CEOCFO

EO2 Concepts® innovative wound healing

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Advanced Wound Care Company, EO2 Concepts is focused on the Development and the Approval Process of their Portable Oxygen Concentrator that Delivers Low Flow Oxygen for Difficult-to-Heal Wounds and to Promote Tissue Viability

Healthcare
Medical Device

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Joe Moffett
President

BIO: Joe Moffett joined the company October of 2011 as President to manage the day to day operations along with the development and execution of the company's strategic plan. He was previously at Philips Medical through acquisition of Respironics and was Sr. VP of North American Sales where he led NA sales with a growth of 10 – 15% per annum to $900 million. He also was VP of Sales for Ohmeda Medical, a BOC company, which was acquired by Instrumentarium (DatexOhmeda) and lastly by GE Medical with sales growth of 20+% CAG.

Joe has held various marketing and sales positions in a variety of medical device markets in his 37 years including sales, marketing/product management and business development. He has successfully established business objectives and strategies for a wide spectrum of home care and critical care products. Joe has experienced the management challenges of large, mid and small capitalized companies including 2 start up companies.

Joe has a BS from Rochester Institute of Technology.

About EO2 Concepts:
EO2 Concepts is an advanced wound care technology company. Our mission is to be the world leader in the development and commercialization of electrochemical low-dose tissue oxygenation and wound monitoring systems for the treatment of difficult-to-heal wounds and promote tissue viability.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Moffett, would you tell us the focus of EO2 Concepts®?
Mr. Moffett: EO2 is an advanced wound care company. Its primary product is a portable oxygen concentrator that delivers low flow oxygen. The oxygen is delivered locally to wounds via a cannula to a dressing generally in the extremity areas. It is intended to assist in improving the healing process for difficult to heal wounds.

CEOCFO: Has oxygen traditionally been used for wounds or is that replacing what we heard when we were kids-let air get into the wound?
Mr. Moffett: Oxygen is not really new. The first time that oxygen was used in wound healing, probably started back in the 1600's with the first hyperbaric chambers. You might be familiar with hyperbaric therapy for carbon monoxide poisoning, or decompression sickness (bends) for deep sea divers. It was also found helpful for treating hypoxic wounds and employs a systemic use of oxygen because you literally breathe it in while the entire body is under greater than atmospheric pressure inside a chamber. If we roll forward, some people had the observation that it was too hard to get patients into hyperbaric chambers, as well as the many contraindications for the use of hyperbaric therapy. Some people then developed a localized hyperbaric chamber, where you only put the extremity, like a leg or a foot, into a chamber, and then you pressurize that with oxygen. That seemed to produce some of the advantages, but it was introducing the oxygen topically to a wound. You were not breathing it, so there were no systemic advantages. Our device was developed about three years ago. It took the idea of delivering oxygen locally to a wound and reduced the delivery system to about the size of an iPhone, so making it portable. You would put our device on a belt or a pack about the waist, and now instead of being put into a chamber for ninety minute sessions, or put into a localized chamber for ninety minutes sessions, you wear this device continuously, and the oxygen is delivered to the wound twenty four / seven, but now at low flow and at atmospheric pressure.

CEOCFO: Is the product in use today or still in development?
Mr. Moffett: We are not currently selling it. Our model is to rent it, because there is no secondary use of the product. If a patient has it, it could only be used as a book end if you do not have a wound to treat. There is no other use for it.

CEOCFO: Has the medical community been accepting or skeptical?
Mr. Moffett: Medical management is probably the most difficult part of any

innovation acceptance. Physicians' will basically embrace technology only after it is carefully and scientifically proven to be efficacious, and then require the anecdotal confidence to move it into their clinical practice. Oftentimes, the patients that have successfully used our technology to heal wounds are patients that have been treated with other modalities for greater than a year; in some cases ten years, unsuccessfully. The physicians in these cases used the technology only because nothing else worked and they knew there was no serious consequence to using it. There are physicians who are early adopters that will look at something, try it anecdotally, and if it produces the results will continue to use it. However, that is the minority of today's physicians.

CEOCFO: How do you get attention?

Mr. Moffett: Right now we have a small sales organization. We will provide product for trial, explain to the physician the science of how the device works, and what we have been able to prove to this point. We will point out to a physician our large patient registry which best presents our significant positive outcomes. Our patient registry currently has over five hundred patients in it. The results we have had in the five hundred patient registry is nothing short of remarkable. The patient records have also all been audited. To give you an idea of what the outcomes are; the average time that a patient in our registry has had an open wound, treated with another therapy, is over four hundred and eighty days. We affectionately refer to them as "train wrecks", because the physician has been working with this patient for a long time and just has not been successful in closing that wound. These wounds have successfully closed, seventy seven percent of time, in 61 days. The patients have a wide range diagnoses like diabetic foot ulcers, venous leg ulcers, pressure ulcers and surgical wounds. These outcomes are pretty remarkable. After we share this kind of information to physicians some will go ahead and try it on their most difficult patients that they have had problems healing. As the patient registry has grown we have consistently produced these kind of results. Second to our patient registry, we have started out Tier I randomly controlled study. Unlike many device studies where it is difficult to "blind" the attending staff and patient, we have created a "sham" or non working device, so that we can actually "blind" everyone in the study to whether it is a working device or a non working device. That random controlled study started about nine months ago and it will probably be completed in the next nine months. These kinds of studies are something that most of medical practitioners require. They want to make sure under controlled conditions that the device does perform to the stated objectives. It is not only what the physicians require from a marketing standpoint, but from a payer perspective, it is also what the Center for Medicare and Medicaid Services has required us to do, in order to have a chance for a covered and payable code. Proving the improved outcomes is a clear gate in today's healthcare device business. It's not good enough to have a good idea anymore. It has to improve outcomes, especially if the healthcare delivery system moves to an outcomes based payments system from fee for service. Without getting a payable code you are not likely to have a successful business selling that product in a fee for service environment.

