CEO CFO

The Most Powerful Name in Corporate News and Information
ceocfointerviews.com
Issue: January 27, 2014

OriGen BIOMEDICAL

Medical Devices for Stem Cell Therapy and Cancer Treatment

Richard Martin - *President & CEO*

Today, OriGen is one of the worlds' leading suppliers of disposables for cancer therapies and ECMO catheters. Our products are distributed in over 80 countries, and we have dedicated sales staff covering the United States.

OriGen's mission, vision, and short bios of out senior staff are available on our website, but in summary we hope to be a force for positive change in the world, treating our employees, customers and partners with fairness, respect and honesty. We take great pride in the contribution our products have in making other peoples lives a little better.

OriGen received its first FDA approval in 1992, and commenced operations in 1997. Our first products were cell culture bags, and specialty critical care catheters for called ECMO. In 2003, we added our line of cryogenic freezing bags and in 2008 added a line of sterile-filled cryoprotectant solutions for use in cancer therapies such as leukemia and lymphoma.

We moved to our current location in 2010 a custom-built new facility. We expanded into the entire building in 2012, now occupying 45,000 square feet, more than doubling the production area, with several Class 7 cleanrooms and Class 4 sterile fill operations. From four employees in 2003, we have grown to a staff of sixty-five as of December 2013. Our rapid expansion has not gone unnoticed; OriGen has received growth awards from the Inner City 100, the Texas A&M Aggie 100, and the Inc 5000 for each of the last three years.

OriGen continues to grow by expanding sales of existing products and continually adding new product offerings.

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

CEOCFO: ***Mr. Martin: What is the concept at OriGen Biomedical?***
Mr. Martin: OriGen Biomedical is a manufacturing company. We manufacture medical devices for stem cell therapy and cancer treatment, primarily. We also have another business unit that manufactures specialty catheters for a respiratory therapy called ECMO.

CEOCFO: ***Are you making devices that are commonly in use? Are there other companies making the same device or is it more of a specialty item that you would be producing?***
Mr. Martin: Neither of our products are not consumer products. They are not in as wide spread use as some of the hospital supplies. Cancer treatment devices are used primarily by cancer researchers at this point. Immunotherapy is quickly becoming the fourth leg of cancer treatment. That means they actually take your stem cells, put them into one of our devices and they expand them from a few thousand to upwards of a billion. They basically teach those cells how to recognize cancer cells. Most of our researchers use your own T cells, give them back to you and those T cells then seek out and destroy the cancer tumors. It has been a fairly successful process and it has been fairly widely reported. It is, however, not as widely used as other cancer therapies like chemotherapy and so forth. Therefore, at this point our product volumes are fairly low. However, we could not possibly be in a better market for potential growth and product expansion. We do have couple of competitors in each of those product areas. One other device maker is in Germany. Another one is in France. We really do not have any other competition from US companies at this point.

CEOCFO: ***Does that make a difference for the hospitals? Do they care where their products are coming from?***
Mr. Martin: I would like to think so, but I think that for them, they just want to get the product that works the best. That is perfectly fair and that is exactly what we are aiming for.

CEOCFO: ***How does your product work? What makes it better?***

Mr. Martin: In the simplest terms, it is a plastic bag. It is made out of very special plastic and is useful for freezing the cells in liquid nitrogen temperatures, which can go as low as -196°C. If you were to freeze blood cells in liquid nitrogen; currently the red cross takes your blood cell donation, they put it in a refrigerator and it is good for between twenty and forty five days, depending on a couple of factors. If they were to put it into liquid nitrogen those same cells would remain viable for at least forty years; probably a couple of hundred. Therefore, the products that we make are very specialized to resist that rather extreme environment. Consequently, we make products for all sorts of applications, including the international space station, where temperatures can get pretty cold, too.

