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Novuson, using Innovative Direct Therapeutic Ultrasound in Surgical Devices to Improve the Safety of Surgeries

Stuart Mitchell
Founder/CEO

Novuson Surgical, Inc.
http://novuson.com/

Contact:
Stuart Mitchell, PhD
425-238-6227
sbmitchell@novuson.com

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www.StartEngine.com/Novuson

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Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: ***Mr. Mitchell, according to the Novuson website, you are "Soundly Simplifying Surgery." How are you accomplishing that and why do we need simplification?***
Mr. Mitchell: We are accomplishing simplification by using ultrasound to cauterize tissue and dissect tissue. Ultrasound is one of the most efficient ways of getting energy into tissue. Increasing the efficiency of energy delivery reduces the potential for complications that arise from energy devices which in turn simplifies the surgery. There are numerous energy devices on the market for cauterizing and cutting tissue, but they cause a lot of harm to the patients. They burn and char tissue and they put a lot of smoke in the operating room which is hazardous to the surgical team. Our technology is called DIRECT THERAPEUTIC ULTRASOUND (DTU), for targeting vessel sealing/dividing, and hemostasis (bleeding control) in surgical and trauma applications.

CEOCFO: ***Why are these other technologies in use?***
Mr. Mitchell: Even with all the shortcomings, the current technologies on the market do make surgical procedures faster and more efficient. The less time a patient is under anesthesia, the better their outcomes.

CEOCFO: ***Are there particular types of surgery where your approach is most effective or is it across the board?***

Mr. Mitchell: It is pretty much across the board. Devices like this, or energy devices in general, are used in about 90% of all surgical procedures. There are numerous configurations of energy devices and different energy modalities for use in a variety of different procedures. They are pretty much across the board used in all surgeries.

CEOCFO: ***Novuson has the first substantive innovation in advanced energy technology in over 25 years; what have you figured out that others have not?***
Mr. Mitchell: We are using a more efficient and safer way of putting energy into tissue. I am not certain why other groups have not looked into this. The current devices work pretty well for what they do but they cause a lot of harm, so I think there is just not a lot of motivation for the manufacturers to improve technology and make surgery safer.

CEOCFO: ***What is different in the way that you are applying the energy?***
Mr. Mitchell: Our devices are basically similar to all the other devices on the market. The difference is that we use ultrasound transducers, so we transmit ultrasound energy into tissue. It can be used to cauterize tissue or cut tissue. The other devices on the market either use electricity or harmonic technologies. The electricity-based devices run electricity from one end effector to the other which cauterizes the tissue and then they use a mechanical knife to cut the tissue. The harmonic devices use a ridged metal blade and then essentially vibrate the blade at ultrasonic speed which generates frictional heat, hence they use friction to burn through the tissue. That is how we differentiate our technology from other technologies.

The other big differentiating factor is how the other technologies on the market cauterize tissue. When they cauterize tissue the other technologies start cauterizing at the surface where the devices are touching the tissue and then they cauterize through the tissue. What this means is as they cauterize the tissue, the impedance of the tissue increases which means they have to put more energy into the tissue to cauterize completely through.

With ultrasound it is exactly the opposite. Ultrasound propagates through the tissue rather easily and we start cauterizing at the midline of the tissue between the end effectors. Thus, the impedance increases in the middle which means we need to put less energy in to make the complete cauterization back to the surface where the end effectors are in contact with the tissue.

CEOCFO: ***Do doctors understand the difference? Do they understand easily; do they care about the technology that is creating the difference or just that it works?***
Mr. Mitchell: I think the surgeons care about the end result. They notice right away that our technology does not produce all the surgical smoke that all the other technologies do and they notice when they are through doing the procedure that we have nice clean cauterization zones and cuts whereas the other devices all have a lot of burning and charring. They notice the difference and they like the end result.

CEOCFO: ***How are you reaching out to let the medical community know about Novuson and the importance of what you have developed?***
Mr. Mitchell: There are a lot of different avenues. Right now, we are fundraising, so I spend a lot of time at investor conferences and talking with key opinion leaders. I also go to medical conferences, set up a booth, and demonstrate our technology. In the future once we get regulatory clearance which hopefully will be in the next five or six months, we will have our surgeons using our devices on patients, writing white papers, and they will be presenting to their colleagues.

