### Ron Myers:

Hi. This is Ron Myers from The Consulting Room. And today I'm interviewing Sue Darcy who's the director of I-Smart Developments. I have known Sue for many years and wanted to talk to her today about a novel LED mask that could help bolster online retail sales for those Consulting Room members who are still actively talking to their customers during lockdown. So hi, Sue. How are you?

### Sue Darcy:

Hi. I'm good, thanks Ron, Thanks for inviting me today.

# Ron Myers:

I know you're really busy at the moment, so thanks for your time as well. I wonder if you could just give us a potted summary of your background and how you started working with LEDs?

# Sue Darcy:

Yeah, no problem. So I'm a qualified research scientist, but moved into more of the commercial side about 10 years after I qualified as a biochemist. And then I ended up working in a startup company called Sage Therapeutics, which some people might recall developed Omnilux, which was the first LED really that did any clinical studies at all. So we published 34 peer reviewed studies, because there wasn't a lot known about LED when we first started. We actually were asked by Cancer Research UK to develop a light source that was LED to activate a drug called 5-aminolevulinic acid for non-melanoma skin cancer. And that's how Omnilux was really born. But how it moved into different indications was quite novel really.

### Sue Darcy:

When we were doing the clinical studies at the Christie Hospital in Manchester, we were treating people's non-melanoma skin cancer, and they were coming back and asking the doctor if they could have their other leg done because the skin looked so good around it. And we all thought, "Wow, this is pretty good. What's going on?" So then we started to look at whether it was actually the drug and the light or whether it was actually the light, because obviously you can see some opportunities there, for not just laser treatments or IPLs, but also for LED. And that's what we developed, and have been developing, for over 20 years.

### Sue Darcy:

So we were the first guys at Omnilux that discovered 830 and 633 for wrinkles. We discovered red and blue for acne. Originally people started looking at just blue, but then we combined it with red to reduce inflammation. And in another company, also LED, we also developed the very first cold sore Herpes Simplex 1 treatment using LED, which was sold in Boots, and is the only LED actually to have a FDA clearance for this.

### Ron Myers:

Wonderful so you've got a huge amount of expertise. And in fact actually for our clinic as well, years ago the first LED device that we bought was an Omnilux treatment. Really interesting actually, because you always knew when that machine was on, because you could see the light underneath the doors. It was so powerful. Incredible.

### Sue Darcy:

A great machine and still regarded by a lot of clinicians as the gold standard of LED. And mainly because we are still the only LED in over 20 years that published so many clinical papers. Because we were all a bunch of sad scientists that really were interested in it. And actually that's going to continue, that's started again now with I-Smart Developments as well, because it's something that we're really committed to.

# Ron Myers:

Well that's pretty amazing, it's refreshing. I mean, I'm a big fan of evidence-based medicine and I'm a scientist myself as well. And I think that there are too many things now that are sold more around marketing rather than around actually proper evidence around whether they work or not. So you've got a huge amount of knowledge and experience around LEDs.... tell me a little about this new mask that you developed recently and why you've done it.

# Sue Darcy:

Okay. So obviously a lot of the LED devices that are out there at the moment in the professional sectors are bigger canopy style masks, like Omnilux were and like Dermalux. And there were lots of little masks popping up all over the place that were saying that they have seven wavelengths, and they did this and they could basically go to the moon and back. And I one day just walked in the office and I thought, "You know what? This is making a ridicule of 20 years worth of work and lots of money spent on clinical data." Because nobody was actually doing any more clinical studies, they were just talking about wavelengths and saying, "Here's an LED that will work."

### Sue Darcy:

And I just didn't want that because that isn't what LED should be about. Proper LED should be, they are, a medical device and they should've been researched accordingly. And so I said to the girls in my office, "Right, we're going to build a mask. What would we like?" So there were lots of hard masks out there, but mostly people were saying, "We want something that's flexible. We want something that can travel. We want something that works, and we want something that's easy to clean, easy to use."

### Sue Darcy:

And so then we came up with our faceLITE device which we're about to demo for you. But one of the key issues for all of us was that we didn't want to compromise the efficacy. And so we really concentrated on our medical heritage, which was Omnilux. And we absolutely used all that knowledge that we had, we extrapolated the sorts of energy that we had to deliver. Because one of the things that people overlook, who don't know anything, who build LED to sell them but don't actually know anything about them, is that it's not just wavelength specific, it should be energy and obviously proximity to face. Because all of those things affect the dose that you deliver.

### Sue Darcy:

Not many people refer to the dose of an LED, but that is the crucial bit. Like I say to people, you don't take a bottle of aspirin if you've got a headache. You actually take a set amount, and that's exactly what you should be doing with light. I used to listen to people saying, "I've got the most powerful LED in the world." So what? That doesn't matter because LED works through a bell curve distribution. So on one side it will stimulate, so if I want to treat my skin and stimulate things, then I use it at a certain level. But, if I want to then treat a keloid scar, I'd use a very high level of energy because that would inhibit. So it

has different mechanisms according to what indication you treat. And that's why I wanted to try and put LED back on the map with some clinical research behind it, and not just stop in the cosmetic side but also try and move more into helping people with burns, helping people with wounds.

