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New Multifunction Applanation Tonometer Device Which Can Be Used as a Risk Assessment Tool in the Management of Glaucoma and Vascular Disorders

Francis Falck, Jr., MD, PhD, MS
CEO

CEOCFO: Dr Falck, what is the basic concept at Falck Medical?
Dr Falck: To develop innovative and disruptive technologies that fulfill particular needs in the medical care marketplace. We are currently working in eye care, where we are introducing the Falck Medical Multifunction Tonometer, the FAT1 device. The FAT1 device was recently cleared by the Food and Drug Administration for multiple indications. These indications allow the device to be used for the management of a wide range of eye related conditions which include glaucoma, diabetes, macular degeneration and vascular disorders. The technology also has applications for primary care practitioners and we are developing a device for that market as well.

CEOCFO: ***It is a pretty wide category in both areas. How do you vet a technology? How do you know when what you are looking at really has the potential to work?***
Dr Falck: That is a good question. It is all based upon determining need, examining what technologies exist, and then discovering what the inadequacies of those technologies are. The goal is develop technologies that improve on the standard of care and add revenue to the bottom line.

CEOCFO: ***Are you able to look at what people might be working on as well? Is it possible to include that in the vetting process?***
Dr Falck: It is somewhat. You can look at patents. You can look at provisional applications that have been filed. You can participate in research meetings and see what papers are being presented. The way that I approach a given technology is to determine how it was developed, what was the scientific basis of it, what were the identified inadequacies of it or the inadequacies that users in the marketplace have identified. When we develop a product that represents a significant technological advance, we file the IP, and protect the technology.

CEOCFO: ***What are you focusing on today?***
Dr Falck: The Falck Medical Multi-Function Tonometer (FAT 1) deals with the inadequacies of the current means of which intraocular pressure is measured. Intraocular pressure is a risk factor for the development of glaucoma. There is a valve that exists within the eye which is called the trabecular meshwork. That valve regulates the intraocular pressure. All forms of glaucoma except one are due to dysfunction of the trabecular meshwork. The FAT1 device can perform an in-office procedure called Tonography to assess the function of the trabecular meshwork. That data can be used to assess risk and also be used to prescribe and manage therapy. For example, you can prescribe a therapy or perform a surgical procedure and use the device to assess treatment response.

CEOCFO: ***When you are at the ophthalmologist and they say they are testing for glaucoma, what are they measuring?***
Dr Falck: They are measuring the intraocular pressure (IOP). However that is not enough. It is known and established that intraocular pressure varies throughout the day. Multiple studies have demonstrated that in those eyes with glaucoma that are not currently being treated, the IOP was in the normal range at the time it was measured. The trabecular meshwork is where the problem exists; therefore it is important to have a device that can assess the function of the trabecular meshwork. There is another issue that must be discussed. Intraocular pressure varies with the cardiac cycle; it is higher during systole and lower when the heart is at rest during diastole. All current devices that are used to measure IOP do not account for this variation. So they are not providing accurate and complete data. The FAT1 device measures, records and displays the variation in IOP that occurs with the cardiac cycle.

CEOCFO: ***How are you actually doing the measurement? What is the device able to read and how?***
Dr Falck: The device is measuring the outflow of the clear fluid called aqueous humor through the trabecular meshwork. In eyes with glaucoma outflow is impaired, or decreased which results in elevated IOP. The data demonstrating this was compiled during the FDA clinical trials.

CEOCFO: ***Where are you in the process of commercialization?***
Dr Falck: We have been cleared by the FDA to go to market. We are currently in the manufacturing phase and distribution will begin in the second quarter of 2016. We have identified independent medical device distributors throughout North America that will be selling the device in their respective geographic areas.

CEOCFO: ***Is the ophthalmology community aware or will you be introducing something that most ophthalmologists do not know about at all?***
Dr Falck: Most ophthalmologists and optometrists have not been exposed to the technology. It will be a process of education, but once they understand that the device will improve the quality of care, prevent transmission of infectious disease and add revenue to their bottom line they will embrace it. From the FDA clinical trial research studies and independent research studies done at Tufts School of Medicine, we have white papers that validate and demonstrate the clinical utility of the technology. Keep in mind this is the only single device ever cleared by FDA with these clinical applications.

CEOCFO: ***There is so much on every doctor's plate, How do you jump out and get the attention?***
Dr Falck: The eye care community is technology driven. We like technology that will give a better handle on preventing and managing eye disease. When you have a new technology which is disruptive, innovative, improves the quality of care, prevents transmission of infectious disease and adds revenue to the bottom line they will embrace it.

"The FAT1 device raises the standard care, enhances public safety and adds revenue. It would be difficult to understand on a rational basis why a licensed practitioner would decline the use of this technology."- Francis Falck, Jr., MD, PhD, MS

CEOCFO: ***How did that happen? Is it because there has been a lot of innovation in ophthalmology? Is it a mindset of ophthalmologists?***
Dr Falck: Yes, there has been a lot of innovation in eye care because sight is a precious and necessary sense if one is to maintain independence. If you talk to the average person and you ask them what sense they find to be the most important they will always say their sight. People fear going blind. Therefore we must be driven to develop innovative technologies that allow us to prevent blindness.

