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IRIX - Q3 2018 IRIDEX Corp Earnings Call

EVENT DATE/TIME: NOVEMBER 01, 2018 / 9:00PM GMT

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Q3 2018 IRIDEX Earnings Conference Call. (Operator Instructions). As a reminder, this call is being recorded.

I would now like to introduce your host for today's conference, Leigh Salvo, Investor Relations. Please go ahead.

Leigh Salvo - *IRIDEX Corporation - Head of IR*

Thank you, Chris, and thank you all for participating in today's call. Joining me are will Moore, Chief Executive Officer; and Atabak Mokari, Chief Financial Officer. Earlier today, IRIDEX released financial results for the quarter ended September 29, 2018. Copy of the press release is available on the company's website.

Before we begin, I'd like to remind you that management will make statements during this call that include forward-looking statements within the meaning of the federal securities laws, which are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Any statements made during this call that are not statements of historical fact, including but not limited to: statements concerning our strategic goals and priorities; product development matters; sales and marketing matters, including our presence at future industry events; sales trends, including our ability to secure orders from hospitals, clinics and ambulatory surgery centers; the markets in which we operate, including South Korea and China; the recall of our LIO product, its impact on our business and results and our plans to return this product to market; our ability to convert backlog orders; our guidance for 2018, including expectations for overall and product line revenues and G6 system and probe shipment levels; and our plans to provide public updates on any of these matters.

Our forward-looking statements are based upon our current estimates and various assumptions. These statements involve material risks and uncertainties that could cause actual results or events to materially differ from those anticipated or implied by these forward-looking statements.

Accordingly, you should not place undue reliance on these statements. For a discussion of the risks and uncertainties associated with our business, please see our most recent Form 10-K and Form 10-Q filings with the SEC.

IRIDEX disclaims any intention or obligation, except as required by law, to update or revise any financial projection or forward-looking statements whether because of new information, future events or otherwise. This conference call contains time-sensitive information and is accurate only as of the live broadcast today, November 1, 2018.

And with that, I'll turn the call over to Will.

William M. Moore - *IRIDEX Corporation - Chairman of the Board of Directors, President & CEO*

Thank you, Leigh. Good afternoon, and thank you all for joining us. We have made significant progress on multiple important fronts over the first 3 quarters of this year, which we believe are positively impacting our market opportunity and growth trajectory in treating patients with glaucoma.

I'm pleased with the solid performance of our team, executing on our strategy to expand the G6 installed base and increase utilization. We are beginning to realize the benefits of investments made in building out our commercial team to increase awareness and acceptance for our G6 platform and MicroPulse technology. I'd like to take the next few minutes to provide some color on our business, then we'll turn the call over to Atabak to cover the financials and guidance for this year.

In summary, progress in the third quarter included: continued momentum in G6 systems and probe shipments; FDA clearance to introduce our updated TruFocus LIO Premiere laser accessory to the U.S. market; a significant number of position presentations around the world; advance with some probe development, particularly on G6 probes; and a capital raise with gross proceeds of $11.5 million to fund our growth.

Total revenues for the third quarter were $11.3 million, including a 23% year-over-year increase in revenues for our G6 business. Our third quarter results are typically impacted by summer seasonality, given doctors' and patients' vacation schedules. However, we were pleased with the performance of our G6 business as well as our retina business following the FDA clearance of our updated LIO laser accessory. Key to our growth strategy and one of the primary goals for 2018 is to improve G6 probe utilization from our existing installed base, while continuing to expand shipments of new G6 systems across the globe.

In the third quarter, we were successful in achieving year-over-year growth in both systems and probe shipments. More specifically, we shift 117 G6s systems and 10,400 probes. Since our launch, in March 2015, we have shipped more than 1,200 G6 systems and more than 100,000 G6 probes.

Geographically, in the U.S., our commercial team continue to drive awareness and acceptance of our G6 platform. We also now have several clinical specialists in the field, supporting our sales team with education and training in key accounts. Early feedback on this program has been very positive towards strengthening existing relationships to enhance customer service and better position training to ensure more consistent outcomes.

In the third quarter, we delivered a steady cadence of G6 system shipments that has been consistent throughout the year. On the probe side, shipments grew year-over-year, but was impacted by Q3 seasonality. However, we're encouraged by the strength of G6 in trending -- or excuse me, in treating late stage glaucoma in patients and continued progress in treating patients earlier in the continuum of care.

