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Mechanical Ventilation Alternative for Increased Mobility and Quality of Life

Martin Dobelle - *CEO*

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

CEOCFO: *Mr. Dobelle, what is the vision and concept at Avery Biomedical Devices?*
Mr. Dobelle: Avery Biomedical is presently a single product company. We have the Avery breathing pacemaker, which is a phrenic nerve stimulator, also called a diaphragmatic pacemaker. It is an alternative to mechanical ventilation. There are a number of conditions, primarily spinal cord injury, where mechanical ventilators are often thought to be the only manner of respiration available. However, our device offers a range of advantages over mechanical ventilation and our primary objective at the moment is to simply make the medical community aware of us.

CEOCFO: *What is happening with your device? What have you figured out to change the whole way it works?*
Mr. Dobelle: Regardless of which diagnosis it is, all of our patients' root problem is that they cannot breathe independently. It could be a spinal cord injury patient whose neural connection has been severed, for example, or a central apnea patient whose brain, for lack of a better explanation, simply forgets to breathe at certain times and doesn't recognize the lack of oxygenation. Rather than place these patients on bulky, risky, and expensive mechanical ventilators, we recommend our breathing pacemaker. The device stimulates the patient's phrenic nerves, and thereby their diaphragms, and allows for a more natural breath as opposed to a ventilator or other positive-pressure ventilation system simply pushing air down a patient's airway. Our device greatly increases mobility and quality of life while decreasing medical complications and the associated costs.

CEOCFO: *How does the device attach to the patient?*
Mr. Dobelle: There is an external pulse generator that we call the transmitter. It is roughly the size of a VHS tape, and it has two antennae that are a meter long each. Those antennas are affixed to the patient's chest and send radio frequency waves through the skin to the completely internal implants. The radio frequency waves are converted by the implants into electrical pulses. This is where you'd be better served in speaking with a neurologist, but the electrical stimulation triggers a natural process within the nerve that activates the diaphragm.

CEOCFO: *Where are you in the development and commercialization process?*
Mr. Dobelle: The technology, in its broad form, was actually developed some time ago and it has gone through only incremental changes since then. Of course we have had various versions of the device, iterations and upgrades over the years, but the technology remains fundamentally the same. Like any other similar company, we always have research and development in the back of our mind. At the same time, however, we passionately believe that this technology works so well, and has stood the test of time, because of its simplicity. We don't want to over-engineer it unnecessarily. I have heard doctors complain about this phenomenon where companies come out with updated and more intricate versions of their products, probably just to demonstrate that they are staying ahead of the curb, but where the design changes don't add practical value and only serve to over-complicate things. Physicians are receptive to our device, in part, because it's simple. Surgeons like implanting our device because it's simple. Patients rarely complain or see problems with the device because it's simple. We don't want to ruin that.

CEOCFO: ***Why has it not been tried before? What were some of the challenges in putting together the current format?***
Mr. Dobelle: Our technology was originally developed in an academic setting. By the time it reached its commercial stage, it was very far along, so the biggest hurdles were really just regulatory and standard business issues – expanding awareness about the device, sales, and building a productive manufacturing operation. Aside from that, the only big obstacle, like with any medical product, was regulatory approval. And little has changed. At this point in the company's history, our daily work principally involves sales, manufacturing, and regulation. We need to sell. And we need to keep the FDA satisfied that we're running a high-caliber operation. Because our device is considered high risk, being a life-sustaining implant, it is regulated in the strictest possible manner. But we've never had a problem with this and we always come up with a clean bill of health after routine interactions with regulatory bodies. For our sake, but mostly for the sake of people who use our equipment, we take every precaution.

CEOCFO: ***What are your next steps?***
Mr. Dobelle: Our primary focus at the moment is simply to spread awareness of our device through the medical and patient communities. Doctors almost invariably opt for our system over mechanical ventilation. And the advantages are obvious to the patients as well. At this stage, it's simply about informing them that this option exists.

"When you have the most efficacious product in the world for a particular purpose, and your only obstacle is letting the world know, then the potential is extraordinary."- Martin Dobelle

CEOCFO: ***I cannot imagine how a doctor would not at least want to look, since it is smaller. How could they resist at least looking at it?***
Mr. Dobelle: The difference is night and day. And I think it is very rare that a doctor rejects the idea outright. There is the occasional case where a certain doctor may have used a certain technology for a long time and simply does not want to go outside of their own comfort zone. But, in the vast majority of cases, it's not so much a matter of convincing a doctor to take a look at our technology, but rather of educating him or her on the fact that there is something out there.

CEOCFO: ***You mentioned sleep apnea. Is that the central sleep apnea different than what we normally think of sleep apnea with a C-PAP machine?***
Mr. Dobelle: Yes it is. The sleep apnea that we are most exposed and accustomed to is obstructive sleep apnea. That is a mechanical problem with the body, for lack of a better word, and causes the airway to become blocked. It is relatively common, affecting tens of millions of people. In central sleep apnea, conversely, the patient's brain essentially forgets to breathe while they are asleep. It is a condition of the central nervous system. It is very rare compared with obstructive sleep apnea, but it is perhaps even more serious.

CEOCFO: ***Are you working primarily in the US today?***
Mr. Dobelle: The majority of our relationships and cases are currently in the United States, and we would expect it to remain that way for a while. However, one of the biggest elements of our expansion strategy is focusing abroad. We do have a long history internationally and we have been dealing with a couple countries such as Sweden and Germany in particular, and Australia and England to a lesser extent. We have been working with physicians in those countries for many years, or decades even, but we certainly have not made the overall impact that we would like to. Only in the past two years have we really concentrated on expansion and working internationally. South America is also a major focus of ours.

CEOCFO: ***What have you learned from previous ventures that is most helpful as you navigate the waters here?***
Mr. Dobelle: I have learned not to let pride become an obstacle and to ultimately be a facilitator. That is the best way to get results.

CEOCFO: ***Will you be looking at partnerships and investment strategy to be able to make a larger push?***
Mr. Dobelle: Potentially we would be open to listening to any proposals, but at this very moment we are not actively looking for those types of relationships.

CEOCFO: ***What are the next steps? What will you be doing for the next year or so?***
Mr. Dobelle: Over the next year or so we will be continuing to attend conferences and continuing to take any opportunity we can to give presentations within hospitals and just educating the medical community. I know that I'm probably boring you to death with the term 'awareness', but that is priority number one at this point. We have a great product with a great clinical track record. So our concentration moving forward is to educate doctors, and patients, and to deliver these devices into the hands of clinicians who can make the best use of them.

CEOCFO: ***Are you able to reach out to patient organizations, individual patients or the public in general? Is it just not a workable strategy?***
Mr. Dobelle: We absolutely do. Many people in recent years have commented on the shift within the medical industry towards reaching out directly to patients. Once upon a time, patients would accept a treatment from their doctor and not question it for a moment. These days, people want to do their own research and work with the doctor to a degree. Our company has made great use of social media, patient organizations, and other means of connecting directly with the potential end-users of our technology. In fact, I think that has been one of the largest contributing factors to our recent growth.

CEOCFO: ***Put it all together. Why pay attention to Avery Biomedical Devices?***
Mr. Dobelle: This is a great company with a great product, and it's worthy of attention because of the patient population that it works with. It is a traditionally underserved patient population, but it exists in significant numbers and there is indisputably a substantial amount of room for our company to grow. When you have the most efficacious product in the world for a particular purpose, and your only obstacle is letting the world know, then the potential is extraordinary.

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