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COMPANY INTERVIEW

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Miramar Labs, Inc. (OTCMKTS:MRLB)

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Miramar Labs, Inc. (OTCMKTS:MRLB)



R. MICHAEL KLEINE is President and Chief Executive Officer of Miramar Labs, Inc. Mr. Kleine has been with Miramar Labs since February 2014. Mr. Kleine is an established leader with a proven track record of success in leading several global biomedical companies. With nearly two decades of experience in C-suite positions, he has experience commercializing new technologies, increasing revenues and growing organizations. Previous positions held include President and CEO roles with EndoGastric Solutions; Sorin Biomedical; Biosensors International Group Ltd., a publicly traded company; Thermo Cardiosystems, which was acquired by Thoratec; and MicroVention, a startup, which was acquired by Terumo.

SECTOR — HEALTH SERVICES

(AZZ601) TWST: Would you provide a brief overview of the company and its core technology? How does that technology differ from the current standard of care?

Mr. Kleine: The company was founded in 2006 at The Foundry, a medical device company incubator in Silicon Valley, and is headquartered in Santa Clara. After conducting extensive market research, the team identified that underarm sweat and odor represented a huge opportunity, as most people around the world are concerned about their personal hygiene. The more research we conducted, the more we discovered it was an aesthetic issue that had significant gaps left by the available solutions.

These solutions include surgery, which is extremely invasive and wrought with complications. There is Botox, which requires over 30 different injections under the arm, and is only good for approximately six months and still fails to address odor. Then, there are the antiperspirants and deodorants that are inexpensive but have minimal efficacy and require daily application.

miraDry is a microwave solution to noninvasively go after the sweat, odor and hair in the underarm. It is a very simple, safe and effective procedure that offers patients immediate and durable results. It takes about an hour to an hour and a half, is affordable for patients as an aesthetic procedure and also has an attractive ROI for doctors. A real advantage for the company is that it is the only noninvasive, FDA-cleared treatment for the reduction of underarm sweat, and the only FDA-cleared device for permanent reduction of underarm hair of all colors.

The reason hair of all colors is important is because lasers that are most often used for permanent hair removal are very color- and skin-type-specific, with a very poor effect on blonde hair, gray hair and fine hair, as well as on patients with darker skin types. Microwave energy is completely agnostic to hair color or skin color because it goes down to the hair bulb itself and destroys it. miraDry is also the only noninvasive treatment available for permanent reduction of underarm odor glands and has the potential to compete in other areas of the aesthetic marketplace.

TWST: On the sweat indication, is it geared toward

somebody with just a little bit of excessive sweat, or is there actually a clinical condition that it is targeting?

Mr. Kleine: There is a medical condition called axillary hyperhidrosis treated by dermatologists, and those individuals sweat much more than the average person. What we have actually found is that the \$18 billion antiperspirant and deodorant marketplace is really geared for people who are bothered by sweat, and that has little to do with their actual amount of sweating. I've spoken with a lot of physicians, and what they have seen is that the amount of sweat a person experiences isn't as always as important as much as the person's perception as to how much their sweat bothers them. For example, a physician may see a woman that notices a yellow stain on her white dress and becomes concerned that her antiperspirants or deodorants are ruining her clothes, or the antiperspirants aren't working, or she's simply concerned about the chemicals contained in deodorants and antiperspirants. So she seeks another option that will reduce or eliminate these concerns for her.

TWST: Your most recent financials were \$17.2 million in 2015. Can you talk about whether those are all from sales of the device and how the sales model works?

Mr. Kleine: Let me tell you first how the sales model works. We have taken a very patient-centric approach that allows physicians to offer an affordable procedure with a high level of patient satisfaction, which is very important for a practice to generate a profit. As reported on RealSelf.com, which is a very commonly used and unsponsored aesthetics review website, our device has one of the highest patient satisfaction rates at over 90%, and that outpaces almost every other aesthetic procedure reviewed on this site.

The way we have the treatment set up is such that the physician does not have to perform the procedure. It can be done by a nurse or PA in the clinic who can be trained properly on the device. This is highly desirable in aesthetics as it frees up the physician to do other tasks.

As you look at our numbers, in the last fiscal year, about 57% of that is generated from console sales, meaning the actual capital equipment, and approximately 43% is from consumables. Almost every quarter, we see our consumables utilization growing.

The other very exciting thing about Miramar is our global

presence. Of that revenue number, about 43% comes from North America, and about 57% is outside of North America. Of that 57%, Asia is almost 35%. We just received regulatory approval in China a short while ago and are just now starting to open up the China market. Our early indications reflect that the markets in Asia are really embracing this technology due to the social stigma around sweat and odor.

“In the U.S. alone, there are over 10,000 U.S. aesthetic physicians, and we have approximately 350 installed machines. The potential is for every one of these physicians to offer miraDry at their practice. We have nothing but growth potential.”

