

Interview by BRETT JOHNSON, CEO of OneMedMarket  
MAY 25, 2016

---



Doug Daniels, CEO of Stroma Medical

**Good morning. This is Brett Johnson with OneMedRadio in New York. Today, I am with Doug Daniels. Doug is the CEO of Stroma Medical, an urban California company that's developed an innovative approach to eye color. Thanks for joining us today, Doug.**

Thanks very much for having me, Brett.

**So Doug, can you first tell us - what does Stroma Medical do?**

Stroma Medical is a --- device company that's focused on eye aesthetics. And our first product is a system that can safely and effectively change the color of people's eyes from dark colors to light.

**Interesting. So is there a big desire in the market for people who want to change their eye color?**

We've found, over the last several years, that there's a tremendous demand for eye color change. What we did was we looked at the market for color contact lenses and we found that nearly 25 million people are currently wearing color contact lenses on a global front. And nearly 75 million people have worn them, but stopped wearing them for one reason or another. That gives us a strong indication that there was a real desire for eye color change. In addition to that, what we found was that - and we did the primary market research - and what we found was that among dark eyed individuals, up to 17% of dark eyed individuals between 20 and 50 years old in the States, would actually want to have their eye color changed. So it gave us a good indication that there was going to be good demand for the technology here in the States. We then followed that up with some primary market research in Asia, and in the study that was done in over 30 countries, what we found was that close to 15% of the dark eyed individuals in Asia would want to have their eye color changed. So there's significant evidence, both on the primary market research side and on the intuitive side, that there is, in fact, a huge demand or desire to have a new eye color change - specifically moving from dark eye colors to light.

**Interesting. So what are the different ways that people can change their eye color today?** Well today,

if you want to have your eye color changed, you can, I think probably the strongest competitor that we have is actually color contact lenses. Almost 25 million wearers of color contacts, are one of the ways that people change their eye color today. In addition to that, there's people who have tried to use implants in their eye. Iris implants have been used around the world in a number of different settings but so far they've received really mixed responses, both from a clinical perspective and from a cosmetic perspective. So those are the two major groups of competitors that we have right now.

**And how does your technology work?**

Well the technology works actually like - if I could go back a second - like most transformational technologies. Our technology is actually a series of inventions - not just one invention. What we do is we use a combination of eye mapping, eye tracking with a proprietary optics system that's driven by our software package that really photo-disrupts the pigment that's in the very interior portion of the iris. We're aiming at an area that's roughly 50 microns and so what we're trying to do is photo-disrupt just the pigment in the very front or the interior portion of the iris and do not harm to the remainder of the eye.

**Interesting, and then what is the safety profile of the device or the treatment today?**

Well, so far in 31 individual patients, what we've seen is that there's no complications that have come out of the procedure. We're monitoring a patient based on things like their intraocular pressure. We're looking at the pupillary response, the size of the pupil, reactions of the pupil. We're taking a look at the eye health in general before and after. We study each of the patients we have on 17 individual metrics and we study them one day after the procedure, one week after the procedure, one month after the procedure, 3 months and 6 months, and so far, we haven't seen any complications. And, as a matter of fact, what we've seen in our latest group of patients in Costa Rica, where we're doing our adaptive study, we've seen actual drops in their intraocular pressure on a consistent basis.

**Interesting, so when did this recent study commence - this is a fairly recent study?**

Yes, we're currently in the process of completing an adaptive study in Costa Rica. The study is being completed at Clinica 20/20 with Dr. Claudio Orlich and we're currently finishing up the adaptive phase. We should be finished up with that phase in the next month and a half, and then we'll move to a full iris. In the adaptive phase, we're treating a one eighth segment in the iris and we're titrating the laser energy to optimize it for safety and to make sure we can get the aesthetic results that we really want.

**I see. So the first one is just a portion of the eye, one eighth, and then the next one will be a more full-blown, will be a complete eye?**

That's correct. And we'll treat the full iris and again, we'll wait for a period, a three-month period, to follow up on the patients to make sure that there's no complications that have come out of that. And then what we'll do is we'll advance to a 120 patient multi-center study.

**Interesting. And when do you expect that to, I guess finish the 120 patient study?**

We anticipate that the study will be completed this time next year. We also anticipate that once that study is completed, we'll be submitting data to the various regulatory bodies around the world. Our whole intention at this point is to get our CE Mark first and then to get those countries that honor the CE Mark around the world and then start the marketing of the technology.

**Interesting. So do you have patents on this technology?**

Yes, so far we've got two patents that have been issued, and eight that are currently in process on a global front. We're looking at really reinforcing that over the next couple of months with some of the things that we've learned to really enhance the safety and effectiveness of the technology.

