Matt.

Matt O'Brien
Analyst, Piper Jaffray & Co.

Q

Okay. So the remainder is all U.S.-based?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yes. So I can kind of break that up for you a little bit. Essentially, when you look at the $12 million to $22 million, there's three main drivers. The two big drivers are obviously the FSNs that John commented around its impact of $4 million to $9 million, it's primarily in the U.S.

The second big driver is this cost to serve adjustment that we are making based on benchmarking by a third-party that John was referring to in the U.S., which will be a combination of U.S. and Europe and that's about $4 million to $9 million. And then the rest of it is the $4 million, which is primarily OUS. So that's the breakdown of the $12 million to $22 million in the second half.

Matt O'Brien
Analyst, Piper Jaffray & Co.

Q

Okay. And then the reduction to OpEx for next year, Vaseem, about $30 million. Can you just walk us through where that comes from? And then post this -- the Deerfield update today, what is the capital position of the company debt levels, potential dilution, is that – if that converts. And then cash on hand, I think it's as of end of last quarter maybe just under $90 million of cash.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So let me take a crack at the OpEx. We will be giving you a lot more detail about the path forward at the investor event we just scheduled for early October. So I just ask for you guys to give us the time to come back to you guys. There is restructuring charge that we will take in the second half of the year, and that's going to impact people in a lot of different functions, in a lot of geographies. So we just want to be mindful that we do that with the utmost respect and give that the right time and process. So we really hope that you give us the time to give me more detail on that at the October event. But those actions are already underway as I commented on my commentary there.

Now, P&L. So the second part is on the Deerfield financing. Listen, it's a pretty big win for us. It's expensive money, no question about that. But it's a pretty big win for us in a sense that what we were trying to do as we reset the business and as John came in to look at the deal that we had been working on for the first half of the year, Matt. It was to really make sure that we had the financial covenants and we had the right debt levels and the right structure on a go-forward basis. And I think what we have tried to do here is to give us that flexibility to manage our [ph] balances (00:33:36) in the three steps that we have laid out in the supplemental deck.

And so, what that's really doing is it's giving us a -- an extra $50 million of availability through the asset-based loan that we talked about. This is something that we already had with Deerfield in the past but we had terminated because we had tripped some covenants at the end of last year. So it's $50 million of availability. The rest of the debt stack has changed because we have taken $40.5 million of the converts that Deerfield owned as part of the 2020 maturities and roll that into the term loan. And I think that's a positive because you're going from a -- an equity-linked transaction to a debt instrument.

We have also negotiated the covenants to levels that we are comfortable. There is no reflection on where the business is heading but it's just to have the comfort that we can focus on operating and running the company on a go-forward basis.

The last one is in return for that, we have to give Deerfield some warrants and it's to adjust the risk premium. Now, they also have an option to equitize if they choose to reduce their risk in the debt that they have, but at the same time, remember with the warrants that they have, the benefit for both Deerfield and the company is increasing stock price. So we feel a lot interests are aligned on that and but it's not automatic dilution. So there's really no impact of the dilution unless Deerfield decides to equitize a portion of their debt. So we feel all in all, with the puts and takes here and adjusting the risk premium for a company which we are not exactly where we were last year in April when we did the first deal with Deerfield, we feel this is a pretty good outcome for the company on a path forward to cash independence and also strategically resetting the company towards this new approach that John [ph] outlaid. (00:35:32)

Matt O'Brien
Analyst, Piper Jaffray & Co.
Q

Got it. Thank you so much.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Absolutely.

Operator: We have a question from Chris Cooley, Stephens. Please go ahead, sir.

Chris Cooley
Analyst, Stephens, Inc.
Q

Good afternoon. Thank you for taking the questions. Maybe just...

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Hey, Chris.

