

Q&A with Quinton Oswald, CEO and Jim Long, CFO, Notal Vision, Inc. providing the first Cloud Based Platform for Patient Administered at Home Vision Monitoring and Diagnosis of Dry AMD and Retinal Disease



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Interview with Quinton Oswald, Chief Executive Officer and Jim Long, Chief Financial Officer conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: *Mr. Oswald, Notal Vision Inc, is advancing vision care through the enhanced monitoring and diagnosis of retinal diseases. How are you doing so?*

Mr. Oswald: Notal Vision is the first ophthalmology company that effectively monitors and diagnoses the patient through a cloud based platform where the patient tests themselves at least 2 + times per week basis. We have patients testing four to five times a week, because vision is such an important element to them. They test on this device called a ForeseeHome®, which is then linked to a cloud based platform. In that cloud based platform we have an algorithm that monitors the patient's vision over time and because dry AMD is a slowly progressing disease it takes a while for a patient to go from dry to wet. There about ten million dry AMD patients in the US. Approximately one million patients per year convert from dry to wet AMD, which is a blinding disease. As you progress along the highway of dry to wet, your risk factor goes up as your dry AMD becomes worse. Therefore, we monitor intermediate dry AMD patients, whose risk factors can worsen from one in ten to one in four and one in two, by the end of the journey.

CEOCFO: *What is the technology and science to do this remotely?*

Mr. Oswald: Our technology is based on preferential hyperacuity perimetry, better known as PHP. What does this mean? When you visit an eye doctor and are asked to read the eye chart, letters of various sizes are presented and your responses determine your visual acuity. For example, 20/20 represents very good vision. This measurement is known as "Snellen" acuity. At Notal Vision, we use a more sensitive vision measurement; "Vernier" acuity. When patients test with the ForeseeHome device, the results are transmitted to our diagnostic testing facility and analyzed by our AI algorithm for a significant change from their baseline testing values, which can indicate the progression from dry intermediate AMD to the advanced wet form.

CEOCFO: *Is the device in use today? Are you still in development?*

Mr. Oswald: The device is in use today. We have about four thousand patients testing over three million times.

Mr. Long: We have conducted an FDA clinical trial and have obtained Medicare reimbursement.

CEOCFO: *How quickly can the change occur and to what degree can you pick up a change?*

Mr. Oswald: That is a great question. Let us take a normal situation. Let me use the visual scale again as an example. On average, from the large database developed by the American Academy of Ophthalmology, we see that more than fifty percent of patients present with a vision of 20/80 or worse. This means that you are functionally blind. When a patient's eye switches from dry to wet AMD, vision can decline in a matter of weeks. Patients are actually very poor at detecting

changes in their vision, therefore in the absence of an eye exam, it takes them a while to recognize the vision loss. When patients use their ForeseeHome device, vision retention at the time of wet AMD diagnosis is significantly better; 94% retain visual acuity of 20/40 or better. This means they may continue to drive, to read, and remain independent.

CEO CFO: *How often might an ophthalmologist, if they see some signs, ask a patient to come back?*

Mr. Oswald: That is a great question. If you have dry AMD, on average a patient sees an ophthalmologist between the frequency of six months to a year, because it is a slow evolving disease. We call this the lottery, because if the patient develops wet AMD the day before the doctor visit they have won the lottery. That is because the doctor will pick it up with the sophisticated diagnostics that they have in the office. If they develop wet AMD the day after the patient leaves the office they might only pick that up in a couple of months for the reasons I have articulated. Therefore, what this ForeseeHome device does is through this activated platform it sends an alert to the doctor that the patient has converted from dry to wet AMD and they need to come in for treatment as soon as possible.

CEO CFO: *Would your device be prescribed by a doctor?*

Mr. Oswald: Yes. It is basically an order. The doctor sends the order to us. We call it a prescription, but it is an order. We then send the device to the patient who does not pay anything for it. That is the critical part about it. We have established a reimbursement rate with CMS (Centers for Medicare and Medicaid Services), and they pay us an amount every month as long as the patient continues the tests. There is little or no cost if there is a copay. In about twenty percent of patients there is a copay which is relatively modest.