**So how different is this technology from --- and what safety measures do you have in place now to ensure that this is going to be safe and when will you really know for sure if it's safe? Is it going to take a year after someone's had this procedure or is it just three months or a little more?**

Well, sure. The answer to that is the safety profile from our medical advisors - we've been told that most of the complications that could potentially come out of this procedure are going to occur probably within the first 48 hours. But we intend to study these patients for over a year and one of the studies is going to extend over a ten-year period to ensure eye health. You know our biggest concern is to make sure that we have no complications that could come out of the procedure. And a lot of the safeguards that we've put in place, like the eye mapping and tracking procedure - a portion of the procedure - are really designed to ensure that there is no damage to the eye at any point in the procedure. And, in addition to that, we've got optics which are more or less say create a super galveant?? beam, which allows us, in fact, to shine a light literally right into the pupil and do no damage. So the idea behind what we're trying to create right now is to create something that's going to give us an added safety margin on each aspect, each critical aspect, of what could potentially happen to a patient.

**Okay, interesting. So can you tell us a little bit about your organization and the team and who's executing this plan?**

Sure. One of the key aspects of the company is really the people who are involved in the company. The founder of the company is Dr. Greg Homer. Gregg had this idea back in 2001 - he actually got the initial patents right around then. Greg is a brilliant scientist and has been a key contributor in almost every aspect of the business to date. Other players in the company right now - Don Robinson was a global vice president of manufacturing and R&D at Boston Scientific, so we've got a fairly heavyweight crew on the science and technology side. Many of the engineers, the optical engineers and laser engineers, were actually members of the team that developed the first interlace laser, so it is very helpful for us to work with the folks who have an awful lot of experience in this space and who've been able to really refine this technology and ensure that it's in fact a safe and effective procedure.

**When do you think that these products would be available on the market?**

The product should be available to the market once we get our CE Mark so it's really going to depend on the completion of the clinical trials and also the completion of our ISO audit, which should be completed by the end of the first quarter, 2017.

**Again, the ISO audit - can you explain to us what the ISO audit is?**

Sure. In order to get our CE Mark, we need to have our manufacturing... first of all, well, you have to have a design that's frozen, and then we have to have a GMP that basically documents that the product that's being built is going to be exactly the same product each and every time. So it's a way of ensuring that the quality of the product remains consistent throughout.

**Right, okay. Could you tell us a little about the business model? How does the business model work in this product?**

Our product is going to; the business model we're going to be using is very similar to the Lasik model. What we do is we actually sell the consoles to the physician or the physician's office, and then what we do is we charge a clip fee for every patient that comes through. And that clip fee is going to depend on the area of the world that we're in, but we're going to use pretty consistent clip fee throughout. And so

the idea is to have both the console sold as well as a clip fee that we get for each of the patients that comes through.

**And so will the physicians then be, in a sense, distributors, will they have a region or, you know, from their perspective, why would a physician or ophthalmologist want to take this on?**

Well a lot of it has to do with their current practice. If they've done a large refractive practice, it really doesn't change too much, and there's tremendous synergies within the organization, as to how to handle the patients, how to handle the marketing of the technology. So in those cases, there's not a big add as far as the cost is concerned, and there's a big upside as far as the number of patients they can pull through for this procedure and additional procedures.

**And how has the company been financed to date?**

To date, the company's been financed through a combination of founders' money and a convertible debt. And right now the company is raising approximately 5.5 million dollars via the convertible debt note, of which we've raised approximately 5.1 million of that convertible debt note. We should be able to, with most of the existing investors in queue right now, pretty much be able to complete the convertible debt round. But we're still in process and so we want to finish that off probably within the next 60 days.

**Interesting. And that funding will be enough to take you through the 120 patient trial?**

No. The idea is to take us through the 20-- the second -- the phase 2 trial and then take us through to the financing of the company. We're going to do a Series B financing as soon as we've completed our full iris treatment. At that time, we'll be going out to the market to do a Series B financing of 15 million dollars.

**Okay. And so that would be sort of estimated to be -- when would that Series B be approximately?**

We'll be doing the Series B in late June, early July, and the idea is that we'll try to coordinate a lot of different sources to get the funding raised in that time period with the idea that we'd like to close it out certainly by the beginning of August.

**Okay. So basically you're right on the doorstep now of a Series B financing - a \$15 million financing - that you want to get done by the end of this summer.**

That's correct.

**So, from an investor's perspective, what are the likely exits, what's the upside, why would this be a good investment for investors today?**

Well the exits and the potential exits for this are kind of in three different pockets. But the largest and probably the most logical is going to be an exit through one of the strategic players in the States. If we are to remain as an independent entity, which - our goal is, first and foremost, to become a profitable business - so, I think that the most important element for us is to build some critical mass up within the product line that we have right now, and that's going to be the first real exit opportunity, per se. The second exit opportunity is going to be to exit through a strategic player, and the third will be to exit through the public market.

**Interesting. Okay well it sounds like you have a very exciting project ahead and thank you so much for joining us today.**

Thank you for having me, Brett.

---

Interview has been edited

Sign up for [OneMedMarkert Newsletter](#).