

Presbia PLC

2015 Analyst and Investor Update Call

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CORPORATE PARTICIPANTS

Monica Yamada – *Investor Relations*

Todd Cooper – *President & Chief Executive Officer*

Randy Thurman – *Executive Chairman of the Board*

PRESENTATION

Operator

Good day and welcome to the Presbia Analyst & Investor Update Call. All participants will be in listen-only mode. Should you need assistance, please signal a conference specialist by pressing the star key followed by zero.

After today's presentation, there will be an opportunity to ask questions. To ask a question, you may press star then one on a touchtone phone. To withdraw your question, please press star then two. Please note this event is being recorded.

I would now like to turn the conference over to Ms. Monica Yamada, Investor Relations. Ms. Yamada, the floor is yours, ma'am.

Monica Yamada

Thank you. Good afternoon, everyone, and thank you for joining us. On the call today, are Randy Thurman, our Executive Chairman of the Board and Todd Cooper, our President and Chief Executive Officer.

Before we begin, please note that the statements made on this call that are not historical facts may constitute forward-looking statements. All forward-looking statements speak only as of the date of this call and are based on management's current expectations, beliefs, and assumptions, and current estimates, forecasts and projections about the industry and markets in which Presbia operates. These forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties, and other factors, including but not limited to the risk factors and other qualifications contained in Presbia's annual reports, quarterly reports, and other reports that Presbia files with the SEC. Therefore, the company's actual results may differ materially from what is expressed or implied by these forward-looking statements. You should not place undue reliance on those forward-looking statements. Presbia PLC undertakes no duty to update any forward-looking statements made herein.

With that, I'll turn the call over to Randy Thurman, our Executive Chairman.

Randy Thurman

Thank you, Monica, and good afternoon, ladies and gentlemen. My name is Randy Thurman, Executive Chairman of Presbia PLC. With me today is Todd Cooper, President and CEO of Presbia PLC. The purpose of today's call is to bring you up to date on the progress the company has made and to provide an overview of our plans for 2016.

I'll turn the call over to Todd at this time to bring you up to date and discuss some of our future plans. Afterwards, Todd and I will take your questions. Todd?

Todd Cooper

Thank you, Randy. Good afternoon, everyone and thanks for joining us today. Let me take the opportunity to provide you with updates in three areas: one, Presbia's market opportunity; two, a review of the FDA approval process; and three, our current and future commercialization plans.

Presbia's Microlens is a refractive corneal inlay that's inserted into one eye, the nondominant eye to address the condition of presbyopia and to restore reading or near vision. The Microlens delivers an average six lines of improvement. It comes in a wide range of powers to offer patients a customizable solution.

First, let me present you with an overview of Presbia's potential market opportunity. Presbia's Microlens technology and the surgical procedure have been completed in over a thousand patients worldwide to date. We've been encouraged by the results in terms of restoring patients' reading vision as well as the lack of significant adverse advance. The worldwide market for Presbia's Microlens is significant with 1.8 billion people having presbyopia, meaning 1.8 billion people requiring reading glasses. Just consider that virtually every adult between the ages of 40 and 50 will develop presbyopia.

Our Microlens provides the potential for those individuals to be free of their reading glasses, and as I mentioned, the lens comes in multiple powers; it allows for a customized solution for each patient. If necessary, the lens is removable and replaceable.

There are currently more than 4,000 refractive surgery centers offering the laser procedure which Presbia can target. Additionally, ophthalmic surgeons are highly motivated to replace their lost LASIK volumes, which have yet to recover since the great recession. The Presbia Microlens procedure fits incredibly well into a refractive practice. It uses the existing laser technology that's used for LASIK procedure, meaning there's no out-of-pocket expense for the practice other than the lens itself, and it's a 10-minute procedure and 100% private pay.

Second, I'd like to update you on our current USFDA clinical approval status. As you may be aware, we have our CE mark which allows for European Union marketing of the Presbia Microlens. We currently have approval to go to market in forty international countries. The USFDA allowed us to conduct our pivotal study in two stages. In the first stage, we treated 75 subjects followed by approval from the FDA to move into the second and final stage of enrollment in February 2015. To accommodate the second stage enrollment of patients, we added five clinical sites to supplement our initial six sites.