“We were very proud of the fact that we can save peoples sight and improve vision with drugs. However, we did not think about the number of patients who were maintaining functional vision. If a patient came in with 20/80 and we got it down to 20/60, that was scientifically very exciting, but practically did not improve the quality of life of the patient. If you think about Notal’s mission of getting more patients from 20/40 to maintain functional vision, that is what basically keeps me up; it is to do the right thing for patients because vision is such a precious issue. To me it is a passion, not necessarily just a business opportunity.”- Quinton Oswald

CEO CFO: *Have you found that patients tend to continue testing, especially if they have not seen a change in a long time?*

Mr. Oswald: Yes, because patients who have dry AMD, if they are well educated, and that is the rider, realize that blindness is a debilitating disease and it really impacts their independence, the ability to drive, see their grandchildren, read and so on. Therefore, they are an extremely well-motivated group of people. Therefore, our compliance rate is up to ninety four percent after three and a half years. That is the extent to which we have had this product commercialized. It can go as much as four to five years. We have got a really high compliance rate, because the fear of going blind is one of the key drivers of qualitative life for these people.

CEO CFO: *Can the test be wrong? Can someone not do it correctly? How accurate is it?*

Mr. Oswald: What happens is the patients receive the device and are required to establish what we call a ‘baseline’, which confirms that they can test with the device. About fifteen percent of patients cannot establish a baseline. After the patient establishes baseline, they begin testing actively. The device was cleared by the FDA, and detects changes in vision that occur based on morphological anomalies. We are reimbursed as a diagnostic for the detection of the onset of wet AMD specifically. Therefore, we occasionally have what we call ‘macular change signals’ that do not result in a diagnosis of wet AMD often indicating other eye pathology. However, the machine is doing exactly what it is supposed to do. It is designed to indicate when morphological changes occur within the eye, which may or may not be choroidal neovascularization (CNV), also known as wet AMD. ForeseeHome is part of a comprehensive dry AMD monitoring program for patients that also includes regular eye exams.

CEO CFO: *What would prevent someone from developing a base line or creating their own base line?*

Mr. Oswald: It could be that the eye is damaged already.

Mr. Long: It could be anatomical reasons.

Mr. Oswald: Or they are of an age where they are mentally or physically encumbered. Bear in mind, the average patient is seventy to eighty years old. It could be condition issues. It could be a number of reasons why; anatomical or physical. It could be that they have rheumatoid arthritis for example

CEOCFO: *What has been the reaction from the ophthalmologic community?*

Mr. Oswald: It has been very good for two reasons. Early detection is a critical element to treatment that you and I could talk about, from breast cancer to prostate cancer. In the eye space, what really impresses doctors is the fact that we are able to identify wet AMD patients and bring them in for treatment earlier. On top of that, if you look at the real-world experience of patients presenting at their doctors with wet AMD, the neovascular lesions are already very advanced. Lesions are measured in square millimeters; 2.54 mm² is called a 'disc area'. Patients typically present with a lesion size of two to four disc areas. In our trial, we showed that the damage to the patient's eye could be caught very early, when lesion size was approximately 0.23 disc areas. Therefore, treatment in ForeseeHome patients can be initiated earlier, with better vision and smaller lesions.

CEOCFO: *Should almost everyone of a certain age be using your device?*

Mr. Oswald: No. It should only be used by people who have been identified as having dry age related macular degeneration. Right now, it should be when they reach the intermediate stage, which is a well-defined clinical diagnosis. The ophthalmologist knows when they reach the intermediate stage. It is then appropriate for them to enter into a testing program.

CEOCFO: *How many people?*

Mr. Oswald: Of the ten million people who have dry AMD, we believe that about three point eight million Americans, that are diagnosed today, would qualify for this device. There is probably an equal number who are undiagnosed..

CEOCFO: *Do most people see an ophthalmologist regularly or is that still not the norm?*

Mr. Oswald: It entirely depends on probably the level of education and the access to an ophthalmologist. Typically, what happens is that these issues get picked up, either at your primary care practitioner or you have been to the optometrist, which is more the case, where they see something in your eye and they refer you to an ophthalmologist. If you have been identified with dry AMD or glaucoma or any other disease that is when you should be seeing a physician that is ophthalmologically qualified, more frequently.

CEOCFO: *How are you reaching out so that all ophthalmologists understand what is available for them and for their patients?*

Mr. Oswald: Let me take a step back. We are an early stage commercial company. In order to grow our funding base, we have to prove that this patient activated, cloud based model works. Therefore, we are currently operating in nine markets. We are basically running an exercise whereby we are proving that our platform works, preparatory to national expansion, probably in 2019. With that proviso, we are reaching out to those nine specific areas with a combination of the following. We have what we call a customer account manager (CAM). We have medical science liaison folks and we have a digital campaign for doctors and patients, targeted in those geographic areas that I have just articulated.