CEOCFO: ***How do you protect the product from the cold?***
Mr. Martin: We actually make the products to work in the cold. We use a couple of different kinds of polymers. One of them is ethyl vinyl acetate or EVA. That is a plastic that has fairly good cold resistance. Like almost everything else, it becomes brittle at a certain temperature. It goes through what is called "the glass transition" temperature. If you were to strike the product at that point it would break pretty much like a glass window. We also make products out of DuPont™ Teflon® or FEP and those products seem to remain flexible in that liquid nitrogen temperature, so there is much less risk of breaking. However, the downside is they are probably four times more expensive than the other less expense polymer.

CEOCFO: ***How do you reach the community that should know about you; the hospital community or the distributors; how do they know about OriGen and what you offer?***
Mr. Martin: We gave a dedicated sales force of five that covers the entire United States. Those are our employees; to they just talk about our products. They have a fairly extensive customer list of people who are doing cancer research and cord blood preservation. Therefore, we try to call on all of those customers directly. We also reach out to them in a number of different ways. We do some advertising and we also exhibit at a number of trade shows every year, to make new customers aware of our products and our presence.

"The primary advantage that we have is that our employees are really dedicated and we are really focused on the quality of the product." – Richard Martin

CEOCFO: ***Would you tell us about some of the other products, like the ECMO respiratory? How does that work?***
Mr. Martin: The technique ECMO is a therapy that replaces putting a patient on the ventilator. What you actually do is put a catheter into the jugular vein in the right side of the neck and that actually goes down in the right side of the heart. The catheter draws blood out of the heart. It runs through an ExtraCorporeal circuit, or basically like a bypass circuit. Oxygen is added to the blood and then it is pumped back and reinfused through the same catheter. Therefore the catheter has two lumens: one for drainage and one for reinfusion. That process obviates the need for oxygen exchange in the patients' lungs. In other words, they do not to use their lungs to get the oxygen delivered that they need to survive. Therefore, that allows therapists to do a number of therapies to their lungs without being concerned about the impact on oxygen exchange within the lungs. This is also very useful in diseases where the respiratory function is interrupted. If everyone remembers Bird Flu, most of the patients that died from that actually died of respiratory failure. Their lungs filled up with secretions that were extremely tenacious and blocked the oxygen transfer to their lungs and the patients basically died from respiratory failure. Therefore, with using catheter and with using ECMO techniques, many of those patients were salvaged. There was actually quite a very large effort in Australia to put most of those patients on ECMO. It really stretched the resources that they had, but they had a pretty amazing survival rate.

CEOCFO: ***How have you decided what products to offer and what areas to either develop a product in or license? How is OriGen structured as a business?***
Mr. Martin: We actually started by making ECMO catheters. I sold my shares in a joint venture I started in Germany. We were making heart valves in Germany and sold my shares in that to the marketing guys and then took the money and started OriGen. My background, at that point, had been in all sorts of medical devices, but primarily cardiac. Therefore, I got started in making catheters. We had originally started to look at making some coronary perfusion caterers when one of my friends, Dr. Bob Bartlett from the University of Michigan, called up and said, "We really need this. No one will make it for us because the market is so small." That is where we actually started; it was making ECMO catheters. It was a pretty interesting marketing decision, because if you looked at the historical data up to that point, the market for ECMO catheters has been growing about twenty to thirty percent a year for the last ten years. Therefore, all of our marketing students just take a straight line and draw that out. The year that we got in it absolutely went flat and it has been flat for the last ten years. Therefore, we did not make a ton of money, but we have made a huge impact. We saved a lot of kids with the catheters that we made. In 1990 we actually received FDA approval for an FEP Teflon bag to use for cell culture. DuPont pulled the material from use in medical devices for while, so we were sort of stuck on that. However, in 2002 DuPont released that back for limited medical uses; non-implant uses. We were able to proceed with manufacturing that product. Therefore, in 2003 we actually got FDA approval for the EVA bag to complement the Teflon bag. We have grown pretty rapidly since them. In 2003 I had five employees, two of which were part time. Now, in 2013 I have sixty-two full time employees.

CEOCFO: ***OriGen was recognized by the Inc. list so clearly business is good. How do you keep up the trajectory?***
Mr. Martin: Through a number of processes. One is that we actually do listen to our customers, rather than just give that lip service. We solicit new ideas from them. We get some pretty interesting development projects. We have got a couple of development projects in each of the business segments that we have that could be substantial. Therefore, we plan to continue to grow and expand our product line through new product development in those areas.

