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Issue: August 14, 2017

CEOCFO Magazine

Interventional MRI – the Next Big Thing? (and a Pathway to Breast Cancer Prevention…)

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CEOCFO: ***Mr. Harter, what is the idea behind Marvel Medtech, LLC?***
Mr. Harter: Our big picture view is to transform the clinical utility of MRI, Magnetic Resonance Imaging, by enabling interventional procedures to be done interactively with real time imaging guidance. We have designed a compact robotic positioning system to work inside the bore of an MRI scanner to essentially extend the physician's reach into the bore of the scanner so that they can do procedures with the patient inside the scanner, while they are viewing things in real-time on the display screen.

"They came up with this idea of what they call an "Early Freeze Protocol". It is the same analogous treatment idea or prevention idea that I just described with colonoscopy. When we detect a suspicious lesion through a breast cancer screening exam, before we biopsy, before we try to get a cancer diagnosis; why do we not just freeze it? The Chinese have demonstrated that there is at least a 50/50 chance that if it was cancer or precancerous and we freeze it, that it will be gone forever and never come back and never spread and never develop into something that is dangerous, and the woman gets to keep her breast!"- Ray Harter

CEOCFO: ***How is the MRI currently being used?***
Mr. Harter: Presently, an MRI is only used as a diagnostic imaging tool. The imaging procedures today are typically done by an imaging tech. The radiologist is typically not present when an MRI procedure is being done. That really short sells the imaging horsepower and the imaging capability of the MRI system. By diagnosing a disease with MR imaging, that is only half the battle. Once you detect and diagnose something you need to be able to do something about it. That is what we are enabling. It is the transformation between diagnostics and intervention. Our technology will allow the superior imaging capabilities of an MRI scanner to be used to interactively guide interventions.

CEOCFO: ***How does your technology work?***
Mr. Harter: Our first application is for breast interventions. We have been focused for quite a while on developing a biopsy tool that would allow radiologists to do an image guided breast biopsy. We have recently received feedback that doing breast biopsy faster with MRI guidance really is not going to add a lot of clinical value. However, there is some very significant and relatively recent interest and excitement, I guess you could call it, with doing minimally invasive ablation therapy procedures for breast tumors. Now, that is not currently a standard of care. However, the idea is to detect breast tumors at a very early stage when they are very small and more amenable to the minimally invasive treatment scenarios. What has been established over the past several years is that MRI truly is the most effective imaging modality for

detecting breast cancer. It has virtually one hundred percent sensitivity. That means that if there is something abnormal in the breast an MRI will almost certainly detect it. But the clinical utility of MRI for breast cancer is even more valuable. It is now known that MRI actually has a preferential bias for detecting the most dangerous forms of breast cancer. So the aggressive, fast growing cancers that are most likely to be fatal are the types of cancers that MRI is naturally best at finding. That gives MRI far superior clinical and patient benefit advantages over competing breast cancer imaging modalities.

CEOCFO: ***Are we talking about replacing mammograms or might this a second step if something is seen in a mammogram?***
Mr. Harter: In my view and the view of many others, the desired outcome would be to replace mammography with MRI screening. Now, one of the reasons that has not moved forward more quickly is that MRI, compared to a mammography exam, is quite expensive. MRI is a big expensive piece of equipment and in today's scenario, women that are at high risk for getting breast cancer can get reimbursement for MRI screening, but normal risk women cannot. However, normal risk women are still dying of breast cancer. In fact, per the American Cancer Society, about forty one thousand women will die of breast cancer this year. There is a disconnect there. We've got this powerful tool that is virtually one hundred percent sensitive for detecting breast cancer and it has this preferential bias for detecting the cancers that are going to kill someone if you do not detect and treat them early, but it is not available to the majority of the population. There has been a recent breakthrough that can dramatically change that economic profile. There is a new MRI screening method that has been clinically proven to detect these cancers with about three minutes of scan time and typically less than about a minute of interpretation time. That breakthrough can reduce the cost of an MRI screening exam by an order of magnitude. That should make MRI much more cost effective and therefore much more available and accessible to all women that need or want breast cancer screening with MRI.