TWST: How were you able to get such an international distribution so quickly?

Mr. Kleine: I wish I could say it was quickly; it has been a long process in markets like China, where a lot of aesthetic companies have not gone, which I think will hurt in the long run because it is such a large and important market. When you look at our regulatory milestones for sweat reduction, we were FDA-cleared in January of 2011 and received CE mark clearance in December of 2013. In China, we received regulatory approval toward the latter part of 2015. We are hoping to get a favorable U.S. FDA review on axillary odor reduction in the near term, which would enable us to expand our labeling of the product.

If you look at my bio, I have run a number of different companies successfully, which allowed me to learn about and live in or spend a lot of time in several international geographies. So from my view point, it is extremely important to not just be U.S.-centric. The way that companies grow is by having a very good understanding of the value of a strong global presence, which we have, and that is why we are approved in more than 40 countries.

TWST: Can you talk a little bit about the market potential in terms of the installed base possibility relative to what it is now and tell us anything else about how you would characterize the product’s potential?

Mr. Kleine: I look at what we have here as similar to that of LASIK. When LASIK first came out, people thought it would be a niche market and wouldn’t really catch on. Of course, as we know now, LASIK has very much caught on and is a common everyday procedure.

Let’s just talk about the U.S. In the U.S. alone, there are over 10,000 U.S. aesthetic physicians, and we have approximately 350 installed machines. The potential is for every one of these physicians to offer miraDry at their practice. We have nothing but growth potential. This is not just another aesthetic laser machine. It is a very unique microwave energy device that is FDA-approved, with a strong clinical profile backing it up. We offer a physician the opportunity for a new procedure in their clinic that the other machines and/or procedures just cannot address.

Furthermore, an exciting aspect of microwave technology

is what we can do outside of the underarm with the same console. We have done first-in-man studies in palm sweat. As we talk to dermatologists and plastic surgeons in our customer base, we find that there are people who have severe palm sweat for which there are no commercially successful treatments.

The vision is that, long term, we will own the sweat space; however, the potential is there with our technology to compete in many other sectors of the aesthetic space. For example, we are also looking at ways to go after hair of all colors outside of the underarm. We are looking at using this technology for acne as well. It makes every possible sense because of the way the microwave works and gets down under the skin to destroy the target gland, whether it be a sweat, odor, hair or acne gland.

TWST: Do you know how many aesthetic centers there are in the United States and maybe what percentage of that you might have?

Mr. Kleine: We did a study back in 2015, and we estimated that there were around 10,000 U.S. aesthetic physicians. So given our installed base, we have around 3% to 4% penetration overall, which means we still have a significant opportunity for growth. This is what has us all excited because we believe in the growth potential as we build market awareness. If you were to ask me what the key challenge of my company is, I would say that we have a great opportunity here due to a phenomenal product that has a high patient satisfaction rate and a high physician clinical satisfaction rate. The challenge is that we are limited in our ability to get the word out, so we are strategically using social and other digital media to help do that.

TWST: You just talked about marketing and generating demand. I would think there would be more demand in hot-weather climates near the equator, or does your data indicate that demand is not driven by that?

Mr. Kleine: At first, I thought this would mainly be driven toward women. But we have done well over 55,000 procedures, and the demand split is about 60% women, 40% men, which surprised me. Also, the product seems to be doing exceptionally well in Asia. But even in some of the areas such as in northern Europe — where you would believe that people do not really sweat that much because it is not that hot — you see some of our stronger sales occurring.

If we look at antiperspirants and deodorants, that represent almost an \$18 billion global market, about 10% of those are categorized as clinical-strength, but if you look at the consumer satisfaction, it is only about 20%. So you have people, probably even in cold weather, who naturally just feel very uncomfortable about their sweat and odor, and they feel that the efficacy of the deodorants and the antiperspirants just aren’t there. The dissatisfaction doesn’t come as much of a surprise as for an antiperspirant, which only has to be 20% effective to be labeled as an antiperspirant. Also, you have to put those products on every day, whereas miraDry is a one-time procedure with 80%-plus efficacy, or almost three to four times more efficacious than what an antiperspirant provides with a daily application. Also, with miraDry, you get the added benefit that it destroys the odor glands.

TWST: Who is your competition, and how are you differentiating yourself?

Mr. Kleine: If you're just talking about sweat, then my competition is, of course, primarily antiperspirants and Botox in the U.S., and additionally surgery in Asia. There are also companies coming out with prescription topical solutions to address the sweat problem, but the topical solution has the same problem as Botox, as they are temporary, and they don't treat odor.

"The initial FDA-cleared miraDry system was first launched with the focus on treating excessive sweat in the underarm. What we learned was that the miraDry treatment not only eliminated the sweat glands but odor glands and hair follicles in the underarm."