### Sue Darcy:

Our consulting business, which also does FDA clearances for lots of different companies. That's one of the things that we will commit to, going forward, will be a wound healing LED device. And this flexible technology that we developed is going to be ideal for that, because obviously Omnilux is a very big machine and we all knew it worked but it wasn't really flexible for a hospital setting. So now we're excited about the future really, and getting things properly regulated.

#### Ron Myers:

Brilliant. Okay. So Sue, could you just tell me with this new flexible mask, what does it treat? And are there clinical trials to support the technology?

#### Sue Darcy:

Right. So we started with masks that just had the 633 which obviously is a collagen stimulator, and it also has 830 which is the two wavelengths that are clinically proven to treat wrinkles at a specific energy. We don't put any other wavelengths in there because with our main indication to treat in the US, we're cleared through the FDA for full facial wrinkles. Over here we are just classified as a cosmetic device still, because obviously with the new regulations with the MDR, us not yet having to adhere to those. So, we're still a cosmetic device. And actually nobody knows yet whether wrinkles with an LED device will move into the medical device category. I don't even think the notified bodies know yet. But we're quite happy for that to happen, because obviously if you've got FDA on an LED, you have to test to a medical device standard anyway. So if you've got to do that, why not make it for the whole of the world?

#### Ron Myers:

Yes, I would agree.

### Sue Darcy:

From a safety point of view, I do think that it needs to have that control. And the reason why I think that is because I think there's a bit of a ridiculous situation at the moment, especially in Europe, where we have devices that have got blue light in, where actually blue light carries some eye hazard. And people don't often look at that properly, and they can just say that they are treating spots, become a cosmetic device and still be allowed to sell. And in my view that is not good. What they should do is if they want to use blue, and they want to treat acne, they should classify the LED as a medical device right now. But companies that don't understand LED are getting around that and actually putting the consumer at risk.

### Sue Darcy:

I've had several conversations with the MHRA about it, and it really needs to change because where you've got blue light which carries some eye hazards, you really need to have the proper eye protection. And that's why I'm campaigning for that really, because I think the consumer needs to be safe. For ours, even though we test to all the proper medical device standards, but the ones for the eye hazards, we went over and above that. Because obviously we're now treating nearer to the face, so we did lots of extra testing for that. Of course, not only did we do medical device testing, then we also did all the

necessary household appliance testing. Because obviously it's cosmetic over here. So our devices got lots of testing, got LGSB, it's got Chinese GB, it's got loads and loads of stuff.

### Ron Myers:

Which is fantastic, especially because this is obviously designed to be a retail product. So people are going to be utilising this in their own home. So I think that's incredibly important, that whatever people are buying is proven to be safe and effective. Especially in today's world where you can buy anything from anywhere on the internet.

#### Sue Darcy:

Absolutely. And some of the things that give us a lot of comfort is that, as I said, we published a lot of papers. But also, when we built this mask, we used the energy levels and the wavelengths that we used in Omnilux. We duplicated that into our mask, and all we did was adjust that energy level for treating near to the face instead. So, we know the safety profile of those two wavelengths very well. And that's one of the reasons actually why we started with red and infra-red, because we know the wavelengths well and we didn't really want to get into the acne market just yet. Not with a light device, because we had already done some studies where we were using a project like we've got where we use a sodium hypochlorous product as a spray for the acne, to kill the bacteria. And then just use the inflammatory side of the acne to be treated with the light. We've got some good results on that. We're not using blue then, we're just using red and infra-red.

#### Ron Myers:

Brilliant. So could you show us quickly how it works, please?

#### Sue Darcy:

I could. So, here it is. So this is called FaceLITE, it looks a bit like you can wear it on Halloween as well. It's completely flexible. You can see all the LEDs, the LEDs in here are bi-LED so they deliver two wavelengths. Which means that we can have less LEDs in the actual mask, because two wavelengths are coming on as one diode. It's very, very easy to use. It has a controller that operates the mask. You can see how much charge there is in the battery. It's a simple on and off switch that switches it on, and then it controls it for 10 minutes. Inside here is all the software that makes sure that we pulse our lights in here for a reason. And we also have some temperature safety software in here as well, so that it would always cut out and not overheat, which again is very important. So basically, that's it and then you switch it on for 10 minutes.

Ron Myers: Just 10 minutes?

Sue Darcy:

Yep.

Ron Myers: And how often would you do that?

