CEO CFO

Harbor MEDTECH

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With an Application into the FDA for Marketing Clearance for their Next Generation Tissue Regeneration Products for the Wound Care Field and the Surgical Mesh Field that attack the out of control Inflammatory Process allowing for the Body's Normal Healing Process to Proceed, Harbor MedTech is well positioned for Growth

Healthcare
Wound Care

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Jerry Mezger
CEO

BIO:
Founded by Jerry Mezger, who has spent the past 30 years as a medtech executive. Founded or restarted several catheter and several heart valve companies now part of Boston Scientific, Medtronic, Radiometer, and others.

About Harbor MedTech:
Focus on next generation Tissue Regeneration products**.** Products to restart, support healing of difficult or chronic wound such as diabetic, venous and pressure ulcers as well as hernia patches and orthopedic soft tissue repair. Over 3 million Americans each year are treated for chronic wounds such as skin ulcers. Skin ulcers come in several primary forms as complications from serious diseases.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Mezger, you have a considerable history in this area; why Harbor MedTech today?
Mr. Mezger: Harbor MedTech was a company that I formed after leaving NeoMend. NeoMend was another venture capital-backed company that I was asked to turn around, and I completed that turnaround in 2010, after getting FDA approval for the only lung air leak sealant in the United States. Once I completed that mission, it was time for me to move on and start another company, and so I started Harbor MedTech basically with a blank sheet of paper. There were a number of things that I learned over the years that I wanted to do that would contribute to a rapid accumulation of shareholder value, and other things that I wanted to avoid that would detract from a rapid build of shareholder value. I took a look around and I worked with some colleagues to identify some opportunities, and found an opportunity in the biologic advanced wound care field that made a lot of sense to me. It is a field that the demographics are well known, and very favorable. Patients that are diabetic, along with an aging population, all of these add up to be very large market opportunities for advanced wound care products. I found technology to meet the opportunity for these advanced wound care products that meant that we could build and commercialize products with a high price point, high profit margins, , and all of these products typically qualify for rapid, 510k review and approval by the FDA.

CEOCFO: Would you tell us a little bit about the products; what is different and what have you found that is not currently available today?
Mr. Mezger: Let us focus on the topical product skin wounds, where today's leading products are human cellular-based products. They are expensive to manufacture, they are expensive to get into the doctor's hands, they are difficult to store, difficult to use, and they require repeat applications. It is an expensive therapy in the treatment of these chronic skin wounds. The most well known chronic skin wounds are diabetic foot ulcers—a frequent complication of diabetes. What we have figured out is that the healthcare system really wants a more efficient, and a more cost effective solution for treatment of diabetic foot ulcers. Our product is designed for a one-time application, as opposed to repeat applications. It is also designed for application to the wound on the day' of presentation, in other words, the first day that the patient shows up at the hospital to be treated. In contrast, the leading products in use today are not approved for use until the patient actually gets worse. For those products, the patient has to go chronic over a period of four to six weeks before the leading products are even approved for use on these pa-

tients. We will be applied on day one, and we are a one-time application, as opposed to repeat applications. Not only will we get the patient on the road to recovery four to six weeks sooner, but also we will do it at a fraction of the cost.

CEOCFO: What is happening scientifically to enable this to happen when it has not happened before—the quick healing, and the immediate use?
Mr. Mezger: We are taking a different approach to biologic wound care products, where the leading products today attempt to deliver various wound healing factors, or growth factors into the wound to stimulate wound healing. Instead, what we are doing on day one is attacking what we think is the root cause of why these wounds do not heal. That is the inflammatory process is out of control in these chronic wounds. What our product does is it acts like a wet blanket on a fire, quiets the inflammatory process, and by doing so, it allows the body's normal healing process to proceed.

CEOCFO: Is it the concept of the inflammatory process being a problem, as well as the solution that is new to MedTech, or have people not found a way to implement a solution?
Mr. Mezger: We are taking a different approach here, because another product gave us the clue. There was another product that came out several years ago called Unite®Biomatrix; it is a product similar in design to ours, designed for another application. Doctors started using that product off label, and they were getting remarkable results. They did not really understand why until they looked more deeply into it, but they were getting remarkable results. Unite®Biomatrix finally got approval for use on these chronic skin wounds, but the product was not effectively marketed by the company making the Unite®Biomatrix, and ultimately the product was discontinued due to just a lack of marketing attention. Our product is similar in design but with significant design improvements. When we get to the market in 2013, we expect to find a number of doctors ready to use it, and eager to use it, because they are familiar with how it works.

