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The Most Powerful Name in Corporate News

Porous Polyethylene Implants for Craniomaxillofacial Indications

Aaron Noble
CEO
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CEOCFO: ***Mr. Noble, would you tell us about Poriferous?***
Mr. Noble: Poriferous is a medical device company that specializes in manufacturing of porous polyethylene implants, indicated for the use in craniomaxillofacial indications.

CEOCFO: ***Would you explain what the porous polyethylene implants are and what they do?***
Mr. Noble: The implants are open and porous to allow for tissue to integrate into them so it becomes part of the person's body. The tissue is actually growing into the implant itself, which is called integration. When that happens it serves to stabilize the implant and prevents scar pocket formation what would typically be with solid nonporous implants.

CEOCFO: ***Is this your SU-POR surgical implants?***
Mr. Noble: Yes it is.

CEOCFO: ***What are some of the variations in this type of implant and what do you offer in SU-POR that is a cut above others?***
Mr. Noble: Because our indication is for all of the cranial facial skeleton, we produce parts that are used across many different specialties from plastic surgery to neurosurgery and oral craniomaxillofacial surgery as well as osteoplastic surgery. These specialties use our chin implants, cheek implants and Malar implants, implants that are used to restore the volume of the orbit following the removal of an eye, as well as cranial implants if someone suffers a traumatic injury where they lose a section of their skull, and we produce a replacement component for that in this porous material.

CEOCFO: ***Are there many companies that provide a similar product?***
Mr. Noble: Historically there has only been one and that was the original company that our team all worked for. That company was purchased and then all the employees were left behind in our hometown. I founded Poriferous in 2012 and reassembled the team of key personnel to create Poriferous and to restart the product manufactured here in Georgia.

CEOCFO: ***Have people come back to you for the product?***
Mr. Noble: Many people have come back. We are once again working with what we used to call the champion surgeons, the leaders that helped develop the shapes and ideas of the different products that we now sell. We have reached back out to these surgeons and have been welcomed warmly.

CEOCFO: ***What is the market opportunity?***
Mr. Noble: Since 1985 when porous polyethylene was initially introduced, there have been over four hundred thousand procedures performed. There are 350 peer review articles that have been written about the use of porous polyethylene in craniofacial applications.

CEOCFO: ***Are you surprised that others have not made a similar product?***
Mr. Noble: It does have a lot of trade secrets associated with the manufacturer of the product. These are processes that require know-how and understanding about porous polyethylene, but it's almost important to understand the end user and the surgeons' use. That is a key advantage that we have because I used to be the senior product engineer for the company previously that was purchased and the experience has allowed me to leverage that further in working with surgeons.

CEOCFO: ***Would you give us an example of what a surgeon might be looking for that you are able to tweak a bit so it is exactly what they need?***
Mr. Noble: We manufacture an ear implant that is used to restore the ear. This is typically for patients that are born with a condition called microtia, which is a fancy word for little ear. The shape of the ear is very different for every person. There was typically an ear implant system made up of two parts that would be customized for each particular patient, so I have been working with a surgeon to come up with a new set of ear implants that makes the technique easier so that we can continue to teach new surgeons how to do it and reduce the technical difficulty associated.

CEOCFO: ***Would you tell us about your distribution agreement with Minogue Medical?***
Mr. Noble: We are very excited to be working with Minogue Medical. They were previously the distributor of the porous polyethylene implants in a previous company that my team worked with. They have all of the experience associated with selling this product and the relationships along with it. Minogue Medical having a strong sales force in the Canada market is going to be key to us to provide a comprehensive coverage there.

CEOCFO: ***Did you need additional clearances to be selling into Canada?***
Mr. Noble: Yes we did. This requires many years of planning. It started initially with our Canadian certification for ISO 13485 CMDCAS. There were additional requirements for our technical file to be able to apply for the license in Canada. Once that was obtained, then we went through the application process with Canada in which we identified a distributor and had all the requirements in place in order to make it through that review.

"Poriferous is an exceptional company because of our drive to continuously improve our quality system and complying with all of our regulatory requirements, delivering excellence to our customers with processes, services and relationships."
- Aaron Noble

CEOCFO: ***Did you also receive a 5-10k clearance for patient specific surgical implants?***
Mr. Noble: Yes we did. The Patient-Specific implants 510(k) clearance covers the sale in the United States. This allows us to take a CT scan of a patient that is missing a section of their cranium or has a birth defect where they need an implant only to restore the volume of the cranial facial skeleton. We can take the CT and produce a 3-D model from the CT and then design an implant off of that data specific to the patient, produce the actual implant, review this with the surgeon virtually online or with the physical model and then deliver that product to the surgeon. Because of the competition in customized implants, we identified early that we needed to have an inside sterilization process. This was very important because the lead time associated with producing these implants in a timely manner for the surgeons is of importance. We went through the extra work of validating not only our implant products but also the sterilization system and we are proud to say we are one of the only manufacturers of this product to have all the processes associated in our facility.