Chris Cooley
Analyst, Stephens, Inc.
Q

Hey. Say, maybe just two quick, maybe qualifiers there off of Matt's questioning. On the charges that I understand you want some latitude around and you're going to [ph] refine (00:35:57) those up for us in October, but can you give us just a rough sense of what percentages obviously you think will be cash versus non-cash when you just think about the restructuring charges that the company will incur here in the back half?

And then similarly, in the bucket there to get to the $12 million to $22 million, what was the last component? I understand the FSNs and I guess the international markets, but I missed the third.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Yeah. So the three drivers, again, was the two FSNs, was the second piece. So, one of the big drivers of the OpEx going from the current levels to what we talked about, we'll give you more detail is this change on the lower to cost to serve in the commercial organizations both in Europe and in the U.S. So, as an example, we are going to go in the U.S. from a sales force of 110 down to 92. So, as you guys know that that creates disruption and that's reflected in the second bucket, which is the $4 million to $9 million in the U.S. and Europe, and we will have to make some similar changes in Europe as well. So, again, from a process perspective, most of the changes that

you'll see in our OpEx reduction are going to be cash-based and a lot of it is going to be people-based. So, that's why we are taking the restructuring charge here in the second half of the year.

Chris Cooley
Analyst, Stephens, Inc.
Q

Understood. And then just from a follow-up on the ChEVAS trial first phase and now enrolling in the first half 2019, has your thoughts in terms of how long that trial will take to enroll or the structure of that trial changed? Just trying to think about just subsequent filing and expected commercialization timelines and how that may or may not have been affected. Thank you.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.
A

All right. It's Matt. So, in terms of the ChEVAS trial, we're still really ongoing in our collaborative effort to get the finalized trial design with the FDA. I think, is you'll appreciate CHeVAS is a completely unique treatment modality and as such, the trial is kind of complex to design and it's very important that we get it right up first stage. So at this particular point in time, I don't really want to speculate on enrollment rates, patients per month, final trial design, final trial numbers. I think as soon as we have a finalized trial design with our partners at the FDA, then we want to share that. If we have any updates, clearly they will come [ph] with us (00:38:35) today or later on in the year.

Chris Cooley
Analyst, Stephens, Inc.
Q

Understood. Thank you so much.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Thanks, Chris.

Operator: We have a question from Robert Marcus, JPMorgan. Please go ahead, sir.

Robert Marcus
Analyst, J.P. Morgan
Q

Great. Thanks for taking the question. What's the new cash interest payments that you have per year now following this new financing?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Yes. So, the term loan with Deerfield had a interest rate of [ph] 6% and 7.8% (00:39:06) and now, it's now down to on a cash basis to 5%. So that's a 27% reduction in our cash expense just for the term loan. And to offset that reduction, we have added a [ph] peg of (00:39:25) 4.7% that essentially adds back to the principal, Robbie. So that's probably a good way to think about it. The rest of it is unchanged.

Robert Marcus
Analyst, J.P. Morgan
Q

Okay. And looking at the restructuring, how do I think about what percentage of your accounts are high volume customers and internationally, how do I think about what percentage of the sales you should be exiting? So how

do I think about if there was a second quarter and you had already done this, what would your U.S. international mix look like relative post your restructuring?

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

A

Yeah, Robbie. It's John Onopchenko. Let me answer that by first kind of giving you and the audience a bit of background on some of the commercial data that I've been immersed in. And if I take a look at U.S. today, EVAR procedures are roughly 45,000 a year and they're performed roughly in 1,600 hospitals. You asked the question regarding top performing or highest volume, roughly 12.5% of the 1,600 or 200 hospitals on average perform roughly 19,000 procedures annually. That's 42% of the U.S. EVAR volume and they average roughly 94 procedures annually or about seven or eight procedures a month.