CEOCFO: What are the steps between now and the marketing?
Mr. Mezger: We have our application into the FDA for marketing clearance, and we are hopeful of getting marketing clearance in the first quarter of 2013. We are in frequent communication with the FDA, and so we have a high level of confidence we are going to get that approval. We are going to market the product directly to hospitals and wound care specialists; this is in contrast to the Unite®Biomatrix product, which was never really marketed directly to hospitals and wound care specialists. We expect a rapid adoption of our product once the doctors see how well it works, and understand the mechanisms that make it work.

CEOCFO: When you are approaching a hospital, does your history come into play, or is it just the product itself?
Mr. Mezger: We know the product works. There is excellent published data on Unite®Biomatrix product that has shown that biologic products like ours works and we have added to our management team a sales executive with tremendous experience in selling wound care products. He knows all of the issues, he knows all of the competitive products, he knows all of the customers, and he knows how to build a very effective and efficient sales organization. We are relying on him pretty heavily, but he has got some tremendous experience, and we are very optimistic about 2013.

CEOCFO: There are a number of other applications that you are either thinking of or working on. What else can be done with the bridge technology?
Mr. Mezger: One of the things that we are very deliberate about in setting up Harbor MedTech is choosing a technology that was a true platform technology, capable of supporting different types of products. In addition to the topical wound care field, the other primary use of products out of the BriDGE technology will be biologic surgical meshes. Our products will be unique for a biologic surgical mesh, in that we have figured out how to manage the stabilization of the collagen in the surgical mesh such that we can manage the rate at which these biologic surgical meshes are resorbed within the body. They are designed to retain very high strength throughout the healing process, but then be totally resorbed within the body. To our knowledge, no other product is capable of doing that that is available today.

CEOCFO: Are you funded through the next step or will Harbor MedTech be seeking additional funding?
Mr. Mezger: We are funded through getting FDA clearance of our first product, the topical wound care product. Right now, we have just started efforts looking for the next stage of funding, and that stage of funding will come in after we get FDA clearance, so that stage of funding will reflect the fact that we have removed regulatory risk from our investment profile. We are looking to raise $5-10 million to fund the commercialization efforts of the advanced wound care product, and to fund the completion of development and commercialization of the surgical mesh product.

"We offer a couple of "shots on goal" for Harbor MedTech investors. One is the wound care field, and the other is the surgical mesh field. Either one of these fields represents a great opportunity for us."- Jerry Mezger

CEOCFO: Is wound care in favor these days with investors in your industry?
Mr. Mezger: I have lived in the venture capital medical device field for thirty years, and I have seen various cycles where one field in favor to the exclusion of others. For instance, in the 90's everyone wanted interventional cardiology products, then in the last decade is seemed everyone wanted spine and orthopedic products. Those cycles have come and pretty much gone. What I am seeing now is a shift to the wound care field, driven by these favorable demographics: An exploding diabetes population,

obesity, and generally an aging population throughout the world. These wound care products are going to be gaining a tremendous amount of favor. They are also typically straightforward inaudible products through the FDA, so there is a lower regulatory hurdle to get these products into the marketplace. All of that is adding up to a field that is going to see tremendous growth and tremendous attention amongst investors over the next five to eight years.

CEOCFO: How does the need for cost reduction in medicine they play into what you are doing now?
Mr. Mezger: It is very important. You really have a difficult time introducing new products into any of these healthcare fields if you cannot show cost improvement over today's therapies. That was a primary strategy for Harbor MedTech is we were putting together our business plan: Go to market with products that offer not only better performance, but also better performance at a lower cost. In our case, we found something that offers much better therapy at a substantially reduced cost in therapy to these patients. It is crucial particularly over the next decade to show that your products offer more efficient and lower cost therapy.

CEOCFO: We speak with many companies in your industry. Why should they, as well as investors and people in the business community, pay attention to Harbor MedTech?
Mr. Mezger: We have important, patented technology. We are targeting a medical field we think is going to see explosive growth over the next decade. We received our first funding just a year ago, and we are going to get our first FDA approved product having spent only a little more than $1 million getting there. That is almost unheard of, and I would say it is a testimony to how good our business plan is, how efficient our management team is, and how efficient we are for the investors into Harbor MedTech. For investors looking for a place to get involved, I think we represent an excellent profile.

CEOCFO: Do you have any final thoughts?
Mr. Mezger: I would just like to add that what we offer is a couple of "shots on goal" for Harbor MedTech investors. One is the wound care field, and the other is the surgical mesh field. Either one of these fields represents a great opportunity for us. They also represent terrific strategic partnering opportunities. Our business planning calls for us to get both of these products in the market in 2013, and achieve profitability and self-sustainability by the end of 2014. We see not only rapid growth, but also a rapid progression towards profitability, and all of this bodes well for new investors coming in.

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