The second stage recruitment started ramping up in mid-April, and we announced in early September that we completed enrollment of second stage patients. The fact that we were able to recruit 346 patients for the second stage in approximately 5 months demonstrated the interest of patients to have the procedure. Four hundred twenty-one US patients have undergone the lens implant and procedure. We are required to follow those patients for 24 months, and after which in Q4 2017, we plan to make our submission to the FDA for approval of our Microlens. That schedule puts us on track for commercialization in the US in Q4 2018, assuming we obtain our FDA approval. As such, we are limited in what we can say about the outcomes of those procedures.

The third area I'd like to discuss is our commercial strategy and execution. While we have the approval to commercialize in dozens of countries, we're taking a highly focused approach. To that end, we are creating two beachheads: the first in Asia Pacific which has begun, and the second that will follow at a later date in Europe. We are currently launching in South Korea and are targeting to have full commercial rollout in Germany likely within the next 12 months.

We selected these countries for the following reasons. We targeted the two most developed ophthalmology regions of the world outside of the US, Asia Pacific and Europe. We sought countries with large presbyopia population and a high incidence of presbyopia per capita. We selected countries with several one million plus population metro areas to concentrate our commercial efforts. We identified high household income countries. We evaluated the consumer desire to buy the Microlens by considering high LASIK penetration as a good indicator of consumer willingness and desire to have an elective eye surgery procedure. We also ensured there's the ability to do the procedure by having a high number of refractive surgeons, laser centers, and lasers

in the country.

Lastly, we selected countries where consumer medical direct response marketing is approved as it's the way for clinics to market and generate leads for the Presbia Microlens procedure just like LASIK.

Another critical aspect to our commercialization is to develop centers of excellence with select clinics in Australia, Ireland, Netherlands, and Canada. We may add additional center of excellence clinics in the future. Having a selection of surgeons globally will help us build credibility to also grow in our target countries.

Specific aspects that makes South Korea a particularly attractive market for Presbia is that it's a large and developed ophthalmic marketplace. There are over 1,100 practicing refractive and cataract surgeons, of which, 275 are refractive surgeons; and there are 170 laser centers in the country. South Korea has 18.3 million presbyopes which represent 37% of the population. South Korea is also the most penetrated LASIK market in the world per capita. This is in part because South Koreans aesthetically prefer not to wear eyeglasses.

In 2013, there were 139 LASIK procedures performed in South Korea. South Korea also has a high household income indicating the ability to pay for an elective surgery, along with the acceptance of LASIK.

South Korea requires non-Korean medical device manufacturers to sell through a distributor. Presbia has secured an excellent distribution partner, Nevis that specializes in ophthalmic medical devices. Nevis has long-term relationships with ophthalmic surgeons as well as expertise in introducing products into the Korean market.

To kick off our launch in partnership with our distributor, we held a symposium in Seoul in late September. More than 30 surgeons were able to attend the symposium. We are now in the process of conducting wet labs, and we will assist the surgeons as needed to recruit patients in order for the surgeons to become certified by us in the Microlens procedure. These initial surgeons will be the foundation of our 2016 commercial activity in South Korea.

Simultaneously, to grow our activity in South Korea, we are targeting key clinics in Australia and New Zealand. Our ability to market directly in these countries will allow us to fine tune our marketing and sales programs to both surgeons and to consumer patients in advance of our launch into other direct markets which may include Germany. We'll be able to apply the learning to South Korea as well. Australia's per capita household income is even greater than that of South Korea's. It has 760 refractive and cataract surgeons of which 124 are refractive surgeons. There are 53 laser surgery centers in Australia, and the country also has 8 million presbyopes, which is 36% of the population.

Now let me turn to Germany. We all know that Germany is one of the largest developed markets in the world. Germany has 37.3 million presbyopes. It has 210 laser surgery centers. Germany also has the benefit of a few large corporate refractive surgery groups. These groups can represent a significant commercial opportunity. The country has over 3,500 refractive and cataract surgeons of which 400 are refractive surgeons.

Our strategy includes laying the groundwork in Germany during 2016 in preparation for a full scale German launch, possibly towards the end of 2016 or early 2017. We've just hired a business development director based in Germany who's expected to start in January for the preparation of a

German launch. This person has deep experience in the ophthalmology space in Germany. We plan to augment the business development director at a later date with a clinical application specialist who will support surgeons and their clinics once we are actively commercializing.

Through our industry relationships, Presbia has entered into a collaboration with Ziemer, one of the largest ophthalmic medical device companies in the world and one of the largest and most respected manufacturers of femtosecond lasers. These are the same lasers that are used by LASIK surgeons to create a flap and the same laser that is used to create the pocket to insert the Presbia Microlens.