For us, we call currently on roughly 800 hospitals and sell on average seven procedures annually. And of the top performing hospitals, we actually have a presence in 140 of the top 200, and generate on average nine procedures annually or 10% of the volume in those accounts. And as I've mentioned in the prepared remarks, we have every intention of critically focusing on these high volume centers and those high volume centers come in one of two forms. First, they may be academic medical centers. As you know, academic medical centers have a primary mission of teaching and conducting research and they are frequently the facilities that treat the previously believed to be untreatable.

The second variety of high volume hospitals I refer to is performance-based hospitals. You can think of those as again not having a teaching mission, but are very volume and outcomes-driven and they have a high sensitivity to labor productivity. And then again, those are averaging 90-plus procedures annually and as a result, obviously are very attractive. So, that's the U.S. business, that's the change that we want to make.

In Europe, again, very similar concentration; about 40,000 procedures annually. However, unlike the U.S., EVAR penetration is relatively low at less than 50%. There's still a significant open surgical repair market. Eight countries in Europe represent over 80% of the procedures. Those are Germany, Italy, France, Poland, UK, Netherlands, Turkey, Spain, and Sweden. And as you well know, while generally [ph] bland (00:43:03) pricing in EVAR has declined significantly in a few of these key countries namely Belgium, Germany, France, and Turkey, in the EU, we currently sell to 23 countries and call on just over 200 hospitals. Those 200 hospitals in direct markets, we average about a half a case a month over the last 18 months. So the shift in Europe is again removing ourselves from low volume and low growth opportunity countries and accounts to higher volume centers where the majority of the business is obviously high and continues to grow.

Robert Marcus
Analyst, J.P. Morgan

Q

Okay. And then last for me, maybe a quick one for Vaseem. You're looking to cut the cash burn by about half but trimming the sales force moderately. So where is the difference in the cash burn savings coming from? Maybe just help put some clarity onto that. Thanks a lot.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah, sure. Robbie, and like I said, it's coming from cuts that we're going to make by making adjustments to our pipeline, by making adjustments to our G&A. And as I mentioned earlier, the October investor event is the time to share the details of that path forward and we'll walk you through the different elements where they are coming from.

Today, what we are announcing here is the top line change and we felt obligated to give you the details on the changes in OpEx as it relates to the change in guidance but also to get everybody comfortable around the fact that this is just not an adjustment in just the top line, it is a pretty significant adjustment in our cost structure. And that's the -- step one was Deerfield, step two is reducing our cash burn through these cost reductions and really then growing the business to cash flow breakeven in 2020. So more to come on that on the Investor Day. We will walk you through some more numbers and give you more detail on where that's coming from.

Robert Marcus
Analyst, J.P. Morgan

Q

Okay. So when we think about third quarter P&L metrics, we shouldn't just think about trimming SG&A. We'll probably also see cuts in R&D as well?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

A little bit. Again, it's all timing, right? So you'll start to see the impacts of the head count reductions as they happen. And really the impact that I'm giving you next year, the $130 million to $140 million is the annualized impact of all of the changes that will happen in the second half.

Robert Marcus
Analyst, J.P. Morgan

Q

Got you. Okay, great. Thanks a lot.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. No problem.

Operator: We have a question from Glenn Novarro, RBC Capital Markets. Please go ahead, sir.

Glenn John Novarro
Analyst, RBC Capital Markets LLC

Q

Hi. Thanks. John, the safety notifications that you talked about, my question is specific to Ovation. When was that issued and do you have any early feedback from the field in terms of how surgeons are taking this notification and as a quick follow-up, does it from a perception point of view, in your view, will it have any impact on Alto when that gets launched next year? And then, I had a follow-up on one of the slides in the slide deck.

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

A

Thank you for the question. So the answer to the first question, we posted the Field Safety Notice on our website Monday. So it is relatively new. I've spent time talking with the sales leadership team. We've well-prepared the sales leadership team with the data that was supported within the Field Safety Notice so that we could have an intelligent and productive conversation with customers, and to be very clear, FSNs are really a prime example of establishing a culture of accountability. It is our responsibility to effectively aggregate customer experiences and then establish a threshold that's once past has us taking action. And it's one of the cornerstones of having an effective and an efficient quality system. FSNs are there to ensure that we're enabling our customers to get the best possible outcomes they can provide.