CEOCFO: *What have you learned as people have been using the device?*

Mr. Oswald: We learned a number of things. As we scale up from a clinical stage to a commercial stage company there is work we have had to do in terms of the processes; getting a patient from being identified to needing this device to getting them on the device. For instance, the point about not being able to establish base-lines, we can work to improve the education of the patient, so that more patients can establish base line. Also, when we call to talk to the patient about how to use the machine, we currently call them on with a 1-800 number. Because of this there will be patients that think that someone is trying to sell them something or scam them, so they tend not to answer the phone. Therefore, we have learned to use different ways to reach out to patients. In fact, this patient demography surprisingly really enjoys getting mail, where if you talk to a millennial the last thing they ever want to get is mail. However, physically getting to the mail box and getting mail is enjoyable exercise for the folks we are appealing to.

CEOCFO: *What do you understand, as a company, as individuals, from the business side that is guiding you and will guide you as you continue to grow the company?*

Mr. Long: For me personally, it is to work in a company that makes a difference in people's lives. So much of healthcare is explaining wrinkles in reimbursement and things like that and this is truly a unique product that saves peoples eyesight. That is one of the biggest drivers for me.

Mr. Oswald: What makes me passionate about what I do, as pioneer in the treatment of the wet age related macular degeneration, both with Novartis for the first treatment for Wet AMD and Genentech with a drug called Lucentis®. We were very proud of the fact that we could save peoples sight and improve vision. However, we did not think about the number of patients who were maintaining functional vision. If a patient came in with 20/80 and we got it down to 20/60, that was scientifically very exciting, but practically did not improve the quality of life of the patient. If you think about Notal's mission of getting more patients to 20/40 or better to maintain functional vision, that is what keeps me motivated; it is to do the right thing for patients because vision is such a precious issue. To me it is a passion, not necessarily just a business opportunity.

CEOCFO: *You said 2019. What will be the evolution? What is the plan for next year? What are the next steps?*

Mr. Oswald: By Q2/18, we believe we will have perfected the best model possible for patient engagement. Bear in mind, we have pioneered the first patient activated monitoring platform that is cloud based in ophthalmology. It has already been done in Holter monitoring and the CPAP sleep apnea machines, but it has never been done in ophthalmology before. It is a bit more sophisticated. We will then track the key metrics that we are implementing. For instance, we have initiated a net promoter score (NPS) tracking system. I do not know if you are familiar with that concept, but it is something that a company like Amazon might use to evaluate the customer service. Tracking our customer net promoter score, we see quarter on quarter improvements in the last half of 2017. We then take all of these elements back to potential investors, be it a private equity group or a crossover investor, preparatory to an initial public offering in 2019. Based on the key metrics, we can now say we have a model that is scalable. We need the money to expand nationally and internationally, so we need new investors to fund growth, not fix our problem statement. Therefore, the strategy is, either a crossover IPO, a private equity take-out or potentially an investment from a Google or an IBM, a pharmaceutical or device company. Those could be exits for us.

CEOCFO: *With regard to the device itself, are there variables? Does lighting in the room matter? Does it matter if you do it when you wake up in the morning or before you are going to bed? What may or may not have an effect?*

Mr. Oswald: We have some really smart people back in Tel Aviv develop this machine. So, they designed a back-light device which has more than sufficient illumination, irrespective of external light conditions, to do the test. To our knowledge, there is not difference between the time of day that you do it, because if you are testing three or four times a week and you get a variation of times it tends to average out, in our experience. You are going to need Wi-fi, or a cellular based modem to communicate.

CEOCFO: *Why does Notal Vision Inc and your device stand out?*

Mr. Oswald: That is a good question. Basically, by proving the model of a patient activated, cloud based device, using ForeseeHome as our first product, we will have proven the overall opportunity that telemedicine offers; i.e. to move patient treatment and patient diagnosis away from the office into the home. ForeseeHome is the pioneer of that in this space. We have other products coming behind that, which utilize this platform that we are developing. Therefore, to us, the platform is critical. The devices that we sell are really taking advantage of the platform that we have created. We have a tremendous opportunity for growth, having satisfied the need for a great patient interface.

Mr. Long: Just a little validity to the fact that we really are unique among the world in this. It was the FDA that had a conference in Maryland about a month or so ago that Quinton and some of our other executives went to and the takeaway there was that we truly are far ahead of the pack in operationalizing the tele-monitoring platform and some of the things we talked about; things we have learned about interfacing with our patients and how to get them the device and how to get them trained. That is all the nuts and bolts that take some time to do.

Mr. Oswald: And just the building and execution of the platform! I think that by seamlessly interfacing with folks sixty-five plus, who are not necessarily as technologically savvy as our children might be; we have overcome their issues through experience and ongoing learning. Therefore, we are pioneers in the space of telemedicine and ophthalmology, but even more so amongst the demography of types of patients who suffer from some of these ophthalmic diseases.