We plan to work with Ziemer in Germany to leverage existing and new relationships with refractive surgeons. This is a win-win for both companies, as the Presbia procedure drives incremental use of the existing lasers in refractive clinics, while it also creates the opportunity to introduce new lasers into the clinics for surgeons, especially cataract surgeons who want to begin the Presbia procedure, however don't have a laser; and this of course creates new customers and volume for Presbia.

We also added Dr. Gerd Auffarth to our board. Dr. Auffarth is one of the world's most respected thought leaders in ophthalmology and refractive surgery. He's currently Professor and Chairman of the Department of Ophthalmology at the University of Heidelberg in Germany. Dr. Auffarth is largely considered to be the leading ophthalmic surgeon in Germany, and we expect he will play a key role in our German launch. The combination of all of these elements forms a strong foundation for us to launch and grow Presbia in Germany.

Let me now turn to the systematic approach to commercializing in a country. Since a surgical solution for presbyopia is a new procedure, it's important to galvanize surgeons and consumers over time. That's why we are dedicated to a focused approach. We'll likely use a symposium-style launch in each new country to immediately bring many surgeons together. We've already seen the effectiveness of this approach in our South Korea launch. Once we have certified surgeons, the next step is to help develop and build their comfort and confidence in performing the procedure. We believe the best way to do that is to provide them with ongoing support in the surgery suite and clinic.

We also want to create consumer awareness of our surgical solution that provides the potential for consumers to be free of reading glasses. So on a case-by-case basis, we may offer clinics co-op marketing dollars to support their patient lead-generation marketing. We also plan to augment this with select consumer PR.

Lastly, as I mentioned already, we'll target the largest cities in each country with the plan of signing up multiple clinics in each city. We believe this will generate an increase in simultaneous consumer marketing creating a heightened awareness of the procedure within that metro area. We believe the focused approach by targeting a few cities in each country is just as important as launching in one country at a time.

In summary, our strategy is to demonstrate the superiority, safety, and efficacy of Presbia's Microlens technology by increasing commercialization in South Korea. We'll apply the learning from South Korea and the select clinics in Australia to get a fast start in Germany next. Simultaneously, we are completing the USFDA clinical trial with the goal of obtaining approval in 2018. The dual emphasis of focused commercialization and working towards FDA approval will remain our central theme for the foreseeable future and represents what we believe to be the best path to value creation for all Presbia shareholders.

Last of all, we recently stated in our 10-Q that it is likely we will need to raise additional capital prior to the submittal for FDA approval. Based upon our current business plan, we believe our current cash will take us into 2017; however, sometime in mid-year 2016, we expect to review our alternatives for raising new capital. As we enter 2016, we continue to reprioritize as necessary to conserve cash. Make no mistake, our number one priority is obtaining FDA approval in the US. It's too early to suggest what our capital requirements may be, so I won't be making any projection.

Before taking your questions, let me provide a recap. We believe Presbia's technology is superior and provides patients with the best solution to presbyopia, an affliction that affects 1.8 billion people worldwide. We've completed over a thousand procedures worldwide. We've completed the surgical procedures in over 400 US patients as part of our clinical trial. The 24-month follow-on study has commenced. Our parallel strategy of one, a focused commercial approach outside of the US; and two, planned FDA approval is the optimal approach for maximizing value for our surgeons, patients, and shareholders.

With that, operator, please open up the call for questions.

QUESTIONS AND ANSWERS

Operator

Thank you, sir. We will now begin the question and answer session. To ask a question, you may press star then one on your touchtone phone. If you are using a speakerphone, please pick up your handset before pressing the keys. If at any time your question has been addressed and you'd like to withdraw your question, please press star then two. Again, it is star then one to ask a question. At this time, we will just pause momentarily to assemble our roster.

The first question we have comes from Raj Denhoy with Jefferies. Please go ahead.

Raj Denhoy

Hi, Todd. Hi, Randy. I'd like you to start with Korea. You mentioned you have 30 some clinicians now that have been at least been exposed to the technology, and you're starting the wet labs and training of those clinicians. Is there any more you can perhaps provide in terms of what that training will look like from a time perspective, and then when those clinicians start to go back and canvas for patients within their practices, over what time period do you think they could actually start to do commercial sales? And then the second part to that question is that when those clinicians do get up and running, what do you think a reasonable utilization or rate of procedures would be for a trained clinician?