On a broader scale, I view my competition as every other aesthetic procedure that is being marketed by the clinics. If you are a physician running a practice who wants a high patient satisfaction rate and, at the same time, bring profit into your practice, you are going to wonder whether to buy another ZELTIQ machine that goes after the fat or get this new miraDry device. Do I buy another Ulthera for the chin, or do I buy a new laser to remove tattoos? I believe these treatments represent our competition in the practice because we have to go in, knowing that the market is there, to convince the clinics that this is a technology that they definitely want in their practices because they can make more money doing a miraDry procedure versus another procedure.

So again, it is kind of a broad-reaching statement on my behalf, but in reality, that's kind of where it is. If you and I were running a clinic and we have \$100,000 to spend on the next machine, we are going to talk about what is going to bring in revenue for us and, at the same time, give us strong patient satisfaction. And we believe miraDry stacks up incredibly well in this analysis.

TWST: In hair removal, aren't there competitive lasers already available? And as part of your sales pitch, are you telling a person running the clinic that the device can do several things at once, meaning to reduce sweat and odor as well as hair?

Mr. Kleine: The initial FDA-cleared miraDry system was first launched with the focus on treating excessive sweat in the underarm. What we learned was that the miraDry treatment not only eliminated the sweat glands but odor glands and hair follicles in the underarm. Since our initial launch in 2012, we received FDA clearance to permanently reduce hair in the underarm and are awaiting FDA clearance for treating odor in the underarm. We see this product as being able to address multiple indications with a single treatment.

If you watched the Dr. Oz segment on miraDry that aired last November, you saw a young lady with a tank top come on and talk about how excited she was about her hair removal in the underarm. So you're absolutely right, that is what she talked about. Lasers didn't get it. She had fine hair under her arms. For patients with light hair under their arm, our system is the only option they have, and this is the message we are going to start to get out.

We have an advertising campaign called miraSmooth directed toward people who want to take advantage more of the hair removal in the underarms. So instead of saying miraDry, we say miraSmooth to emphasize that it removes the hair. But at the end of the day, it is the same machine and disposable that treats the reduction of sweat, hair and odor.

TWST: You talked about new indications being your growth strategy. Can you maybe expand on that and tell us the next indication? Would it involve co-development deals, and if so, are you seeking one right now and for what purpose?

Mr. Kleine: Right now, we are not looking at any co-development deals because our growth strategy is focused on making a strong impact in the sweat market. We are extremely underpenetrated in the underarm market, and as we build awareness, the growth of the company will greatly expand from that. That said, we are looking at ways to do things. Like I said, we have already done first-in-man studies on palm sweat, which would use the same console combined with a different hand piece.

In terms of other indications, as we get the funding, we are looking at possibilities that I mentioned previously, such as acne and light hair on other parts of the body. But right now, we are a small company and very focused on the tremendous growth opportunity in just the sweat and odor market on a global basis. The key for the company is to build market awareness.

TWST: What do you want a potential investor in Miramar Labs to know today?

Mr. Kleine: Exactly what I look for when I am an investor. I have always felt that any investment really has to hit four critical areas. First of all, look at the market. I come from a farming background where you can have the best seed in the world, but if the field is not fertile, then nothing will grow. You can have the best technology in the world, but for whatever reason, if that marketplace is just not fertile, you can't expect sales to grow. So if you look at the aesthetic marketplace, it is direct to consumer, and it is exciting with a lot going on. It is fertile. Merz purchased Ulthera two years ago for \$600 million. You look at ZELTIQ, which is currently about a \$1 billion-market-cap company. Aesthetics is strong and strong all over the world. In Asia, aesthetics is extremely strong.

Next, as an investor I would ask: Is it an innovative technology, or is it coming in with just another me-too technology? What is different? Microwave technology has been broadly used in medicine in neurology, cancer and for hypothermia, but it has never been used in aesthetics. I look at how the microwave technology works and whether it is innovative.

The third piece I look for as an investor is one that I believe every company has to have: strong clinical evidence, strong regulatory approvals and a strong patent portfolio. miraDry is built on a foundation of very sound clinical data that the FDA has cleared with strong regulatory acceptance on a global basis and a strong patent position. We have over 37 worldwide patents, including 11 U.S. patents. We have 84 active trademark patents. So the company believes it is in an excellent position from an I.P. perspective.

The last and the most important piece is the management team and the employees. You can have all those other three things that I just talked to you about — great market, great innovative

technology and strong clinical data — but if you don't have the right people to help you succeed, you may not. So I would ask your investors to look at the management team of Miramar, starting with myself on down, and you will see a core group of people that know how to win and have very, very successful track records.

TWST: Thank you. (KJL)

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