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IRIX - Q2 2018 IRIDEX Corp Earnings Call

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PRESENTATION

Operator

Good day ladies and gentlemen and welcome to the Q2 2018 IRIDEX Earnings Conference Call. (Operator Instructions) As a reminder, today's conference is being recorded for replay purposes. It is now my pleasure to turn the conference over to your host Leigh Salvo, Head of Investor Relations. Please go ahead.

Leigh Salvo

Thank you. 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 June 30, 2018. A 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 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 on 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.

All forward-looking statements are based upon our current estimates and various assumption. 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 projections 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, August 2, 2018.

And with that, I'd like to 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 set 2 priorities through 2018; first, improve G6 [probulization] from our existing installed base while continuing shipments of new G6 systems across the globe. And second, to introduce new products that have the potential to improve the quality, reliability and manufacturing cost for our entire portfolio.

Our second quarter progress demonstrated execution in both of these objectives as we continue the shift towards a glaucoma disposal-oriented business model provided by our G6 platform. Second quarter highlights included continue momentum in G6 system and probe shipments; G6 regulatory approval in South Korea, one of our key target markets for global expansion; new data published further highlighting the safety and efficacy of our MicroPulse laser therapy and advancements in product development, particularly on G6 probes intended to broaden our market opportunity and drive utilization.

Financial results for the second quarter included a 58% year-over-year increase in revenues for our G6. Total revenues for the quarter were \$10.3 million, primarily driven by new G6 system placements and increased probe utilization. In the quarter, we shipped 125 G6 systems and 11,500 probes. Since our launch in March 2015, we have shipped nearly 1,100 G6 systems and nearly 90,000 G6 probes. I'd like to take the next few minutes to provide some additional detail on our recent business highlights and then we'll turn the call over to Atabak to cover the financials and guidance for the remainder of the year.

Our commercial teams have made progress placing G6 systems with new customers, as well as expanding placements with existing customers. We were delighted to recently announce the shipment of our 1,000 G6 system to one of our customers in Japan. While we now have well exceeded that number, this milestone highlighted the traction we have gained worldwide and the opportunity we have to grow probe utilization on an extending installed base.

In the U.S. driving G6 systems and improved utilizations through better sales and marketing execution and the deployment of clinical specials in the field remains a high priority. Shipments and probe utilization in the U.S. were strong in Q2, reflecting a growing awareness and acceptance of our G6 platform. Moreover, we are seeing a positive impact from improvements in our sales-force productivity resulting from improved training and tenure as we pull through from the investments made and the worldwide marketing activities and growing KOL support.

We are encouraged by the early feedback we received as our clinical specialists entered the field to support our sales reps and key accounts. While this is a process still in its early stages, I am confident that these efforts should improve our probe utilization given the expected benefits of enhanced customer service and better physician training to ensure more consistent outcomes. Internationally we saw a continued growth in shipments of our G6 systems and probes in existing markets as well as expansion in the new markets.

In Japan, our G6 launch is progressing very well because of our KOL support; positive clinical data; and a strong distribution partner. Our commercialization plan in Japan may prove and provide a model for expansion in other OUS countries. In Germany, we continued building out our direct sales organization as planned. Our primary target customers are large hospitals and hospital networks where we believe we can ultimately expand penetration once we have navigated the lengthier sales and procurement cycle.

G6 approval in South Korea was a key target for 2018 and we are delighted to have received approval by the South Korean's Ministry of Food and Drug Safety during the second quarter. We had begun KOL development activities and have experienced some early successes.

And finally, China remains a priority in our international expanded goals as the last major market awaiting G6 regulatory approval. On the marketing front we are maintaining a high profile at key industry events worldwide to raise awareness that benefits our MicroPulse technology in treating all stages of glaucoma.

We had a busy second quarter with participation at 9 global trade shows including significant presence at 4 major trade shows and scientific conferences, American Society of Cataract Refractive Surgery; Association of Research in Vision and Ophthalmology; European Glaucoma Society; and the World Ophthalmology Congress. At these events 23 glaucoma papers and posters were presented regarding our MicroPulse technology, covering data in 610 eyes and 4 podium presentations were held with over 1,500 physician attendees.