I am particularly proud that 37 of the best 39 U.S. ophthalmology hospitals, as ranked by the U.S. News and World Report, are G6 customers. Overall, I am pleased with the improvements in our sales team's performance as well as benefits realized with investments made in marketing activities and growing KOL support.

Internationally, we delivered a solid number of G6 systems and probe shipments despite the impacts of seasonality, which are even more pronounced in this region.

More specifically, we made excellent progress on several fronts, including Japan, which continues to be a strong region for us and is serving as a model for expansion in other OUS countries. Record G6 sales in the quarter can be attributed to ongoing KOL support and strong distribution partner.

In Germany, we're making nice progress in selling the KOLs in large hospitals, which we believe sets the foundation for further penetration in this market. We recently expanded our direct sales organization to 3 sales reps to cover this region.

In South Korea, we achieved G6 approval in the second quarter and are pleased with our launch progress. In particular, we have made nice progress in selling systems to KOLs, and the first clinical paper regarding the G6 in Korea has already been presented.

On the marketing front, we continue to maintain a significant presence at key industry events around the world to raise awareness for the benefits of our MicroPulse technology in treating all stages of the glaucoma.

Importantly, we are starting to see a growing awareness and support among comprehensive ophthalmologist advocating for the use of our G6 in treating moderate disease stage patients, signaling the versatility of the procedure to extend the treatment of 2 patients with earlier stage glaucoma.

As we gain traction in earlier stage treatments, we expect this to further drive utilization.

During Q3, we had exceptional presence that included trade shows at 10 countries around the globe. In particular, we had significant presence at 2 of the largest trade shows, ESCRS and AAO.

At the ESCRS meeting, we hosted a G6 symposium that had over 250 attendees. Also at the recent AAO meeting, we hosted multiple in-booth panel discussions, featuring doctors from across the globe with over 300 attendees and proctored a dry lab to train physicians on site. We were also included in the official AAO and ESCRS glaucoma training courses. We are very pleased with this growing activity and positive sentiment towards our products at these key events.

From a clinical perspective, we continue to have a nice cadence of clinical studies, papers, posters that support the value proposition of the G6.

Over the last few months, there were 2 new peer-reviewed publications in respected international journals that reviewed 67 eyes, and 2 posters were presented at the AAO that reviewed 88 eyes. One of the posters that AAO presented, data regarding the treatment of patients earlier in the continuum of care, which we believe is important as we migrate towards treating this patient population.

I'm especially proud of the growing support we're seeing from our physician customers around the world, and how our G6 is meaningfully changing the lives of their patients.

On the product enhancement front, we are nearing completion on several advancements across our entire portfolio that will improve product quality, provide additional features and reduce costs. In particular, we have made progress in the G6 probe design to improve the ease of use and consistent outcomes. I expect to be able to share more detail on these advancements in timing of availability by early next year.

Turning to our retina products. As noted earlier, we are pleased to have received FDA clearance in late August to introduce our updated TruFocus LIO Premiere laser accessory to the U.S. market. The clearance allowed us to fulfill our U.S. backlog related to the voluntary LIO recall and to take and fulfill new orders.

Internationally, we fulfilled some large orders from distributed customers that include a pull forward on expected G6 revenues. Our retina business remains a meaningful contributor to our current revenue. However, as we continue to focus on G6 product sales for the treatment of glaucoma, sales of retina products have not been a growth driver for our overall business. We intended to continue to work towards stabilizing this line of business longer term.

Before I turn the call over to Atabak, I'd like to welcome Dr. Robert Grove to our Board of Directors, who officially joined us this month. Bob is a perfect fit for our board and will be an excellent addition. He has spent his extensive carrier in the field of laser-based medicine and has repeated success both developing and commercializing noble laser technologies.

At this point, I'd like to turn the call over to Atabak to provide further detail of our financial results for the quarter and guidance for 2018. Atabak?

Atabak Mokari - *IRIDEX Corporation - CFO & VP of Corporate Development*

Thank you, Will. I will begin with an update on the G6 business.

In the third quarter of 2018, G6 revenues increased approximately 23% compared to the third quarter of 2017. We shipped 117 G6 systems in the quarter compared to 111 in the prior year period. System ASP increased relative to the second quarter due to a lower portion of sales under our probe-to-purchase and trade-in programs.