"It's not good enough to have a good idea anymore. It has to improve outcomes, especially if the healthcare delivery system moves to an outcomes based payments system from fee for service."- Joe Moffett

CEOCFO: Are there any potential downsides? If it does not work is there anything that the oxygen can do to harm a patient?

Mr. Moffett: We don't know of any negative outcomes associated with using too much oxygen for treating wounds with our approach. The limited risk comes from the fact the oxygen is not inspired. It is not a systemic application. The TransCU O2® only delivers a maximum flow rate of 10 milliliters per hour, or about the volume of a golf ball. That small volume of oxygen is delivered underneath a bandage or a dressing and it fills the volume or space underneath that dressing. The oxygen then diffuses across a fluid medium in the tissue to help support healing. The low flow of oxygen does not dry the wound bed out, but is enough to support the diffusion process across the fluid medium.

CEOCFO: What are your next steps? How else do you get attention? How can you go directly to patients?

Mr. Moffett: The company does have to continue to build the product's case of improved outcomes and also that it is a solution to help solve the high cost of healthcare. It will be increasingly more important in the evolving healthcare system that we only use devices, procedural interventions or drugs that produce improved outcomes. The difficulty in our case is that it is a long and arduous task to get a new medical device successfully into the market. I'll give you an example of some things that are changing. Look at what is going on in the pharmaceutical business. Their "go to market" strategies have changed from what it used to be ten years ago, where they would have thousand of sales reps sit in doctors offices waiting for five or ten minutes to see a physician and pitch the benefits of their drug. These companies have the same "go to market" resistance on new drugs that we have on the medical device side, which is getting the physicians attention in the myriad of alternatives and getting them to change. The pharmaceutical companies have now demonstrated that going directly to the consumer, or have the patient identify their symptoms and have the patient believe this is a solution to their ailment. The patient now goes into the physician's office prepared and says "I saw this on TV, I think I have the same symptoms; what do you think?" If the physician knows of the drug and has some positive opinion that there is no interaction or a limited downside, the physician will go ahead and write the scrip for that patient's re-

quested drug. The physician's motivation is to keep the patient. Device companies take similar approaches; however, the medical device industry is a microcosm as compared to the size of the pharmaceutical industry. We do not have the billions and billions of dollars of opportunity to pay for the investment that it takes to conduct direct "go to market" strategies.

CEOCFO: What do you see a year or two down the line?

Mr. Moffett: First is to conclude our randomly controlled study to prove the science and the medical outcomes under controlled conditions. That is what the regulators in Washington, as well as most physicians will expect to see. We will continue to grow our patient registry, which is an anecdotal, but a very powerful tool to demonstrate efficacy. Ultimately, when we have a payable code from CMS, it will create the ability for all physicians to utilize this technology through the Durable Medical Equipment community. We will then be allowed to recoup the investment and make a profit on the delivery and support of this innovative product. There is one other thing that we are doing, and it happens to be more in alignment with the changes that are going on in the whole medical delivery system. We know that the financial risk of the cost of healthcare has been moving away from the government. Whether they are accountable care organizations or insurance companies, to providers meaning the physicians themselves, risk "shifting" is also producing different opportunities, and also different mechanisms for "go to market" strategies for companies like ours. Therefore, inside of two years I would expect that even if we do not have a payable code, because we are approaching at risk providers and at risk insurance companies, that we will be able to prove the efficacy of our technology and the improved outcomes from the use of our technology to the companies or providers that have financial risk. They really do care about the financial consequences of continuing to use therapies and interventions that do not produce results. These at risk entities will not continue to use outdated low outcome interventions because they are the ones paying the bill now. I would contrast that with a more historical norm which is still largely in place right now; in a fee for service environment a provider will treat a patient, send a claim in to an insurance company with a code that is payable, and he will be paid for his services. If the fee for service business disappears, which is what many are predicting, in favor of an outcome based or an incentive based payment system, then the technologies and interventions that truly produce results will be used by insurance companies sharing the risk with provider networks. If we have a code and we can play (and I affectionately refer to it as playing) in the healthcare industry on a fee for service basis, we will. However, if we do not have a payable code, but continue to produce the results that we have heretofore been able to demonstrate, then we will have a very interesting business because of the cost savings that we can produce for treatment of the very expensive wounds.

CEOCFO: What should investors and people in the business community know about EO2 Concepts?

Mr. Moffett: We are a small, innovative company with a solution to a very large problem in an industry that is looking for solutions to bend the financial cost curve of healthcare delivery. It is how good device companies start; having a solution to a very large problem. In our case, the problem with diabetic foot ulcers has a growing patient base of diabetics, largely due to lifestyles with nutritional problems and the usual lack of exercise. We all know that the number of diabetics is not only growing, but is expected to continue to grow for quite a while. Therefore, there is going to be a higher incidence of these very expensive, very difficult to manage wounds into the future. We are well poised for providing a new approach to the effective treatment of these wounds, and we will be participating in a large and a growing marketplace. We believe that we have a very interesting business proposition; not only for our customers, but also for our shareholders. We believe that we are going to be a pretty significant player in the device side of healthcare, simply because we are focused on producing the right results and effective outcomes at a lower cost of care. Companies that can keep their eye on the ball; meaning deliver real value in real problem areas, will be awarded and rewarded with good financial returns.

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