Overall, the continued cadence of support for our G6 products and MicroPulse technology is encouraging. On the product enhancement front we are working towards advancements across our entire portfolio that will improve product quality; provide additional features; and reduce costs. In particular if we have made progress in probe designs to improve the ease of use, consistency of outcomes and manufacturing costs of the G6 procedure. I'm very encouraged by the steady progress our team is making towards commercializing these product enhancements.

Turning to our retina products, as we have transitioned to a glaucoma-focus business model and continued to be impacted by a voluntary recall the LIO premier laser accessories, our retina sales have declined. We continue to see strong overall demand for our surgical and medical retina products and expect to realize more of this opportunity when the LIO recall is resolved. During the quarter we resumed sales of the LIO laser accessory outside the U.S. and fulfilled the backlog.

In the U.S. we are waiting the FDA's response to our 510-K which we filed in the second quarter. We continue to expect to resume shipments in the U.S. upon clearance and are prepared to fill the backlog.

At this point, I'd like to turn the call over to Atabak to provide further detail on our financial results for the quarter and guidance for the remainder of 2018. I will then share some closing remarks and open the call for questions. 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 second quarter of 2018 G6 revenues increased approximately 58% compared to the second quarter of 2017 and was up 10% sequentially relative to the first quarter of 2018. In the second quarter of 2018, we shipped 125 G6 systems compared to 69 in the prior year period. System ASP declined relative to the first quarter due to a greater portion of sales under our probe to purchase program. On the G6 probes side, we shipped 11,500 probes in the second quarter of 2018 compared to 7,100 in the prior year period, an increase of 63%. Probe ASP in the U.S. was relatively flat and increased modestly of U.S. compared to the first quarter.

From a geographic perspective, in the second quarter approximately 45% of our G6 systems were shipped in the U.S., while approximately 67% of our G6 probes were in the U.S.

Total revenues for the second quarter of 2018 were \$10.3 million, an increase of 3% compared to the second quarter of 2017. Growth in our G6 revenues was partially offset by a decrease in retina product revenues, primarily due to the LIO recall issues that Will described.

In the second quarter of 2018, domestic system sales decreased 29% to \$1.3 million from \$1.8 million in the second quarter of 2017, while our international system sales increased 32% to \$3.3 million from \$2.5 million in the comparable quarter. Our domestic system sales were primarily impacted by a decrease in retina product revenues given the dynamics that Will described. Recurring revenues in the second quarter of 2018 were flat at \$5.7 million compared to the prior year period as growth in our G6 probes was offset by a decline in our legacy probes.

Gross margin in the second quarter of 2018 was 41.4% compared to 44.9% in the second quarter of 2017. Gross margin was primarily impacted by unfavorable geographic mix, partially offset by the benefit of higher margin G6 revenues and a decrease in manufacturing overhead spending. Our G6 contribution margin in the second quarter was approximately 65%.

Operating expenses for Q2 2018 were \$7.6 million, up from \$7.2 million in Q2 2017. The level of our operating expenses reflects our growth investments to support our expanding commercial infrastructure, including increased sales and marketing expenses. Consequently, our operating loss in the second quarter of 2018 was \$3.3 million compared with a operating loss of \$2.7 million in the prior year's second quarter. From a balance sheet perspective, we ended the second quarter of 2018 with \$16 million in cash and no debt.

Turning to our guidance for 2018, we are increasing our range for G6 probes and G6 systems. We now expect G6 probes shipments of 42,000 to 46,000 and G6 system shipments of 370 to 420. This compares to previous 2018 guidance of G6 probe shipments of 40,000 to 45,000 and G6 system shipments of 350 to 400. We are also raising the lower end of our total revenue guidance to a range of \$38 million to \$41 million. This compares to our prior total revenue guidance of \$37 million to \$41 million.



Q3 has historically been impacted by summer seasonality when both patients and physicians take vacations. As a result, we typically experience higher sales trending towards Q4.

With that I'll turn the call back over to Will for some closing remarks.

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

Thank you Atabak. In closing, I'm pleased with the solid performance that IRIDEX team is making and executing on our strategy to expand the G6 installed base and increase utilization. We are beginning to realize the benefits of the investment made in building out our sales clinical and marketing teams to increase awareness and acceptance of the G6 platform and MicroPulse technology and bolster worldwide commercialization.

