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With their E-Matrix Scaffold Tissue Regeneration Technology that was Previously Commercialized now in Late Stage Development for Diabetic Foot Ulcers (DFUs), MxBiodevices, LLC is well positioned to enter this Large Wound Healing Market

Medical Devices
Wound Management
(Private)

Dr. Ronald Hill
Managing Partner

BIO:
Dr. Ronald Hill, Managing Partner has more than 13 years of experience guiding the technology commercialization efforts including fund raising, partnering, IP development, regulatory approvals, pre- and post-marketing clinical study management and overall management of the Greenville NC operations and 20 years of medical device experience from start-up to Fortune 50 companies. After obtaining his doctorate in Cell Physiology at the University of Illinois Champaign-Urbana, Dr. Hill worked for 6 years at Baylor Medical School in Houston and was Diabetes Core Laboratory Director at Baylor's Diabetes and Endocrine Central Research Center. Dr. Hill moved to the Baxter Healthcare corporate research group where he received the Baxter Outstanding Scientific Achievement award and later joined Baxter's spin out in California, Neocrin, developing a bioartificial pancreas for diabetic patients. He moved to North Carolina 13 years ago to lead the development of E-Matrix. Dr. Hill has 12 patents and 8 patent applications, more than 60 publications and presentations at national and international meetings and has been awarded more than $2M in NIH funded grants. Dr. Hill is on the Board of Directors of the NC Center of Innovation for Nanobiotechnology.

Company Profile:
MxBiodevices was formed in 2009 and has acquired the exclusive rights to a patented tissue regeneration technology for the treatment of chronic dermal wounds including diabetic foot ulcers (DFU's). The product is an injectable nanoscaffold that has been shown to heal DFU's in two IDE based clinical studies. MxBiodevices' product will be a significant advancement in therapy for this costly and devastating medical condition representing a more than $6 billion wound healing market worldwide. MxBiodevices is actively pursuing a $3M financing to commercialize this product.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Hill, what prompted the creation of MXBiodevices?
Mr. Hill: We have an opportunity with the technology that we have worked with for many years to impact a major complication of diabetes, diabetic foot ulcers. The technology that MX has licensed is a scaffold called E-Matrix. The E-Matrix scaffold was developed by a company that I worked with for many years, Encelle. We were developing this product for use to treat diabetic foot ulcers and we had completed two clinical trials with good results. In 2007 Encelle was acquired by Pioneer Surgical. Pioneer Surgical is an orthopedic and spine company and they were interested in the technology for use in orthopedic and spine applications. They focused the development path on orthopedic and spine trials. From 2007 until now, we developed E-Matrix products for orthopedic and spine that resulted in six products FDA cleared that are now available through Pioneer Surgical for use in spine and orthopedic surgery. Pioneer, as part of the acquisition of Encelle, agreed that the former board of Encelle which consisted of Jim Woodward, former CEO and president of Encelle, Dennis Dougherty of Intersouth Partners, and John Koerner of Koerner Capital, three of the board members from Encelle, would retain the right to license the technology in

therapeutic areas outside of Pioneer's field. Having worked with the Encelle board for a number of years, they knew us and our capabilities, and in February of this year agreed to license the technology to MxBiodevices for DFU's giving us the opportunity to again pursue the use of E-Matrix for the treatment of diabetic foot ulcers. Diabetes is an area that I have worked in virtually my entire career, except for that period when I was working with Pioneer for orthopedic and spine products. Diabetic foot ulcers are a potentially devastating complication for many diabetic patients. We have a product that we believe can be an effective treatment for DFU's.

CEOCFO: Could you explain the technology for us?
Mr. Hill: The technology consists of an engineered scaffold structure. To repair injuries the body needs a structure to build new tissue on. E-Matrix uses naturally occurring biological molecules that make up the extracellular matrix of tissues in the body. These molecules are reassembled into the scaffold structure that is implanted into the area of the body that needs repair. Cells recognize this structure, crawl into it and begin the repair process. Basically, we are providing the framework for cells to start the wound healing process.

CEOCFO: How does that differ from what is available today?
Mr. Hill: The answer is fairly technical. We have a number of patents that involve how we manufacture the scaffold to produce this unique structure. Competitive product also uses this connective tissue- collagen. Collagen provides the basic structural element for the tissues of the body. Collagen is synthesized as a triple helical structure, three interwoven strands, analogous to the DNA double helix with two interwoven strands. How our product differs is that other products use intact collagen and we take the triple helix apart to single stranded molecules and then crosslink those with a very high molecular weight carbohydrate, essentially a large sugar molecule, to form our scaffold structure. This synthesized scaffold is the product that provides the structure for tissue repair.