CEOCFO: ***Is this all in the US?***
Mr. Noble: We offer custom implants worldwide. We manufacture in the US.

CEOCFO: ***Is that more important outside than inside the country?***
Mr. Noble: It is a balance. The US market is a strong one but this is a product that is used universally.

CEOCFO: Ar*e there other types of implants that a surgeon might use instead of polyethylene?*
Mr. Noble: Yes there are. Polyethylene has some advantages but the other products are 1020, which is a polymer which is used to produce these implants. The reason porous polyethylene stands out amongst these other materials is its integration potential to allow the tissues integrate which helps to stabilize the product but also its ability to be modified. The porous polyethylene and particular SU-POR above all other porous ethylene can be easily modified by the surgeon if there are any additional modifications required. For example, when a patient presents with a traumatic injury, there is often swelling associated with that where there is a section of the skull that is removed to allow for that swelling to subside before they go back and make the reconstruction. From the time of the initial CT scan, which is what we base our design on, until they come back in for surgery, that can be several months and it there can always be remodeling associated with the human anatomy from the time of the original CT until they were ready for surgery. Having an implant material that can be bent and shaped easily is very important to be able to make those last-minute adjustments to get an optimal fit.

CEOCFO: ***Do you have an inventory of standard pieces and then work on customizations as well?***
Mr. Noble: We have a standard line of off-the-shelf products. This is an extensive line that covers all the different types of indications. We then have the customized implant program as well.

CEOCFO: ***What is the shelf life of the standard products?***
Mr. Noble: The shelf life of our products is two years. Every year we expand that through real-time agent studies.

CEOCFO: ***How do you keep up with the medical side and regulatory issues that could come into play?***
Mr. Noble: This is what drives Poriferous. What drives our company is in fact innovation. Those opportunities come from our surgeons through their frustrations, where they have an idea or a concept that they want to try. We have laid the foundation for Poriferous to allow us to rapidly develop new products and to do this at the speed that will not frustrate the surgeons so the burden of having a new shape made is practical enough that the surgeons can act on those ideas, contact us and work with us quickly. We can produce those parts for them with very little frustration. You can imagine that typically with the very large manufacturers that can be slow to respond, the surgeon might not take the effort to try to get a design developed because the bureaucracy associated with it is too challenging. By opening up this opportunity of this direct working with our company, they can get those ideas to us and we can rapidly develop those ideas into both products specific for the surgeons needs as well as for new production products that can come from those collaborations.

CEOCFO: ***What surprised you as Poriferous has evolved?***
Mr. Noble: What is surprising the most is that there is more involved in getting your product to market than just getting your regulatory clearance and that is producing a high-quality product. I am a developer and an innovator so the sales side of our business is something new for me. I had to bring on additional team members that had the strength of being able to move the product because just from an innovation standpoint that does not always equate to sales.

CEOCFO: ***Did you realize that early on?***
Mr. Noble: I expected it. Just from the fuzzy front end if you will of laying out the plan for Poriferous, we expected about a five-year penetration in the market before we started to go. While that is a great deal of time for any startup company we are pleased to say that we are starting to gain ground quickly and we have not been to market for five years yet so we are moving earlier than the initial plan.

CEOCFO: ***What is involved in the manufacturing process?***
Mr. Noble: The basic principle of manufacturing is consistent with what has been done for many years with porous polyethylene. That is important because we do have an equivalency review with the FDA, which is how you obtain a 510(k) by demonstrating significant equivalence to an already cleared device. There are subtle process enhancements that we have been able to accomplish that allowed us to understand more of the science of how these products are made and to gain certain advancements. An example of that would be suturability and the ability to bend the material, which are some properties to SU-POR that have not been introduced to the market before. That same ability allows the material to be cut very easily with a scalpel so now the surgeon can readily carve and manipulate the material into the shape they want and those three main advantages add to the overall usability and ease-of-use of the product.

CEOCFO: ***Why is Poriferous an exceptional company?***
Mr. Noble: Poriferous is an exceptional company because of our drive to continuously improve our quality system and complying with all of our regulatory requirements, delivering excellence to our customers with processes, services and relationships. This is something that sounds like the goal of any company but with experienced professionals that we have, have made this particular product for so many years where I feel that Poriferous is doing a really good job of meeting that.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

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