I look forward to updating you on our progress in coming quarters and 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 Scott Henry of Roth Capital.

Scott Robert Henry - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

I'd like to just get started talking about the G6 systems sold; 125 in the quarter was a pretty good number. Last year Q2 was kind of a weaker part of the year. How should we think about that 125 number? Is there any seasonality left? It looks like last year people bought going into the end of the year, but then the year before they didn't. Just trying to get a sense of how we should think about that system number from quarter to quarter? And plus any comments you can have on the strength of Q2.

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

So -- this is Atabak. So from a seasonality perspective, our -- the main seasonality we see as Q3 as our weakest quarter due to the holiday schedule that I just referenced and Q4 tends to be our strongest just for the end of the year kind of budgeting reasons. And then Q1 and Q2 are roughly the same. That's more of a generic general trend that we've seen in our business over many years. With the G6, obviously we're in a different stage in the launch there, but it's -- it does follow some of those trends as well. And as you look back to last year, one of the reasons the first half of the year was impacted was due to lot of the expansion efforts that we were doing as we built out our sales and marketing teams and some other changes. So I think as we've talked about before, the first half of last year, we were impacted by that and we started to see the benefits of those investments in the second half of last year and into the first half of this year. So that explained some of the anomaly that happened last year, but otherwise it's -- it follows more the path that I talked about on seasonality.

Scott Robert Henry - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

And with the upside in the quarter for G6 systems, how much of that was international? Do you breakout Japan or just trying to get a sense of what made that such a robust number?



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

So as we talked about 45% of the G6 systems came up in the U.S., so the balance came outside the U.S. So OUS was -- had a nice quarter in terms of G6 system placement. And that was really across the board, including some of the countries that we talked about. Japan continues to trend nicely and the approvals in Korea, but it was really across the board on -- outside the USA.

Scott Robert Henry - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

And then if I could just talk about utilization and kind of updating the model as we go, so these are kind of the preliminary looks at it. But it looks like the utilization per system kind of bounced above what we had as a low point and we may calculate it different than you in Q3 of last year. Do you think the utilization has kind of put in a bottom as far as it should only improve from here as far as utilization or just any -- how you think about the trend because there was some upside there in this quarter?

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

Yes, no. So in particular I think you're referencing the utilization in the U.S. because of the utilization outside the U.S. bounces around a bit more, but the utilization in the U.S., I think the way you characterize it is fair in that it seems to have troughed in Q3 of last year and it feels like we are -- so we've hit that trough and hopefully are on the trajectory to improve from there. That certainly is our objective given the investments that Will talked about in terms of both the existing sales-force getting more seasoned and up to speed and as well as the investments we're making on the specialist -- clinical specialist side.

Scott Robert Henry - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

And then I guess the final question and will jump back in the queue, as far as the LIO returning to the market, do you have any sense of the time line we should expect at least in kind of general terms?

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

Yes. I think in general terms, Scott, I think you should expect that the FDA to give us the authorization to begin shipments sometime during this quarter. Little more specifically, we filed that documents in Q2. We received the first round of questions, they were very minor. We've received the second round of questions, they've been very minor. And so we're on a fairly short clock winding down now. So I expect it pretty soon.

Operator

Our next question comes from Larry Haimovitch of HMTc.

Larry Haimovitch - *Haimovitch Medical Technology Consultants - President*

So obviously the glaucoma business is starting to really perform. Is there anything, any other strategic things you need to do or do you have kind of all the pieces in place now, Will, to ensure that this business really reaches its full potential?

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

Well, I think that first thing is the continuation of the expansion on the clinical specialists. We've got -- it's a 2-prong approach; one is you've got to get the installed base up and continue that with your sales-force. And then the follow-up pieces to make sure they're trained well so they could do the preliminary training and then get the expanded -- excuse me, to expand the clinical specialist group now that we have that recipe down, so they can get into the training. Because the long-term growth of the business really is the utilization of the probes, but the first piece is to make



sure you have the installed base. So I would say the models -- we've got the model down, the recipes down and now it's advancement of the clinical specialists and whether that then turns into additional salespeople, we'll just have to see.

Larry Haimovitch - *Haimovitch Medical Technology Consultants - President*

And the clinical specialists, I joined the call just a tad late, did you give the number of clinical specialists you've now got onboard, Will?