I think aside culturally and operationally, we've previously acted that FSNs were something to be ashamed of. And regrettably, we have allowed our competition in some cases to focus the customer's attention toward the product exclusively through the lens of the FSN. And candidly, our products were competitive products, should be judged by their totality of the evidence, the rigor by which that evidence was accrued, how relevant the evidence is framed by contemporary practice, and then by an impartial comparative framework.

So the headwinds are a reflection of this kind of cultural and operational shift that's grounded by enabling better outcomes and reintroducing the totality of the evidence. We will never be able to discount entirely our competitors' responses to FSN. But overall, this change will take time but again, it's anchored by our patients first value.

Glenn John Novarro
Analyst, RBC Capital Markets LLC

Q

And then do you have a feel for how surgeons will take this FSN and how it will -- may translate to [ph] out focus, (00:48:45)? The platforms are somewhat similar and this is a big launch for you in 2019.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Hi. It's Matt. So I can give you a little bit of just insight into how I think some of the sort of high volumes will feel about the FSN. I mean, as John said, really the ethos of the FSN is really about a culture of transparency and accountability. And the root cause analysis when we kind of dig into small, single tight graft failures actually provides physicians with a blueprint of how to do the cases. So I'm sure you'll read the Ovation FSN that's on our website. But what we actually found when we looked into the root cause of this particular complication was that well over 50% of these were entirely attributable to the technical aspects of the procedure and in particular doing steps out of order. So getting that information out to the field to the surgical and to the anesthesiology teams is really the correct and responsible thing to do. And actually I think we will overall get credit for that sort of behavior.

In terms of how it translates to Alto, so what I think is important to realize is Ovation iX and Alto are both grafts that are predicated on injection, molding them with polymer when they're in the body, and that comes with certain advantages such as a customized feel, such as [ph] whether you need to get the (50:27) profile of the endograft [indiscernible] (50:29). But it does come with a single unit failure mode and that is one of polymer leak.

Now there really isn't anything else to compare polymer leak rates too because the product is so unique and opposed those unique advantages. So I don't think that this particular field safety notification that is essentially addressing technical aspects of the procedure and polymer leak is going to translate to any diminution of enthusiasm for Alto.

Glenn John Novarro
Analyst, RBC Capital Markets LLC

Q

Okay. That's perfect. And then to the slide deck going back to their revenue guidance bridge, you talk about the reset for the backend of the year being $12 million to $22 million, a decline in guidance. $22 million being a worst case, I'm assuming, $12 million being a best case, maybe talk to us about what are the factors that would lead to the worst case being the $22 million decline versus the best case being only a $12 million decline? Thanks.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So, Glenn, again it's all based on certain assumptions that we have made on the three drivers. So the $4 million o-U.S. impact is us exiting markets, so that one is pretty binary. And we have already taken steps to address that the presence in some of those really small markets and really focus on the bigger markets where the volume standards and that make economic sense with the company.

If you remember, we did the same thing in France last year, and in hindsight, looking at what happened with the reimbursement in France today, that was the best decision we would have made, and I think there's a lot of other people who are falling too. The second big driver that we talked about was this cost to serve adjustment in the U.S. and Europe, which is primarily related to head count adjustments when it comes to the commercial team.

Now we know that in the past when we have had uncontrolled attrition, we typically lose about half of the business. And if we have controlled attrition, we lose about a third of the business. So there are some assumptions on that cost to serve adjustment on the commercial teams, both in U.S. and Europe that gives us that range of $4 million to $9 million. So if you're able to manage that attrition better and we can control it through some retention programs and what have you, we feel that we could manage it down to $4 million, but right now the range is $4 million to $9 million. On the FSNs, Matt's point here and John's comments about how competition has used it and the extent of impact is the range where we think that we can manage it best case to about $4 million number and then worst case $9 million.