Sue Darcy:

So in our studies where we combined twice a week for four weeks with Omnilux, we did three times a week for 10 minutes with this light and we got similar sort of improvement in wrinkles and the other cosmetic improvements like skin tone and so forth. We've done two of our own studies, which we haven't published yet because we've got some exciting stuff to publish at the end of the year that we're going to put together in a whole publication. But we also have developed this little hydrogel mask. So one of our studies is with the hydrogel, and one of our studies is with just the mask. And what I would say is, this hydrogel, you don't need to use every time that you use the mask, but probably once a week. Because it has got hyaluronic acid in and it's great for moisturising, from the moisture point of view.

# Sue Darcy:

So when we use this, our hydration levels that we tested were much higher afterwards. It's a nice product, you can put it underneath. What I would say, if anybody was using this in the clinic where you're not treating on intact skin, or where you've done micro-needling or something like that, this is a great barrier to put over and then use your mask.

### Ron Myers:

I believe you are developing some other versions of that as well, is that right? For other areas?

# Sue Darcy:

Of our devices, yeah. So our new one that's coming out next week is for the neck and decolletage area. So, for the lines and wrinkles. So you can see it does this area where there's always lots of sun damage. We actually recommend, because we're looking at pigmentation here mainly, we actually recommend a six, our studies were six weeks in duration, not four weeks. So actually we recommend a little bit of a longer treatment with that. Of course, one of the things that we know about LED that we didn't know when we developed Omnilux, is that LED treatments are cumulative. So you really want to keep using it regularly. So that's why we're saying to clinics now, "What we should do is treat this as part of the skin care routine."

# Sue Darcy:

And we should be saying, you're prescribing a course of microneedling, some peels, this skincare to use at home. You should be saying, "Use this at home." Because if they can use it three times a week. They can bring it back to the clinic if they're coming in for a peel or a microneedling. And actually, people are loving that because it's something to them just to put into their normal routine. And I mean, when we launched Omnilux first of all, in Japan, it was actually called the Happy Light because obviously red lights raise the serotonin. So in these lockdowns this is quite a nice little addition.

### Ron Myers:

I can imagine.

### Sue Darcy:

People are enjoying doing it. For the clinics and salons now it's a great way to stay in touch with your clients. Some of our other people that we have dealt with have actually branded it, so they'll brand it to themselves if they want. It's a great addition because it enhances things that you're doing already.

Ron Myers:

Excellent. Okay. So I know that you've already told me that a number of clinics are already successfully selling these online now, even during the lockdown. So could you just tell me how that works from, if a clinic wants to buy some of these, how that would work from a pricing point of view?

# Sue Darcy:

So they get in touch with us, and obviously it depends how many they want to buy. If they just want to buy one to try first of all, and then put it out there to their customer base. But they don't want to be concerned with delivering it and then taking the payment or whatever, we will sort all that out. They can just phone us up, we'll deliver one to them to try first of all. And then they can present it to their patients, and then we'll just deliver it directly to the patients and that's it. There's no commitment to any amounts. Sometimes, and what we've found now that clinics are selling quite a lot, if they still want us to deliver but have a better price because they're buying 10 or 20, we're happy to do that too. So the pricing changes a little bit on volume. But our Clinics are doing well with it because with what's happening now, it's a great opportunity to stay in touch with your clients but have something that actually works

# Ron Myers:

I know a lot of people are at the moment also doing Instagram webinars, Facebook webinars, that kind of stuff. Some live events. And I suppose this is something that's a little novel and different, apart from just talking about skin care. So just so I can clarify, just roughly then, can you give me the wholesale price band and then the retail price band please?

### Sue Darcy:

So, it varies on volume as I said, between £150 and £200. And we retail our product online at the moment at £349.

Ron Myers: £349. Okay, fine.

### Sue Darcy:

We've got obviously our warehousing and our shipping, we do charge this... If a seller ordered, we would charge them to deliver it to their customer as well. Because that's something we have to pay, carriage. But it just means that they don't have to worry about anything, we'll do it all. So they can just give us a ring and we can talk them through how to do it anyway.

### Ron Myers:

That's wonderful. So it's nice and flexible from a clinic's perspective at this point in time, which is probably really important. If they really can't get kind of get out and get this in the post themselves.

### Sue Darcy:

Absolutely. We've got the setup already going, so it's fine. I mean we're delivering to some clinics over to France and Holland. So they're talking to all their friends, I think. Not just the customers.

### Ron Myers:

Okay, Sue. Well thanks. I mean, I think personally, it's a really nice novel different idea. And I know that with your heritage in this as well, it's absolutely a quality product. And I think that's the key thing. If you're selling anything now to consumers, you want to make sure that it's a good device that's evidence based. So, that's fantastic. So what I'll do at the end of this, I'm going to include your details as well. And so if anyone wants to get in touch with you, they'll have your details direct. But, I really appreciate your time. Thank you very much for this.

Sue Darcy:

Thank you for inviting me.

For more information about the device or to order a sample email: Sue D'Arcy - <u>s.darcy.ismart@gmail.com</u>

To view videos on the LED mask visit: https://www.youtube.com/channel/UCyI\_gtEsb45G\_qqkQ61d0HA