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Issue: September 17, 2018

CEOCFO Magazine

Q&A with Dr. Nicholas Pashos, Founder and CEO, and Billy Heim, COO of BioAesthetics Corporation using Regenerative Medicine and Tissue Engineering to produce a revolutionary Nipple-Areolar Graft for Mastectomy Patients requiring Reconstructive Surgery

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CEOCFO: *Dr. Pashos, what is the idea behind BioAesthetics Corporation?*

Dr. Pashos: BioAesthetics' mission is to transform plastic and reconstructive surgeries through regenerative medicine and tissue engineering. Our inaugural produced is a nipple-areolar graft for mastectomy patients. Women who have undergone mastectomies to treat breast cancer will generally have their breasts or part of their breasts removed, including nipple-areolar complex (NAC). Therefore, we are developing a nipple-areolar complex graft without any cells that a plastic surgeon would simply suture onto a patient and patient's own cells grow into it and essentially regrow the patient's own nipple-areolar complex. This will greatly enhance the reconstruction of a patient's breast after mastectomy and impact the recovery process.

CEOCFO: *How does this work? What is the science behind it?*

Dr. Pashos: The science is essentially trying to regrow part of our human body. We need to understand how to regrow pieces of skin and blood vessels without using cells. Therefore, we start with donor tissue and we take donor tissue and remove all the cells and DNA from it. What is left is this protein matrix that is in the shape of a nipple-areolar and we engraft that back onto a living body or living biological model. We see that living cells grow into it and essentially take it back over and reestablish a blood supply and brand-new skin. It then becomes part of that patient's or a recipient's own body. The science behind it is making a graft, deriving it from a natural structure such as a nipple-areolar complex and engrafting it back onto another person and helping the body reestablish both skin and blood supply.

CEOCFO: *Would someone have to specifically donate that part of their body?*

Dr. Pashos: We are working with tissue banks right now. We work with tissue banks that then work with organ donors loved ones to get their permission to donate their nipple-areolar complex. It is much like organ donation.

CEOCFO: *Does it make a difference what part of the body people are thinking of donating or is it somewhat routine these days?*

Mr. Heim: Generally, when any organ or tissue is being donated they are either registered as an organ donor or the organ procurement organizations or tissue banks will go in and actually consent the deceased individuals' families. There are certain tissues and organs that are part of a standard recovery. Some of that includes skin and liver and things like that. However, like for us, the nipple-areolar complex is a nontraditional recovery, so we are a line item with the tissue banks for which the families are specifically consented.

CEOCFO: How does this work with the overall breast reconstruction and what, if anything, might be similar today? How is this area treated now?

Dr. Pashos: The current strategies to reconstruct the nipple-areolar complex are solely focused around nonliving and nonpermanent structures. Many times women can utilize prosthetic nipples, which are just rubber nipple-areolas that women can take on and off at nighttime. Those are nonliving and nonpermanent structures. A woman can also have a tattoo of an image of a nipple onto her reconstructed breast afterwards. However, these tend to fade over time and they are also nonliving, so from a side perspective or a side view there is no protrusion. It is only when it is straight on that it looks like a nipple. Those look like very fantastic reconstructions if you have a tattoo of a nipple-areolar, but that is not living and may fade over time, so it is also nonpermanent in a way. Or you can have a reconstruction of a nipple where they take pieces of skin from a different part of your body, like your thigh or arm or even part of your breast tissue and they suture it up to be a nipple protrusion or a nipple protrusion-like structure. With these you do get the structure intact, but they tend to lose that protrusion or the structural integrity within a few years. In addition, every surgeon will reconstruct the nipple slightly differently. A few surgeries will occasionally actually not work out, because it is a living tissue that is being transplanted from one part of the body to another, that is contingent upon a blood supply. Therefore, sometimes there are blood supply problems and that patient needs go back under for a revision surgery, so they need to be knocked back out and have their nipple reconstructed again. With that one it is a living structure, but it is also a nonpermanent structure, so the three main reconstruction methods right now are all nonliving and nonpermanent. However, BioAesthetics built this graft and developed this graft for a permanent reconstruction and a permanent structure that is living; both living and permanent. We have built it to work with the current reconstruction procedure in plastic surgeons' workflow. Just like they would reconstruct a normal nipple right now, where they prepare the wound bed on top of the breast tissue, the reconstructed breast mound, to do that skin transplant from another part of the body to reconstruct the nipple, instead of taking skin from another part of the body they would simply open up a package and take BioAesthetics' graft out and engraft that directly onto the patient's body. By doing this we will standardize nipple reconstruction during the last phase of a woman's breast reconstruction, so that everyone will have very similar outcomes with a living, permanent structure intact.