So we will continue to give you updates at the Investor Day at the next earnings call on how that's playing out. But at this point, these are assumptions that we have made to make this adjustment.

Glenn John Novarro
Analyst, RBC Capital Markets LLC

Q

Okay. Great. Thanks for taking the questions.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

No problem. Thanks, Glenn.

Operator: We have Joanne Wuensch, BMO Capital Markets. Please go ahead, madam.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Yes. Hi. This is Matt Henriksson in for Joanne. Thanks for taking the questions.

A

Hi, Matt.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

The first one is with regards to just how steep of a disruption the restructuring is, can you just walk us through about your thoughts about how this decision-making versus kind of making it more of a streamlined decline as you correct things? And then with regards to success, John, you mentioned earlier that you're seeing early evidence of your approach taking hold. Can you give us some examples of that and future signs of success?

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

A

Sure. Maybe I'll start by answering your last question first, and that is to say, this pivot that we're purposely making away from our traditional customer base, which is candidly a lower volume annually of accounts to these academic medical centers and performance-based hospitals. With the introduction of the ENCORE data and the realization that Ovation actually requires a learning curve, and as Matt well described, it is important to stick with the procedural steps that are defined in our IFU in order to get the kind of durable long-term data that ENCORE represents. And that's very attractive to academic centers. That's also very attractive to performance-based hospitals that differentiate themselves in their local markets based on outcomes. And it also, as a result, when you have surgeons that are performing 7, 8, 10 a month, they can do their first Ovation case on Monday. They can have a second or third case on Thursday, and then then a fourth case the following week. That enables recency and that enables a learning curve to take hold and therefore good procedural implementation of the device in order to insure those benefits of the long-term outcomes that are reflected in ENCORE.

And so at our investor event, we'll have examples of physicians who have taken that journey with us. So it's still early days, too soon to throw confetti, but it is in fact taking hold, and we think -- are we going to win everywhere? No. Are we going to win all the time? No. But I have a high degree of confidence that will substantially increase our penetration and presence in these valuable accounts.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. That's helpful. And then my follow-up is in the asset-backed loan that you guys have with Deerfield now. I noticed in the financial covenants that trailing 12-month revenue for 2018, it then dips to 2019 and then 2020 kind of recovers. I know you're not giving 2019 guidance, but should we follow that cadence when we are updating our models?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

No. You should. And the reason I'd say that is these are financial covenants are meant to be a reflection of risk and how you compensate for that risk to your lender, have no reflection quite frankly on the actual strength of the business or how we kind of manage the business or what we are trying to grow to. So the way to think about it, Matt, is that we will have internal plans that are going to be higher than guidance and covenants that are going to be lower than guidance. That's how you got to think about the show. So this is meant to just being transparent here and telling you the reason we wanted to do this deal was to buy ourselves that comfort that in the worst-case scenario, we don't drip these covenants and for that we have compensated to a more expensive risk premium Deerfield on this deal.

So having said that, listen, we will you know we want you to think about the business on sequential growth for the second half of the numbers and into 2019. We will provide more clarity at the Investor Day and then formal guidance as part of our Q4 earnings call. And we are confident in Ovation and the data that supports our margin to high volume accounts, Alto launch will actually help that. And so I don't want you to walk away from this meeting that these financial covenants are what the business can fundamentally do here. So there's a big difference and should not be looked at in the same light.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. Thank you very much.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

No problem.

Operator: The next question is from Chris Pasquale, Guggenheim. Please go ahead.

Christopher Pasquale
Analyst, Guggenheim Securities LLC

Q

Thanks. John, I wanted to follow up on Robbie's question, the plan changes to the customer base. The stats you provided were great in terms of framing the market. But I'm not sure I understand the scope of the contraction that you're planning here. So what does the 800-customer base in the U.S. and the 200-customer base in Europe look like after you've completed this reset?