CEOCFO: ***How do you overcome the hurdle of changing what the medical community has been doing?***
Mr. Harter: There are a couple of things that we have just recently discovered ourselves that we are going to promote and try to move this forward from the business and the clinical side. One opportunity is the growing interest in cryoablation, that is, freezing a breast tumor. It has been known since about 1960 that if you freeze a tumor to destroy it, that induces a natural anti-tumor immune response that can actually prevent recurrence and spreading of the disease. There is a lot of research going on in the U.S. and around the world to try and prove that this is in fact as clinically effective as the current standard of care, which is surgery and chemotherapy and radiation therapy. If this new approach proves to be effective, it is truly a paradigm shifting opportunity. That is because it would truly reduce the cost and really increase the efficacy, and avoid all of these horrific morbidities that come with mastectomy and chemotherapy, etc. The Chinese have been using this approach for about fifteen years and they are getting some amazing results. They do not have early detection programs in China. Therefore, up to eighty percent of the patients that they are treating for breast cancers and other cancers are being treated with advanced stages of cancer. They are freezing these tumors and they have established through their clinical studies that about fifty percent of the time this natural anti-tumor immune response alone is effective in preventing a recurrence or spreading of the disease. The Chinese researchers have shifted their focus to figuring out how they can super-charge this immune response to improve those efficacy rates. More recent research is claiming that they have gotten their effectiveness rates up to about eighty percent. By cryoablating a tumor and then following that with an immunotherapy regimen, they are claiming to be getting eighty percent remission of cancers. That is very exciting! What we are planning on doing to do an end run around this snail's pace of research progress and resistance to adopting new things in the U.S. is to first start working with the Chinese. We have contacted the folks in China that are doing these procedures and they are very interested in our technology. Their response was along the lines of, "We need this. When can you bring your technology over and teach us how to use it!" There is a lot of excitement and a lot of enthusiasm and momentum there to move that quickly forward. The other thing that we are doing is something that was started by a group of breast healthcare advocates that have not been affiliated with Marvel Medtech until recently. They have been promoting a compelling new idea that entails a preventive approach to breast cancer. It's the same approach used now in colon cancer screening. Many of us who have had colonoscopy exams as part of a cancer screening know that if a suspicious polyp is found, it will just simply be removed. They do not first do a biopsy on it or anything else. They just simply remove it. It is safe. It is effective. It is proven to work. If there was something suspicious there and it has been removed you are probably not going to get colon cancer.

CEOCFO: ***And it makes sense as well!***
Mr. Harter: Yes! It is very common sensical! As far as we know Laura Ross-Paul was the very first woman in the U.S. to have her breast cancer cryoablated back in 2003 and she has been cancer free since then. Laura has become very frustrated that this proven method has not become more readily available to the entire population of women that could benefit from it. Laura and her husband, Alex, have teamed up with some other folks such as Ingrid Edstrom, FNP M.Ed.

CTT, of Proactive Breast Wellness. They came up with this idea of what they call an “Early Freeze Protocol”. It is the same analogous treatment idea or prevention idea that I just described with colonoscopy. When we detect a suspicious lesion through a breast cancer screening exam, before we biopsy, before we try to get a cancer diagnosis; why do we not just freeze it? The Chinese have demonstrated that there is at least a 50/50 chance that if it was cancer or precancerous and we freeze it, that it will be gone forever and never come back and never spread and never develop into something that is dangerous, and the woman gets to keep her breast! Think of the improved quality of life and cost savings from not having to do any of these things that are now considered the standard of care.

CEOCFO: ***I am assuming that the cryoablation will not hurt?***
Mr. Harter: There are many ablation technologies that are being researched right now. Virtually all of the other modes use heat from an energy source to kill the tumor. Cryoablation, because it is freezing, it actually has an analgesic effect. So the freezing itself reduces the pain. There are a number of companies that provide cryoablation probes to do these procedures; it is a current standard of care for treating non-cancerous breast fibroadenomas. These are typically outpatient procedures where after the procedure the woman gets a band aid and perhaps a Tylenol and that is the extent of it! There is very little pain. The discomfort is relatively low compared to some of the other ablation procedures and it is quite effective. The other thing that we are trying to engage is to leverage this superior cancer detection capability of MRI using our technology to be able to do these procedures, minimally invasively, interactively, with real time imaging guidance, so that you know exactly what you are doing with MRI. If you are doing a cryoablation procedure with MRI you will actually be able to see the iceball grow in 3D so you will know when you have gotten an iceball big enough to encompass the tumor and have safe margins. There are all kinds of benefits for using MRI to do these procedures. We are going to aggressively try and promote this idea of this Early Freeze Protocol; get this technology out there, get it in the hands of clinicians who can start doing these procedures. We think we will start to see some dramatic results with reducing the number of fatalities from breast cancer. Again, it is going to take some time, but we think that there is enough momentum, right now, to get this going. In fact, we are an early stage company and we have been really struggling to try and get financing to continue our work. We are seriously investigating doing a crowdfunding campaign to raise the money that we need to really accelerate our development to get this technology to the point where it can be used clinically and get it through the FDA regulatory compliance hurdles that we have to get through, and get it in the hands of clinicians who can start doing these procedures. Also, at the same time, get it into the hands of these Chinese physicians who, at this point, I would guess are about ten years ahead of where the U.S. is in terms of using cryoablation to treat cancer.

CEOCFO: ***How do you deal with some of the frustration, knowing you have something that potentially can make such a big difference and it is a struggle to get the attention and eventually get it into use?***
Mr. Harter: I have been accused of being persistent. Our company was founded in 2002, so I have been at this now for coming up on fifteen years. In fact, I think at the end of this month we will celebrate our fifteenth anniversary of our founding. I guess it has just become part of our DNA! We truly believe in what we are doing and we are convinced that this is going to happen. We are further convinced that we are a big part of the reason it is going to happen. If we do not persist in this, I guess we have taken the attitude of if we do not do this nobody will, so we have to.