On the G6 probe side, we shipped 10,400 probes in the third quarter of 2018 compared to 7,800 in the prior year period, an increase of 33%. Probe ASP was relatively flat on a global basis compared to the second quarter.

From a geographic perspective, in the third quarter, approximately 45% of our G6 systems shipped were in the U.S., while approximately 65% of our G6 probes were in the U.S.

Total revenues for the third quarter of 2018 were $11.3 million, an increase of 4% compared to the third quarter of 2017, as growth in our G6 revenues was complemented by relatively flat retina product revenues. As Will mentioned, our retina product revenues benefited from the LIO FDA clearance in the U.S., and some large orders internationally that were a pull forward from the fourth quarter.

In the third quarter of 2018, domestic system sales increased 2% to $2.5 million while our international system sales increased 11% to $3.3 million.

Our domestic system sales were primarily impacted by an increase in retina product revenues, partially offset by a decline in G6 system revenues.

Our international system sales were primarily impacted by an increase in G6 system revenues. Recurring revenues in the third quarter of 2018 increased 1% to $5.5 million as growth in our G6 probes was partially offset by a decline in our legacy probes.

Gross margin in the third quarter of 2018 was 40.4% compared to 40.2% in the third quarter of 2017. Gross margin was primarily impacted by a favorable shift in product mix, partially offset by an unfavorable geographic mix.

Our G6 contribution margin in the third quarter was approximately 66%. Operating expenses for Q3 2018 were $7.6 million, up from $7.4 million in Q3 2017. The level of our OpEx reflects our growth investments to support our expanding commercial infrastructure including increased sales and marketing expenses.

Consequently, our operating loss in the third quarter of 2018 was $3.1 million compared with an operating loss of $3.1 million in the prior year's third quarter.

From a balance sheet perspective, we ended the third quarter of 2018 with $23.7 million in cash, which includes $11.5 million of gross proceeds from the public offering we completed in September, and we continue to carry no debt.

Turning to our guidance for 2018. We're -- we are increasing our range for G6 systems in total revenues. We now expect G6 system shipments of 430 to 450 and total revenue of $41 million to $42 million. This compares to previous 2018 guidance of G6 system shipments of 370 to 420 and total revenue of $38 million to $41 million. We are also raising the lower end of our G6 probe shipments guidance to a range of 44,000 to 46,000. This compares to previous guidance of 42,000 to 46,000 G6 probe shipments.

With that, I'd like to turn the call over to the operator for questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question comes from David Solomon with Roth Capital Partners.

David Michael Solomon - *Roth Capital Partners, LLC, Research Division - Director & Research Analyst*

So I just wanted to start off on the G6 side. I believe you said it was possibly around 53 systems sold in the U.S. and 64, so they were OUS. So trends look pretty good. So just kind of looking at guidance. Baseline utilization rates that you've had, and the system sales you've had recently in the last couple of quarters, I'm just looking at this probe guidance and the overall guidance, and I'm starting to think that it's hard to see how you're going

to get less than that number of probes unless you're expecting system sales to be a little bit more challenging. Is there any reason to believe that, that system sales won't continue to improve?

William M. Moore - *IRIDEX Corporation - Chairman of the Board of Directors, President & CEO*

Hi, Dave, it's Will. There was a number of questions in there. I'm trying to answer them. I think that -- I do believe that system sales will continue to improve, and that's why Atabak raised the number up to 430 to 450. I think -- and then the earlier question I'm trying -- I'm struggling with getting exactly what that question was. If you could give it to me again, I would appreciate it.

David Michael Solomon - *Roth Capital Partners, LLC, Research Division - Director & Research Analyst*

No problem, I apologize. Well, just starting with the systems. 450 would imply 109 for the world, and that would be sequentially down significantly on a relative basis from the last couple of quarters. So I'm just trying to get a sense given it's Q4, and I'm assuming it's supposed to be a heavier quarter, historically. So I'm just trying to understand why it wasn't raised maybe a little bit more than that on the systems side? And then just going with probes, just based on the number that you sell with systems, there's a certain amount that kind of, you factor into the number that make it seem unlikely that probes would also be as low. So I'm just trying to understand.