CEOCFO: ***What has been the reaction from the investment community; have you figured out what attracts attention?***
Mr. Mitchell: It depends on the type of investor and there are a lot of different types of investors. Most angel investors will invest in less technical businesses that looks like they have a quick exit. It is just what they do. They typically will not invest in something like a medical device because it is a long-term return on your investment and it will take an average of eight years to get a return on your investment from a medical device. The sophisticated angel investors are better, but they spend a long time understanding the technology and its' benefits. They will invest in medical devices. What I focus on is primarily working with strategic partners, partners that have an investment arm in the medical device space. Micro venture capitalist, or smaller investment firms who like to work in the medical device space.

I try to focus on my fundraising in areas where there is interest in medical devices because these organizations are looking to not only make money but also most of them have initiatives to make an impact, improve healthcare.

CEOCFO: ***Regarding using the device, would an individual surgeon, a hospital group or even perhaps an insurer, insist on using a device that is better, safer with less complications?***
Mr. Mitchell: It is interesting. Depending on the facility, the individual surgeons do not have a lot of say. There are some surgeons that are very influential, they can go to their value committees and request a device because it is a better device, and the committee will listen to them. How you get around that a little bit is who you sell to, there are different categories of surgical centers out there.

Our initial sales will be with ambulatory surgical centers where they are surgeon-owned places so that the surgeons are the value committee. They are the ones making the decisions as to what equipment they use.

Getting into hospital systems, they all have purchasing agreements with all the large manufactures. This is where strategic partnerships become important for small companies like Novuson. We will try to do strategic partnerships with manufactures such as Johnson & Johnson, Medtronics, etc. If they think our technology is interesting, then they may help us by letting us use their distribution channels.

CEOCFO: ***You have a number of different devices; is that a matter of size or are there different features that we should know about?***

Mr. Mitchell: All the manufacturers make different sizes and shapes that work better for different surgical procedures and surgeons have different preferences. We will make all these the same configurations as all the other manufacturers. Where we differentiate ourselves more than the other manufacturers is we make a device that is designed for a whole-organ cauterization as well. If you wanted to remove a tumor from a kidney or liver, we have a device that you can actually isolate the tumor and cauterize completely through the organ. Then you can dissect the tumor out without any bleeding which is really unique in the surgical field, nothing like that exists.

CEOCFO: ***What do you need to do further for FDA clearance?***
Mr. Mitchell: For the first devices we are working on, which are categorized as sealer/dividers, we have some validation studies that we need to complete. It is primarily bench studies, looking at safety of the device, sterilization, and shelf life of the devices. We need to finish all those validation studies before we can apply for regulatory clarence, and once those are completed, we will apply for regulatory clarence. FDA clearance can take from 30 to 90 days.

CEOCFO: ***What if anything has changed in your approach from founding the company to today?***
Mr. Mitchell: The biggest change in my approach is on the fundraising side. When we first started we were presenting to a lot of angel investors and I pivoted away from that several years ago. I still present to angel investors now and then, but I usually try to target groups that are more sophisticated angel investors. Now I spend most of my time with venture capitalists and potential strategic partners.

CEOCFO: ***With so many new ideas in the medical field why is Novuson important; why should the company get attention?***
Mr. Mitchell: The key thing is safety in surgery and reducing the number of surgical complications. In the US alone, just looking at surgical smoke, you think "smoke is not a big deal" but it affects 90 million patients per year, its equivalent to the staff smoking 27 cigarettes in an 8-hour shift, and the smoke contains viruses, bacteria, and toxins. With the protective equipment that the surgical team uses, the size of the particles in the smoke are smaller than the protective equipment can filter out. Thus, the protective equipment doesn't protect the surgical team from this hazard.

CEOCFO: ***Should patients know about what you have at Novuson Surgical and talked with their surgeon or is that just something is too far down the chain?***
Mr. Mitchell: I do not think it is too far down the chain. This is something that other surgical device companies have done. They marketed to the patients and not the surgeons or the hospitals. They convinced the patients that they needed to have a particular type of surgery with a particular device. Then the patients demand it. The patients are going to go to the hospital that have the technology they want used and the other hospitals just have to get onboard. It actually turned out to be a smart marketing scheme and we will do something similar to that and we will appeal to the patients and do some sort of outreach to patients to let them know there are safer technologies out there.