CEOCFO: ***What is next?***
Mr. Martin: We are going to expand the ECMO product line. Currently, we only make catheters for that product line. It is an industry that we understand very well and we are very friendly and familiar with almost all of the actual physicians in that industry, at least in the US. Interest in that technique is now spreading outside of the United States. There are societies in Japan and Europe that specialize in teaching ECMO. Therefore, we intend to expand that product, both internationally as well as adding other products to that line. We had originally only made three pediatric sizes of catheters and this year we will add three adult sizes of catheters. The adult ECMO market is growing very rapidly. Therefore, we continue to expand that product line as well. That actually makes us a bit safer to have a footprint in two rather diverse market segments. If there is a disruption in one or the other it really does not affect the company as much. Therefore, we plan to continue to expand in those two markets.

CEOCFO: ***Where do you manufacture?***
Mr. Martin: Everything is manufactured in Austin, Texas. We have several cleanrooms. We have a sterile fill operation. We have a very trained, dedicated, experienced staff and it is all done here. We now export our product to more than seventy countries throughout the world.

CEOCFO: ***Would you give us an example of some feedback that you got from a customer and the change that you made based on that?***
Mr. Martin: We continue to develop new products based around the products that we make. However, probably the biggest divergent product that we made is one that we make for the UK. It is a product called the CryoDoc. There are regulations in Europe that were promulgated and became effective a couple of years ago that say if you have the cleanroom in a hospital it has to be validated. That is a big expense. You have to validate the number of particles in the cleanroom. You have to validate the bacteria. You have to challenge the challenge the HEPA filters. It is really expensive proposition to maintain a cleanroom. Therefore, our response working with our customer was to eliminate the cleanroom. There is a technique called sterile docking which basically takes two sterile tubes and aseptically welds them together immediately. It means that you can connect cells that you collect from the patient to a set of tubes and connectors holding cryoprotectant so that you can add the cells and the cryoprotectants in a sterile manner, but you could basically do it in your office. Therefore, it has been a very big savings for the National Health Service in the UK. The product has been very well received as well. It basically means that they do not have to maintain and validate their cleanrooms, because they just do not use them anymore.

CEOCFO: ***Why does OriGen Biomedical stand out as a company?***
Mr. Martin: I would say that we really stand out because of our employees. Every single person here; every time they touch a product they are all aware that it is not just so much talk about the customer focus. Those products are actually used in life saving situations. We talk about that and talk about our ultimate customers, who are the patients in cancer therapy or in an ECMO setting fairly frequently. Therefore, I really think that the primary advantage that we have is that our employees are really dedicated and we are really focused on the quality of the product. That shows up whenever someone rips open a pouch of one of our products and pulls something out. They can see that we really care about what we are doing.

BIO: Richard founded OriGen Biomedical in February of 1996. Taking an ever-growing education and life/work experiences in engineering, leadership, management and an entrepreneurial spirit he sought to do two things–improve and innovate the design and manufacture of life-saving medical technologies AND create an excellent workplace for his employees.

Engineering experience in the biomedical industry involved product research and development; and management of production/manufacturing and quality for companies such as Baxter-Travenol Labs, Alcon Labs, Shiley Inc., Hemex Scientific. A growing interest in improving on mechanical heart valve medical devices led to executive level and co-founding positions in Pacific Biomedical in Singapore, Jomed Implantate GmbH in Germany and Jostra USA.

Richard received a BS in Mechanical Engineering from Texas A&M beginning his career as a Navigator with the Electronic Warfare Office of the United States Air Force flying a variety of aircraft during and after the Vietnam War. He received his MBA from Pepperdine University. He also holds the recognition of Registered Mechanical Engineer and as a Certified Quality Engineer.

OriGen Biomedical
7000 Burleson Rd Bldg D
Austin, Texas, USA 78744-3202
512.474.7278
www.origen.com