"BioAesthetics' mission is to transform plastic and reconstructive surgeries through regenerative medicine and tissue engineering. Our inaugural produced is a nipple-areolar graft for mastectomy patients... We want to help the breast cancer survivors and with more than three million breast cancer survivors currently living in the United States, this is a massive community that has gone through a tremendous amount."- Dr. Nicholas Pashos

CEOCFO: Your site mentions unique structure and that the collagen breast can be matched with a patient's preference. Is that size or shape?

Dr. Pashos: Every patient has a different style, shape for the nipple-areola as it is. No two are even the same or even on one patient they are slightly different. We have also noticed that when speaking to patients and also plastic and reconstructive surgeons that patients do have preferences on how big or what size they want the nipple, the areola or the protrusion of the nipple to be. Therefore, what we can do is actually create a catalog so that they can request, "We would like a nipple this big, this long," and try to match that patient's preference with a brand-new nipple-areolar.

CEOCFO: Why did you start in this area first or did you start with this and now want to move into other areas, eventually?

Dr. Pashos: This is actually a spin out from my PhD project at Tulane University. I had actually gone to school to work in a lab to regrow lungs outside the human body as an alternative to transplant. In that case we were taking organs from humans and removing all the cells and DNA, just like what BioAesthetics does with the nipple-areola. However, we were trying to regrow the lungs in a bioreactor outside the body. The idea was that we could regrow an organ inside the laboratory and transplant that organ to a patient. This would help subsidize donor/recipient numbers, because there are not enough donors to go around for lungs as there are recipients who need lungs. One night, about 2012/2013 I was watching a Netflix documentary, probably one or two o'clock in the morning and in the documentary they were talking about mastectomies. The patient and doctor where having a very serious discussion about the potential outcomes of the mastectomy and it was not having nipples anymore; that after a mastectomy that this patient would not have nipples anymore caught me by surprise! I did not really understand what a mastectomy truly was until I was watching that documentary. I stayed up all night to read about it and I came to the realization that there really were not living and permanent methods to reconstruct the nipple-areolar right now. I figured we could do what I was trying to do with the lung and transfer it over to the nipple-areola. Therefore, I switched my PhD project about a year or so into school to focus on the nipple and areola and I have been working on it ever since. That was about 2012/2013. I have focused on just

developing a graft that a surgeon would utilize in the surgery suite without any cell line; just the material. That is how BioAesthetics developed. Eventually I started a company in 2015 around it to understand what that market was, to talk to breast cancer patients and survivors, to get their take on the actual method itself and to talk to plastic and reconstructive surgeons. I sat in on operations to watch the reconstruction of the actual nipple on the breast to see if it was something a plastic surgeon would want to use as well. That is because at the end of the day, if we create a product that a patient does not want and that a surgeon does not want to use we do not have a product. It was important to get that feedback from both patient and physicians to begin with, so I got a small National Science Foundation grant to do over one hundred customer interviews and that is what we did. In 2015 I took off about three or four months of school and just traveled around and spoke with mental health professionals like psychiatrists whose patient clientele are breast cancer survivors. I spoke with breast cancer survivors, people who are currently undergoing mastectomies or undergoing reconstructions and spoke with multiple plastic and reconstructive surgeons to get all that feedback.