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

A

Well, in the U.S., we don't intend to give up any customer. We intend to grow our customers, but more purposely grow them in the top 200 where I've mentioned earlier we are currently serving 140 of them.

So there is no attrition in terms of the customers we're serving. An important element to enable that to happen is we need to have improved productivity by our clinical specialists who in more than 75% of the case coverage should be able to cover our base business accounts thereby enabling our sales representatives to more purposely focus on developing new relationships in those high volume centers or expanding their existing relationships in those high volume centers.

In the case of Europe, right now we're in 23 countries, we intend to reduce our footprint down to 10. The aggregate contribution of the 13 is de minimis but yet our expense to maintain our presence there is significant and it only increases over time as your ability to be a compliant partner in those local geographies continues to rise. So we don't have -- we would never have a clear path to profitability with that kind of EU footprint, that's the reason for the change. For the customers that we will retain in those top countries the same thing, greater amount of primary support to existing base business accounts coming from clinical specialists [indiscernible] (01:00:55) representatives then more purposefully targeting high volume centers.

Christopher Pasquale
Analyst, Guggenheim Securities LLC

Q

Thanks. That's helpful. And then I want to – maybe Matt can speak to this, but you talked about prioritizing the next gen EVAS project adding funding there. What's that coming at the expense of. You're still going forward with Nellix with ChEVAS, but obviously expense control is a focus right now, so is there something is being de-emphasized to make room for that extra investment in the next-gen EVAS?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Well, let me take a crack at it. As we mentioned, we'll give you more clarity on the OpEx and the puts and takes on where the savings are going to come from at the Investor Day. But you're right, we are prioritizing various elements of our R&D team. We've been spending a lot of time on some of the maintenance efforts, and so again just give us the time, we'll walk you through the details at the Investor Day. And I'll just leave it at that.

Christopher Pasquale
Analyst, Guggenheim Securities LLC

Q

All right. Thanks.

Operator: We have a final question from Mathew Blackman, Stifel. Please go ahead, sir.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Good afternoon, everyone. Thanks for taking the questions.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Hey, Matt.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Hey. Maybe if we could start on the sort of the newly reset what's called a $150 million base business. Can you give us some sense of the growth trajectory of this remaining business or simply have these higher volume accounts that you're now going to focus on. Over the last 12 months to 18 months, have those accounts been growing, have been flat, or they've been down just some sort of flavor for what's left? And then sort of a follow-up on that as you sort of shift the focus to these larger higher volume accounts, should we assume that the revenues lost, so to speak, are largely AFX revenues rather than Ovation? I think I've got a couple of follow-ups.

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

A

So, it's John Onopchenko. Just again in these either academic medical centers or performance-based hospitals, our presence currently is really driven by niche and anatomical cases. So tapered mix and AFX were tough access innovation and in these accounts, AFX has been relatively stable and obviously Ovation has been growing.

Now again, the commercial priority is to really expand the base of Ovation business in these customers, with these customers on the back of the evidence that we've created and as a result, the way we will go to market is first and foremost leading with our outcomes at the end of the day, that's what these centers are ultimately acquiring in the form of a partnership with the company. And in our case, we need to establish not only a relationship that is built by procedural assistance and procedural presence with a vascular surgeon, but they got to expand to include hospital administration, administrators overseeing surgical services. It's got to include residency and training programs where it's a larger conversation around how we jointly own and how we jointly share in creating the outcomes that we're intending to achieve.

If you can repeat the second part of your question, I ...

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Well, to the first part was any sense of to the first part was any sense of whether your business and in sort of these top accounts have been growing the last 12 months to 18 months or flat, some sort of trajectory. And then

the part B of that question was as we think about these revenues that are going to go away so to speak relative to where we were starting the year are those largely AFX revenues you know rather than Ovation.