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

We have the manager and 3 in the field.

Larry Haimovitch - *Haimovitch Medical Technology Consultants - President*

And at this point, likely to add more or not?

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

Yes, we said in previous calls we thought the field-force would be upwards of the 24. We then put the periscope up and look and see what we want to do next. And we're marching towards that still.

Larry Haimovitch - *Haimovitch Medical Technology Consultants - President*

Will, I just lost you. I don't know if you're hearing me.

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

I can hear you.

Larry Haimovitch - *Haimovitch Medical Technology Consultants - President*

I can hear you now, I lost you for a seconds. Could you just say what you said for -- there was about a 10-second pause when my phone just went blank.

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

I said we were -- we are still marching towards the 24 people in the field. And right now that -- the sales number is consistent and we'll move on forward with clinical specialists, get to 24 and then put up the periscope and look and see whether we want to add more salespeople and more clinical people.

Larry Haimovitch - *Haimovitch Medical Technology Consultants - President*

So that business is really starting to perform as great potential. Let's talk about the -- I hate to call it this, but our retina business which I know you -- I know you're very disappointed and we're all very disappointed in it. I know you've got some initiatives going to improve that business and I'm sure it will over time. Can you give us a more detailed update about some of the programs in place that could get this business from declining to growing again?

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

I think the first one is just getting the U.S. LIO back on the market. Orders have stayed, we haven't had a cancellation-type request. The OUS retina business was quite good this last quarter. And I think this situation first and foremost is getting it back. We did receive quite a few positive responses from physicians with their comments being thank you for providing patient safety over corporate profits. So I think the brand is going to receive a little bit of positive rebound from that. And then in regards to the retinal business, we all know that's a huge number of people that are going to have Diabetic Macular Edema, I mean it's 430 million people that have diabetes and approximately 28% will come down with some form of edema. What we've got to work on is addressing the business model to find a way to become a capital equipment, with it is a captive disposal. That's about as far as I'll go on talking about that. That's really -- the next phase is to figure out how to do that.

Larry Haimovitch - Haimovitch Medical Technology Consultants - President

And when do you think you can -- when do you think you can introduce a next-generation retina family? I know you're working on that of course, you've said that publicly.

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

Yes.

Larry Haimovitch - Haimovitch Medical Technology Consultants - President

What's the kind of timing on that, Will?

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

I really -- it's really hard to give timing on that. I mean the main focus we have right now as I said on the call is getting the new probe for glaucoma on the market to try to eliminate -- I'd say discrepancy in results, so you get more consistency in the outcomes. That's the primary focus. The next piece will be going into dealing with the retinal business, and I really at this stage don't want to give any kind of timing on that.

Larry Haimovitch - Haimovitch Medical Technology Consultants - President

And will -- and just to jump back to glaucoma for a moment, will the new glaucoma probe address some of the reuse problems you've seen in some parts of the world or is there no way to deal with that?

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

No, it's not designed for that. It's designed for improved consistency of outcomes. I mean the reality is what we're trying to do is to make sure the light -- the laser light is going to the exact spot of the eye you want. And that's really the design that we're looking through at I should say, how to reduce the reusable piece to it, there are some things we're looking at, but the reality is all that said to me is that we have some pricing issues we've got to deal with OUS. There's always going to be [summaries] in the U.S., but not that much and I'm not really worried about it. As Atabak explained, ASPs are staying pretty consistent, volume is going up. We may see a few people to use it a couple of times, but I don't think that's a big thing we should be worrying about.



Larry Haimovitch - *Haimovitch Medical Technology Consultants - President*

Atabak, what was the ASP for the glaucoma probes in the current quarter?

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

So in the U.S. was relatively flat and around the \$200 range and then outside of the U.S. it's -- was marginally up in the \$130s.

Larry Haimovitch - *Haimovitch Medical Technology Consultants - President*

And would you say that going forward in building models that a \$200 ASP is a good place to be?

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

Yes sir, it's been pretty stable.

Operator

Ladies and gentlemen, this concludes today's question-and-answer session. I would like to turn the call back to William Moore, CEO, for any closing remarks.

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

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

Operator

Ladies and gentlemen, thank you for participating in today's conference. This concludes the program and you may now disconnect. Have a great day.

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