CEOCFO: *Where are you today in development?*

Dr. Pashos: Today we are transitioning over from research based to clinical based. We are finishing up in vivo preclinical efficacy trials. We want to make sure that what we put onto a woman or a patient is safe for them and does what we say, in that we are regrowing the natural nipple. We are in a preclinical model. We show very, very positive results in a preclinical model and our goal is to be first in human by this time next year. Therefore, we are building up the supply chain and processing room right now and then we will be going through with FDA filing to be in a person by this time next year.

CEOCFO: *What did you learn so far that surprised you?*

Dr. Pashos: I would say the thing that surprised me the most, being a scientist and being in the lab so much or being an engineer and being in the lab; you never really get to go and speak with people who are actually going to utilize a product that you are trying to create. I think the most surprising portion of this so far is how much of an impact we could actually make in the lives of breast cancer survivors! We get emails very often through our LinkedIn page, through our facebook, personal emails from the patients themselves, asking when it is available, what they can do to help, can we hop on the phone and just discuss where we are with it and asking if they can be put on a wait list. As a scientist and engineer being in the lab so much, that takes you back a little bit, because it is not just a project anymore. It becomes real to you. You get to see the faces of the people who it will impact. I think that is what is the most surprising. Both Billy and I are engineers and we have been in the lab, but definitely the most surprising and probably the nicest part of this job as well, is to meet the people that we may be able to help in the future. It is a pleasant surprise, actually having the opportunity to see the faces that are most impacted by breast cancer. Breast cancer survivors are probably the strongest people I have ever met in my entire life. They are not about looking backwards. They are always about looking forward and looking for the best for themselves and the rest of the breast cancer community. Therefore, it has been quite a treat, actually.

CEOCFO: *What are your plans on funding as you go forward?*

Mr. Heim: We are getting ready to kick off a Series A round in the third quarter. We will be looking for around four million dollars. Basically, the funding will take us into the clinic and get this on patients. Then in addition begin some sales and try to get more products distributed. We also have some research and development that we want to conduct on some future products for different indications as well as improvements to the current product.

CEOCFO: *When you speak with people in the investment community or the medical community do they easily understand what you are doing?*

Mr. Heim: It is much easier to explain than other science. However, from the invest community, to most people we have talked to, I think everyone understands the need and the impact that it could make on the patient. Then sometimes in terms of the science, I think it is relatively easy concept to understand for most people, just in terms of that we take a tissue with cells and remove the cells basically by washing it, like you would throw your clothes in the wash and remove any dirt. Therefore, it is very similar. We just wash it and we remove the cells and then we are left with a structure. I think some people do not quite get the concept that your cells live in this other material; basically a scaffold in your body that your cells live in and occupy and thrive in, so I do not go into that. However, we basically remove the cells, you are left with the scaffold and then you take that scaffold, just like a building, and then you repopulate it. People are familiar with organ transplants or tissue transplants like in orthopedics with ACL repair or bone grafts and things like that; I think people are relatively familiar with these things. However, in terms of taking a nonliving material, putting it on the outside of the body and then having a new living tissue within six weeks; I think people are very surprised, but appreciate it.

Dr. Pashos: Something that Billy and I always try when we have these discussions is to bring a sample of the actual product and once they see the actual graft of the nipple-areolar and we tell them, "This is not living at this time, it is just a material," it starts to make sense to them and they can start putting it together. One out of every eight women in the US is diagnosed with breast cancer. Generally, almost everyone knows someone or multiple people that have had breast

cancer and sometimes people do not understand what a mastectomy really is and what breast cancer patients and survivors have to go through. That realization and then showing them the product itself; then it begins to make sense to them. We have received very positive feedback from investors, plastic surgeons and patients; we have been very fortunate to be in a very supportive environment.

CEOCFO: *Why should people pay attention to BioAesthetics Corporation? What sets the company apart?*

Dr. Pashos: What sets us apart is that we are focused on, not just transforming plastic and reconstructive surgeries, but we are focused on the patient outcome. We want to help the breast cancer survivors and with more than three million breast cancer survivors currently living in the United States, this is a massive community that has gone through a tremendous amount. Therefore, if we can make the recovery just a little bit better I think that is something that that alone should be attention grabbing to plastic surgeons and investors alike.