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Faster and Healthier Healing



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Interview conducted by: Lynn Fosse, Senior Editor CEOCFO Magazine "Here at SanMelix, we have been able to combine science and nature to create the ideal wound care solution."- Diana Sabacinski

CEOCFO: Ms. Sabacinski, what is the concept behind SanMelix Laboratories, Inc?

Ms. Sabacinski: Here at SanMelix, we have been able to combine science and nature to create the ideal wound care solution. We are a buckwheat honey-based bioactive wound care company.

CEOCFO: Before we talk about your solution, would you tell us a little bit about the problem of wound management today?

Ms. Sabacinski: There are three major problems that are global threats that our product addresses. The one that we have focused on has been the diabetic foot ulcer in our case studies and the internal research that was done. There are 26 million estimated diabetics that will develop diabetic foot ulcers. Of these, 15% will have amputations and 47% will end in death. You have a better five-year mortality rate with certain cancers than you do if you have an amputation from a diabetic foot ulcer.

In addition, it also treats radiation burns. 85% of all cancer patients will have severe to moderate skin reactions to radiation. Our products will help with that pain and suffering. The third problem addresses the antimicrobial resistance (AMR) crisis. It is projected to have 10 million people die from these super infections by 2050. Honey has no microbial resistance, so it treats and kills these super infections such as MRSA.

CEOCFO: What is it about honey that allows for all these good things to happen?

Ms. Sabacinski: Honey has been used for its medicinal properties since ancient times. It is actually recorded on cave walls in 8000 BC. It has anti-inflammatory, anti-oxidant, and tissue regeneration properties along with antimicrobial activities. Honey was used for wound healing until the discovery of antibiotics. Now, the overuse of antibiotics has resulted in the antimicrobial resistance (AMR) crisis. The resurgence of honey is coming back because of its natural antimicrobial properties.

CEOCFO: What is in honey, and particularly the buckwheat honey that you use? Do we know why it works? Does it matter if we know as long as it works?

Ms. Sabacinski: It has three major healing functions: debridement, antimicrobial and skin regeneration; it is really difficult to get all three of these together. This is why it is an ideal wound care solution.

Buckwheat honey inherently has hydrogen peroxide for the antimicrobial function. However, most of the medicinal dressings have manuka honey, which has methylglyoxal in it. This is where we have added our science. We put a standardized dose of methylglyoxal in addition to hydrogen peroxide in our dressings.

Once we look at all the antimicrobial properties, then we look at the anti-oxidant, anti-inflammatory and tissue regeneration activities. Buckwheat honey has higher anti-inflammatory, higher anti-oxidant and higher tissue regeneration than manuka honey products. It kills the bad cells, keeps the good cells and preserves them, and helps to regenerate the skin. Therefore, it is crucial to have all three functions in order to have the best wound care outcome.

CEOCFO: *Is the medical community paying attention?*

Ms. Sabacinski: What has happened is something that you often see with natural products, and why we patented our formulation to combine both nature and science. You have to have a proper dose so that you really are comfortable that you will get the same results every time you use the dressing. In order to have a predictable outcome and have evidence that it will be consistent, you need to use a little bit of science. That is why you combine both. Anytime you have an antimicrobial and tissue regeneration, it is a balancing act.

If you look at all wound care products on the market, they just address one of these functions. Either they have an antimicrobial to prevent infection such as silver dressings; or they provide tissue regeneration such as collagen, but they do not have an antimicrobial component; or they purely do debridement of the wound. We are the only wound dressing that does all three, and once we get through evidence based clinical trials, the medical community will agree this is the best solution. When we met with the Navy, the Army and the Air Force in panel meetings, they referred to our wound dressing as the "Holy Grail"!

"We have high margins, a large market, IP protection, but even more than that, what is so important is that our products are going to save limbs, they are going to save lives, and again, they are going to increase overall health and happiness."- Diana Sabacinski

CEOCFO: Do you have the products now? Do you have prototypes? Where are you?

Ms. Sabacinski: Yes, we have prototypes. We have done case studies. Dr. Kenneth A. Sabacinski, DPM, MHS, FACFAS, who is my husband, is a Harvard trained podiatric physician, and he has been working in this area for thirty years. He has the expertise in wound care. He did his residency in Boston, at Harvard and the Joslin Diabetes Center. He used our dressings for his case studies and had amazing results on diabetic foot ulcers. They usually take thirteen months to heal on average, but it took thirteen weeks to heal using our product. In all the case studies on our website, the patients were recommended for below the knee amputations, and they healed in weeks. After we received the results, we were very excited about the product. We also have a prototype of our radiodermatitis product.

We are following a 510(k) FDA regulatory pathway. The Air Force is doing all the 510(k) testing on the wound dressing. It should be done by Q1 2020. Then with our radiodermatitis cream, we will also need to do 510(k) testing.

CEOCFO: Are you seeking funding, investment or partnerships as you move forward?

Ms. Sabacinski: Yes. We are currently in the funding stage. We were one of the presenters at the MicroCap Rodeo event in Austin, TX. Right now, we are in the midst of an equity crowdfunding campaign. We wanted to give the public the opportunity to help us heal others, and the campaign is at www.startengine.com/sanmelix. We will also be looking for a preferred stock offering when our crowdfunding is completed.

CEOCFO: How do you stand out at a conference, when there are so many companies with so many ideas? How do you garner the attention you deserve?

Ms. Sabacinski: We like to stand out by telling people, "Why would you invest in SanMelix?" We have a unique patented formulation. It is being tested by the Air Force because they are interested in it. We also have superior clinical outcomes based on case studies. Everybody usually knows somebody who has either had a super infection, a diabetic foot ulcer, or is going through radiation therapy. We honestly feel that it is a huge market estimated to be \$13.5 billion in 2026; so, it is a good investment and margins are high.

We have high margins, a large market, IP protection, but even more than that, what is so important is that our products are going to save limbs, they are going to save lives, and again, they are going to increase overall health and happiness. Therefore, we feel that is a good reason to invest in our company.