Todd Cooper

Sure. You're right. Right now, we are completing the wet labs with surgeons, and at this point in time, I believe we've completed wet labs on in excess of 35 surgeons. The next step from that standpoint is to recruit patients, and we have a small number of sites in Korea beginning to do that. Now, Korea is like much of the rest of the world, is shutting down for the holidays in terms of for recruitment from the patients, so they're focused on LASIK activity, so we'd anticipate in January that beginning again. Our hope is that the majority of those people will come on board within a reasonable timeframe. How fast that's going to be — until we start completing the certification of those surgeons, it's going to be really too early to tell that, Raj, but we will update over the course of time as we hit milestones in Korea with respect to the certified surgeons in Q1 and beyond.

Second question you asked was in terms of utilization rate, and that's another question that we

don't have a specific answer for at this point in time, and that's because until we start to see what the take rate is with the surgeon and how comfortable and how fast they get comfortable with the procedure, we're really not going to know that. We do know that there is some reticence from surgeons who have been exposed to other technologies that they haven't been as satisfied with. So our expectation is that they'll want to get a handful of surgeries under their belt, observe those patients for a period of time, and then begin to expand from there.

Raj Denhoy

So are you or your distributor in South Korea, is there any sort of requirement or minimum levels that these clinicians have to commit to in order to get trained by you? Or is it really once they moved through this, it's really incumbent upon them or up to them if they select to actually start to get commercial?

Todd Cooper

No. We are responsible directly for the surgical training and the certification of surgeons. So for each surgeon, we would anticipate approximately five procedures to be completed before a surgeon would get certified, and that's based upon our surgical trainer being satisfied that the doctor is comfortable doing the procedure and doing it efficaciously and also the surgeon being comfortable as well.

Randy Thurman

I think Raj was saying too is there any commitment on their part in terms of number of patients after we train them? And I think, Todd, the answer to that is no, and it's not just up to them, it's really a collaborative effort between our distributor, the surgeon, the Presbia staff on site in Korea, and the surgery centers to then begin to recruit the patients — so very much a collaborative effort post their training.

Raj Denhoy

No, I understand. Again, I also respect that it is early, so you haven't yet sort of learned these things, so I realize these are difficult questions to kind of answer given where we are in the launch. Just really my last question is just on Germany. If you think about a similar path forward in Germany with training clinicians or exposing clinicians as you mentioned through a symposium, and then beginning to train, is there a gating factor or some event that will trigger your willingness to move forward in Germany? As you mentioned, you hope to start by the end of '16, but what will inform that decision to begin there?

Todd Cooper

Sure. The decision to inform there is going to be driven in large part with Korea because Korea is a very significant opportunity for us, and based upon the take rate with the surgeons that we certify and our ability to certify additional surgeons, the time may be warranted to spend more time in Korea going deeper because when you look at the size of the marketplace and the number of potential surgeons and procedures you could do there, once you start to build awareness and competition amongst the surgeons in those key cities within Korea and then you start to begin to have increased marketing activity by each of those surgeons within those cities, you start to create enhanced consumer awareness of a procedure of which in itself may start to accelerate the activities there. And so, the answer is wherever we feel that we are going to get the best return of our invested time and capital, based upon our success there will in some sense dictate that.

More specifically to Germany though, what we see we have as an opportunity to do is to develop some clinical data with German surgeons over the course of 2016 that we will be able to utilize once we go commercial in that market, but that's not really the gating item at this point in time.

Raj Denhoy

That's helpful. Thank you.

Operator

Next we have Caroline Corner of Cantor Fitzgerald.

Caroline Corner

Hi, Todd. Great to hear about all of the progress here. A couple of questions from me actually. The first one regarding your FDA timeline for approval, you mentioned your 24-month follow-up time period. Lately, we've seen in the MIG space, micro-invasive glaucoma stents, FDA talking about the possibility of letting companies leapfrog the data to do 12 months instead of 24 months of follow up in order to get some of these products potentially on the market more quickly. Whether that's a good thing or a bad thing remains to be seen because certainly the physicians want to see safety demonstrated, but I was curious if there was anything in your space that is similar to that where we might see kind of a narrowing of the time period that is going to be required for follow up, or are you pretty sure that 24 month is in place and will be for the foreseeable future?

Todd Cooper

I can't really comment outside of us and what the implications are. To my knowledge, I haven't seen an extensive acceleration of timelines. I can tell you that at the time when we were working with the FDA to set up the parameters, we were interested in a 12-month timeline. They were interested in a 36-month timeline, and we settled on 24 months. At this point in time, unless there is something very unforeseen to happen for that 24-month timeframe to change, now that we're underway with it.