William M. Moore - *IRIDEX Corporation - Chairman of the Board of Directors, President & CEO*

Yes. Okay, I get it. In regards to the OUS number, I think the OUS number is going to continue with this cadence. As Atabak said, there was some large orders that came in that might have -- might effect Q4. Japan has been substantially strong in Q3, and I'm not sure how much more would be in Q4, there'll be some. But -- there'll be some. I think, from my standpoint, I think the cadence of systems is fine. I expect us to be in the 430 to 450. We're trying to maintain our viewpoint of providing guidance in meeting or beating. And there's a lot of background noise. Okay. So if -- we're going to be conservative looking at these numbers. And I'm perfectly satisfied with where we are at the moment. In regards to the probe pieces, I think you have to look at the situation as we talked about seasonality. And in this world, the procedure is really an elective procedure. And when holidays come and go, those procedures slowdown. And so we were going to see a little bit of drop in the probe utilization, and we should see some increases as we go forward.

David Michael Solomon - *Roth Capital Partners, LLC, Research Division - Director & Research Analyst*

I understand. And then just regarding the data that you've been seeing and kind of ton of shift to treatment paradigm towards more moderate severity glaucoma patients, what kind of discussions or what kind of color can we have regarding the recent conference on this matter? And what kind of -- where do you see it going and then in as well in combination with stents potentially?

William M. Moore - *IRIDEX Corporation - Chairman of the Board of Directors, President & CEO*

Okay. So in the beginning, we went after studies that dealt with safety around the late stage of glaucoma. I think we've done that. It's been validated, and we're well on our way of having a large portion of that business. Once the safety profile is accepted in the marketplace, the next question that starts to come forward is the question around method of action. Those papers have started to come out. We've got 1 posted from University of Washington. We've got another one poster coming out of U.K. Once those start to come on the rise, and we're after the next piece, which is how do you move the -- from the glaucoma specialist that treats to, what I'll call the, train wreck eyes, to a comprehensive that's treating the healthier eyes. The risk reward portfolio or profile changes a little bit because you're treating people that -- with the sick eyes, that if it doesn't work, you can -- and not much is loss. You can do other treatments. On the healthier eyes, you want to make sure that safety profile is there. You want to make sure your doctors are explaining to other doctors on how to use it on those eyes. They have good visual acuity, and that's what happening. So we've the first one showed up at the ARVO meeting earlier this area. We've had a couple more. And we had a 1 from this AAO, from Mayo Clinic and University of Buffalo, looking at healthy eyes at reducing the pressure, but more predominantly, looking at being able to reduce the pressure slightly but to eliminate drugs and maintain that controlled glaucoma at a lower cost to the patient. As those come forward, you will see the

migration. I think everybody wants it to move faster including us, but it takes the time to get the comprehensive doctors in line with the safety profile and the treatment of those patients. And I'm comfortable that all things we're putting in place are there. Many of the presentations in our booth that -- was well attended. We're on the situation of treating healthier eyes.

David Michael Solomon - *Roth Capital Partners, LLC, Research Division - Director & Research Analyst*

Excellent. And then just lastly, given the safety profile and the recent recall in the stent market, did you have any color there regarding conversations you're having with doctors? Or are you seeing potentially the G6 benefit from that in the MIGS market?

William M. Moore - *IRIDEX Corporation - Chairman of the Board of Directors, President & CEO*

Well, I think that the benefit I'm seeing has to do with the power of the message of MicroPulse, regardless to retina or glaucoma. Ophthalmologist talk about it. The idea about the MIGS situation, we're seeing -- we're obviously seeing some benefits from the conversation. I don't really see that we've -- we're not in competition with glucose, the other devices that may try to treat earlier. They're still invasive, and the doctors are more inclined to look at what we're doing. So I think there was just more curiosity and confusion, but not really - oh, they stopped doing the side pass, and they're going to start doing ours. I think they stopped doing it and they're trying to forget what they're going to do next.

Operator

And our next question comes from Jon Block with Stifel.

Jonathan David Block - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst*

Maybe just first question on the clinical specialist. I know it's still early days, but, Will, what are you seeing in the accounts? Were they deployed? And what do you need to see if you were to decide to start moving forward with additional hires?