CEOCFO: ***Where does cost of the equipment come in? Is there a question of reimbursement using this test as compared to what is being done today?***
Dr Falck: The exact market price has not been set yet. But it will be set at a price point that every eye care practitioner can afford. We have been very efficient in producing the technology and have maintained our targeted cost efficiencies. Some of the tests the FAT1 device performs will generate revenue, so over time the device will pay for itself.

CEOCFO: ***What else is on the agenda for Falck?***
Dr Falck: The FAT1 device can perform a test called ophthalmodynamometry, which is an assessment of the pressure in the central retinal artery. The central retinal artery provides blood flow to the eye and is a branch of the internal carotid artery. The major cause of stroke is disease in the internal carotid artery; a narrowing due to atherosclerosis. Due to normal vascular physiology, a reduction in central retinal artery pressure can be a sign of disease in the internal carotid artery. During the clinical trials we were able to save the life of a young woman who had an undiagnosed internal carotid artery aneurysm. FMI will be moving into the primary care marketplace with a device that they will be able to use.

CEOCFO: ***Would you be moving into cardiac arena as well or should problems be caught earlier at the primary level?***
Dr Falck: Yes, a portable version is being developed that any primary care doctor, family practice physician, vascular surgeon, or cardiologist can use.

CEOCFO: ***Does the medical community understand the correlation, but have just never been means, or do primary care physicians need direction that this can exist and that the relationship does exist?***
Dr Falck: There will be a process of education. The exciting part about this is that from a public health point of view we need to move towards preventing the vascular event. For example, right now before someone will get a vascular workup,

they must either have had a stroke, a mini-stroke called a TIA, significant signs of carotid artery disease, or temporary blindness called amaurosis where a piece of cholesterol plaque breaks off the internal carotid artery, and lodges in the central retinal artery.

CEOCFO: ***Are the tests easy for a doctor to do?***
Dr Falck: The device was designed so that the tests can be done by a nurse, a medical assistant an ophthalmic assistant, or optometric assistant.

CEOCFO: ***Are you funded for the steps you would like to take? Are you seeking investments or partnerships?***
Dr Falck: FMI is self-funded, privately held and at this time has the capital required to bring the product to market.

CEOCFO: ***Would you like to remain self funded?***
Dr Falck: FMI would entertain collaboration with outside entities that would serve to benefit and promote the technology.

CEOCFO: ***What have you learned throughout the process on the business side that gives you confidence you can accomplish your goals?***
Dr Falck: The FAT1 device raises the standard care, enhances public safety and adds revenue. It would be difficult to understand on a rational basis why a licensed practitioner would decline the use of this technology.

CEOCFO: ***Will you be selling equipment or a device? Are there disposables that you would be offering with it? What is the business model?***
Dr Falck: With all of the current existing tonometer devices that measure intraocular pressure there is a documented serious risk of transmission of infectious disease. It is well known that tears contain infectious prions in those with Mad-Cow disease, the HIV virus in those with AIDS and the type A, B, or C virus in those with Hepatitis A, B or C. The problem is it cannot be determined who is infected, some are carriers who do not manifest the signs of the disease. The Centers for Disease Control, the FDA and other independent researchers investigated and dertermined that the tip of the contact tonometer devices, which touches the eye cannot be completely sterilized. To respond to this problem the manufacturers have developed tip covers. But there use is not required. The devices can still be used without changing the covers or even using the covers. Non-contact air puff tonometers are also a potential source of infectious disease. The air puff aerosolizes the tears which are now infectious airborne particles, which are inhaled. With the FAT1 device the contact tip must be changed between each patient. The device has an internal patented detection system that allows the device to determine whether a prism has been used previously. The tonometer tip is a fixed used disposable. The tip must be changed before the device will allow a measurement on another individual. It is an absolute barrier and eliminates the risk of infectious disease transmission from one individual to another.

CEOCFO: ***In addition to being better, is it safer!***
Dr Falck: In addition to being better it is safer. It is important that the public be protected against the risk of transmission of infectious disease.

CEOCFO: ***How do you deal with some of the frustration surrounding the time it takes to get a device to market?***
Dr Falck: Commitment to the vision you have for your product and persistence are necessary to overcome all the obstacles on the path to the marketplace.

CEOCFO: ***There are so many companies and so many ideas in the health community. How does Falck Medical offer a meaningful breakthrough?***
Dr Falck: The FAT1 device raises the standard of care. It eliminates the risk of disease transmission from one individual to the next, it measures intraocular pressure throughout the cardiac cycle, capturing the increase in intraocular pressure that occurs with systole, it allows the user to assess the function of the trabecular meshwork, providing a tool that can be used for glaucoma management and the ophthalmodynamometry function has potential for vascular status assessment.

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