Caroline Corner

Okay. Fair enough. Thank you. And then, just wanted to ask you a little bit about pricing, clearly, your enrollment in the US trial has been going very well and quickly, which implies some pent-up demand there. If we think about the pricing in terms of it being a laser procedure, should we consider it to be something like a LASIK kind of pricing, or since this is replacing reading glasses rather than regular glasses, should we expect it to be lower than what someone would pay for LASIK? How should we think about this in terms of the US market?

Todd Cooper

Yes, absolutely. I think our view is consider it roughly around what LASIK pricing is in a given market. The only exception to that is in some markets you'll see that LASIK is a more commoditized procedure today and more competitive, and so the pricing may have deteriorated more than in other markets. But on average around LASIK pricing, when we see what's been going on competitively, it's not uncommon to see \$3,000 or \$4,000 as what a practice might charge. Of course, it's completely under their control as to what that price might be, but that's something that we've seen as not unusual.

Caroline Corner

And then, and I know it's early because we're not approved yet in the US, but do you think pricing will be globally consistent, or will it vary a lot between different markets? I guess what I'm asking is will people travel to get this procedure done in other geographies if the price is different?

Todd Cooper

My expectation is that there might be some variations by market; again, depending upon the economics of the marketplace and what competitively is going on. So it's not uncommon to see in

South America where you might have pricing that's a little bit lower just because of the economics of the population, but when you take a look at LASIK, at least in its prime, there was pretty consistent pricing across the board. I think one of the other things which I'll say is it's not unusual even with an existing market to see some variation; if you have a highly skilled, well known surgeon, they will be able to charge a premium for that product, but I don't think you'll be seeing people necessarily moving from country to country to get the procedure done. That's not what I experienced with LASIK.

Caroline Corner

Great, thank you and then one more quick one on the market. Over the course of a lifetime, I know you mentioned that these things are pretty easy to replace and change, how many lenses would you expect a patient who, for example, shows up at 45 for their first one, how many lenses would they go through in the course of their lifetime?

Todd Cooper

Yes, very good question. So this is one of the strong benefits and differentiators of our product is that the pocket that's created allows for the lens not only to be removed, but it's intended to be replaced if required. We come in nine powers, so you're getting the customized therapy specific to your visual needs. So if you have the procedure done initially in your mid-40's, there's a very good chance that you might have one or even two replacements of that lens over your life. By the time you turn 55, your near vision will stabilize, and it won't change after that. So the closer you get the procedure done to that, the less likely you will need to have it replaced. But again, the point that you've drawn upon is if your vision continues to deteriorate, just like what happens with people with LASIK, if they get it done early and their distant vision continues to deteriorate, they get what's called an enhancement. Our product is the only one in the marketplace that's designed to be removable to be able to give you those six lines of near vision back again should your near vision deteriorate.

Carole Corner

Great. Thank you for that color and congratulations with all the progress.

Todd Cooper

Thank you very much.

Operator

Again, as a reminder, if you would like to participate in today's Q&A, please press star then one on a touchtone phone. Again, that is star then one to ask a question.

Next, we have Carol Valenski of VM Financial.

Carol Valenski

Hi, Todd. Hi, Randy. You speak about the 1.8 billion people market opportunity. Why do you believe patients will want a procedure like this?

Todd Cooper

Hi, Carol. Thanks for the question. We have a product, as I just mentioned that on average delivers six lines of vision improvement; enough, on average, to be able to read the smallest type on the back of a soup can after you've had the procedure.

We've conducted some of our own research with past patients, and we see two primary reasons that arise for people wanting to get this procedure. The first one is freedom, and that's the

elimination of the hassle factor of having your glasses on and off all day long, especially with things like smart phones that people use frequently today. And second is confidence. It makes patients feel more youthful and more confident in their day-to-day lives. And then, lastly, we've implanted over a thousand lenses to date with limited commercial support, including over 400 in the US as part of our clinical trial, and that demonstrates, we believe, the strong patient-doctor interest in the Presbia Microlens procedure.

Carol Valenski

Okay. Thank you.

CONCLUSION

Operator

Well, at this time, we have no further questions. We will go ahead and conclude today's question and answer session. I would now like to hand the conference back over to management for any closing remarks. Gentlemen?

Todd Cooper

I'd like to thank everyone for joining our call today and for your questions. Operator, you may now end the call. Thank you.

Operator

We thank you, sir, and to the rest of the management team for our time today. The conference call has now concluded. At this time, you may disconnect your lines. Thank you, take care, everyone, and have a great day.