William M. Moore - *IRIDEX Corporation - Chairman of the Board of Directors, President & CEO*

So what we've been seeing in the accounts that they have gone to, we've seen an increase of probe utilization in those accounts. So let's say there was an account that tried it and the outcomes were not exactly what they wanted for some reason and other. They stop -- they slow down the use or maybe a doctor stops using it. We send the clinical specialists in. They go through the training and all of a sudden, the probe uses goes back up again. So I think we've seen -- and I've got enough of those accounts now to be comfortable that the clinical specialist program will enhance the probe utilization, will improve the education, will improve the -- and get consistent outcomes. And therefore, the decision is being made to move forward with the clinical specialists. The final outcome will be as we finished the operating plan for 2019, but I think the evidences are already there, that they are an asset that hospitals are looking for. They put in a program, Jon, that's called MD certification, and so many hospitals really want their doctors to be certified on all procedures before they do it. So this is a great, great situation for us and the doctors that are using our product.

Jonathan David Block - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst*

Okay, helpful. And maybe just to push you a little bit. I don't know if you're able to provide specifics. But can you talk about the utilization in clinical specialist accounts versus nonspecialist? I guess where I'm trying to go with this is, the increase in utilization that I think we're starting to witness in the U.S., Will or Atabak, is that broad based across all accounts? Or is it mostly confined to those accounts where the clinical specialists have been deployed?

William M. Moore - *IRIDEX Corporation - Chairman of the Board of Directors, President & CEO*

I think it's broad based. What we're seeing is that we have a large bucket of accounts that are doing everything we want. That has something to do with clinical specialists, something to do with sales reps that are well trained and are focused on the probe utilization. The accounts that don't -- either weren't trained appropriately and they had an adverse event that it was transient and then -- so they stopped using this much. And those get corrected by clinical specialists, and then we'll see those go back up. But a lot of our sales reps do a good job on training. Some are just little -- not quite as good, I'll say.

Jonathan David Block - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst*

Okay, good. And maybe 1 or 2 more for me. At AAO, I saw you guys there. I saw the booth, and there was certainly a very good buzz, I'd say, at AAO and G6. And I don't have a great baseline going back a couple of years. So maybe you can just talk about, do you feel like this was a step function? I know you're at many meetings throughout the year. So do you feel like this is a step function versus prior meetings? Maybe if you can just comment on that and the types of questions that you're getting from docs. Are they more, I'm ready to purchase-oriented types of questions, if that makes sense.

William M. Moore - *IRIDEX Corporation - Chairman of the Board of Directors, President & CEO*

Yes. I think it is a step function and has been for the last couple of years since 2012. But the introduction, all the questions, at that point in time was, what is it? How does it work? Why do I need it? To a little more curiosity last year. But this year was -- the questions were substantially different, partly due to the fact that we went to that in-booth format with multiple doctors doing presentations at onetime a panel. We had more than 300 doctors witnessed those conversations. The questions were really more buying questions. How do I deal with kind of patient? What about this one? And that, that, I believe, is what we're looking at and seeing the momentum moving forward. And that's the same in the U.S. as it was at the ESCRS in Vienna. The number of leads we've written in the last -- those last 2 shows for us are basically staggering, triple what we had a few years ago.

Jonathan David Block - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst*

Okay, that last part was very helpful. And maybe just one more for you, Will or Atabak, you're probably you're offline. The new products that you alluded to earlier, I want to make sure I've got the comments correct. So I think you said you'll provide an update in early '19, is that correct? And then should we still think about the commercialization as '19 as well? Or is that more of a 2020 event?

William M. Moore - *IRIDEX Corporation - Chairman of the Board of Directors, President & CEO*

Well, I think, Jon, early -- what I will start talking about it as we're ready to file with the FDA 5, 10-Ks or letter of files or whatever is, it's not going to be DMA-type product. Then it's really a matter of time after that. So I'm expecting some revenue in 2019. I'm expecting us to have a couple of -- was it from the disposable line or on the hardware line, products can be forward on that point. But your comment about revenue, I think it has a major impact as we move into 2020.

Operator

And that does conclude today's question-and-answer session. I would now like to turn the call back to William Moore for any further remarks.

William M. Moore - *IRIDEX Corporation - Chairman of the Board of Directors, President & CEO*

All right. Thank you, once again, for joining the call today. We look forward to seeing many of you during the upcoming conferences and marketing trips. Have a great evening. Thank you.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude today's program. You may all disconnect. And everyone, have a great day.