CEOCFO: Where are you in the development and commercialization process?
Mr. Hill: The plan going forward is to commercialize by first obtaining regulatory approval in Europe and follow that with a Pre-Market Approval by FDA in the United States. We have completed two clinical trials, a feasibility and pilot study, under an Investigational Device Exemption (IDE) from the FDA. There were a total of sixty-two patients in those two studies. In order to get a US Pre-Market Approval (PMA), we will need to do complete a pivotal clinical study which we estimate will require a total of three hundred patients. In Europe, we may have the necessary data based from our US clinical data for regulatory submission. We are in the process of determining whether additional clinical data will be required in Europe. We are still working with the appropriate Notified Body to determine whether we need the additional data. We just came out of the gate in February when we acquired the license and I left Pioneer in March to pursue this opportunity full time. We are fundraising right now. The plan is to raise a three million dollar round to fund regulatory clearance in Europe and launch the product with a marketing and distribution partner in Europe. Then, based on success in Europe fund the US pivotal trial, PMA approval and product launch ideally with a multinational strategic partner in addition to venture capital funds.

It is a unique opportunity from an investor's point of view. It is a late-stage product- no manufacturing development is required, but an early stage investment. - Dr. Ronald Hill

CEOCFO: Does it help that the technology has been used by other companies, or is it about starting from scratch in both medical community interest and investor interest?
Mr. Hill: The advantage of other companies having used the product is it reduces regulatory risk. The regulatory agencies have seen it already in another context, so that is helpful. For example, in Europe the product has a CE Mark as a bone graft. There is another company that is using the product for reducing scarring and it also has a CE Mark for this indication. In the US, we have an IDE for diabetic foot ulcers with the FDA which defines our US regulatory pathway. Another key advantage is that the product is currently being manufactured in an ISO certified/cGMP facility and no manufacturing development is needed.

CEOCFO: Has the investment community as well as the medical community been paying attention to MxBiodevices?
Mr. Hill: Yes. Just recently have been selected for two venture investor meetings- the Mid Atlantic Bio Conference in Bethesda at the end of September and the Southeast Bio Conference at the end of October in Palm Beach Florida. We also have received a company inception loan from North Carolina Biotechnology Center. As a new company just out of the blocks, we appreciate this early support. There is a recognition that MxBiodevices is late stage product with no manufacturing development required, but an early stage investment opportunity. We are in the process engaging both local investors in Eastern North Carolina and more broadly to investors nationally.

CEOCFO: What is most important that you have learned in your background that you can draw from for this project?
Mr. Hill: It is an understanding of the process of successfully commercializing a medical device. I am a PhD in cell physiology from the University of Illinois and then worked at Baylor College of Medicine in Houston. I was then recruited to work in the Baxter Corporate Research Group in Round Lake, Illinois. We were working on technology to improve biomaterials and understand biomaterial interactions with the body. This technology was spun out into a startup company in southern California and I moved from Baxter to southern California to participate. I came to North Carolina in 1999 to lead E-Matrix technology

development. This has given me a broad overview of what it takes to find partners, raise money, manage clinical studies and navigate regulatory pathways. In summary, its the overall experience of taking a product to commercial success that gives me confidence we can now successfully commercialize E-Matrix for the treatment of diabetic foot ulcers.

CEOCFO: Why should investors be interested and why does MxBiodevices stand out from the crowd?

Mr. Hill: It is a unique opportunity from an investor's point of view. It is a late-stage product- no manufacturing development is required, but an early stage investment. The product is being manufactured in a cGMP ISO-certified manufacturing facility in Eastern North Carolina- no manufacturing development is required. Investors will leverage funding that supported the successful commercialization of this product for orthopedics and spine and invest in a Series A funding round for commercialization of E-Matrix for diabetic foot ulcers and other chronic wounds. The pathway forward is clearly defined- European approval and launch followed by PMA approval and launch in the US. Previous success limits development risks: intellectual property- covered by issued patents; manufacturing- no manufacturing development required; preclinical work- done; and regulatory risk- 6 FDA cleared and 2 CE Marked products using the technology. MxBiodevices is building on previous successful commercialization to bring E-Matrix to the multi-billion dollar diabetic foot ulcer market.

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