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.
A

Yeah, they in these high volume accounts, it really mirrors what we conveyed in the earlier prepared remarks and that is there has been a decline in AFX sales. Those are products, those are clients that are predominantly attributed to lingering AFX STRATA IIIbs that obviously erode confidence. But there was obviously Ovation growth in these centers, and our principal point of attack is to focus on a specific anatomic need and then obviously expand from there. So we would expect the AFX business to stabilize by the end of the first half in 2019 broadly and then expect Ovation growth and then further bolstered by Alto growth to start to appear in 2019.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.
Q

Okay. That's helpful. And then, Vaseem, I don't think you mentioned it, but if you did I apologize. Did you say what Ovation growth was in the second quarter? And then I have one last follow-up for Dr. Thompson I'll just lob it in. I think Dr. Thompson I heard you say that 50% of the Ovation leak issues were procedure based. I didn't hear or maybe you didn't say what the other 50% of the issues were, if I heard that correctly. Thanks.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

So let me take your first one and then Matt can give you the answer on the [indiscernible] (01:06:49). So really I think the way we think about it, Matt, I mean, the challenge for us has always been kind of giving you clarity on the details and fundamentally product line reporting and stuff of that. So we have kind of shied away from that, but I'll tell you Ovation had a very fantastic strong quarter. We grew close to high teens year-over-year and sequentially. So Ovation, as a product line, in spite of what you're hearing here to Matt's point and John's point, the incidence of polymer leaks is a very small number, and that product line is doing really well. So again we haven't given out numbers, but directionally I can tell you that it's high teens, year-over-year and sequential.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.
Q

I appreciate that.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.
A

Hey, Matt. So in terms of the sort of etiology of the polymer leak, so, I mean, just a couple of sort of high level views on it, it's always been very difficult get to the exact cause of the polymer leaks because the leak rate is so low, there are simply not many cases on which to do a root cause analysis. But with the growth in the product, we now have slightly more numbers to work with. So, 50%, 60% we think we can find a cause that is directly attributable to failure to follow the procedural IFU in terms of how it's been [indiscernible] (01:08:25). That leaves a diminishing number of other causes, and I can't give you a single root cause for the other polymer leaks.

There are a mixture of things like there's a very sharp spike of calcium that be able bifurcation in the aortic met. There has been some twisting of the graft that was maybe more or less if than one might have initially thought. I think the other point just to note is that it is a polymer-based endograft and therefore without wishing to kind of socialize deviances as it were, we are always going to have a number polymer leaks. [indiscernible] (01:09:07) we have a perfect procedure and a perfect patient. But that number needs to be as close to zero as we can get.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Okay. So but it sounds like it's not a manufacturing issue and it's not an inherent design flaw issues, is that a fair statement?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

No, I think that's a fair statement. And as part of our root cause analysis, Matt, just in terms of doing due diligence, we've undertaking a root cause analysis of this very extensively that has looked at design, that has looked at manufacturing, that has looked at procedure, that has looked at rep training, and really we think we can make the biggest impact in reducing this failure mode just by making everyone understand that if you follow the IFU as written then it is likely that the majority of these polymer leads are avoided.

I think the one other thing that I just did want to stress from a sort of physician's perspective at the end of this is that if you assess the endograft performance in the round, and that is even if you include the polymer leaks, you look at the data of the Ovation platform and we are looking at acute major adverse event rate, i.e., the events surrounding implantation that's pretty much as low as, if not lower, than anything else that's on the market.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

All right. Thank you very much.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Thanks, Matt.

Operator: There are no further questions at this time. I'd like to turn the floor back over to Mr. Onopchenko for closing comments. Please go ahead, sir.

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

Well, again I want to thank everyone for their participation in our Q2 earnings call. I also want to thank the questions from those who've participated and look forward to seeing many, if not all of you, at our investor event on October 2. Thank you.

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