Wearable Ambulatory Electrocardiogram Devices with Windows Based Software Monitor Atrial Fibrillation and other Heart Rhythm Disturbances

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CEOCFO: *Mr. Brockway, your site indicates VivaQuant is quantifying vital signs accurately. How are you doing that?*
Mr. Brockway: We are focused on developing software that will more accurately and efficiently extract information from the electrocardiograms (often referred to as ECGs) of people as they go about their daily activities. We are also developing a wearable device that uses the software technology to monitor patients at home in a way that is more comfortable for them, provides more accurate diagnostic information, and does so at a lower cost. Patients that will initially benefit from this technology are those with a chronic cardiac condition that requires evaluation of arrhythmias. Many people with cardiac rhythm issues require longer-term and frequent monitoring to assess their heart rhythm and determine if the medications or other therapies are working. The physician uses this information to make adjustments to keep the patient feeling better and out of the hospital. One particular need that we are addressing is for improved monitoring of atrial fibrillation. Atrial fibrillation is important because the incidence in the general population increases rapidly with age and the consequences of AF can be significant, including stroke, progression of heart disease, and poor quality of life.

CEOCFO: *What are the problems with the standard technology that your Windows based system can help alleviate?*

Mr. Brockway: The most significant issue with monitoring these patients, which our technology addresses, is that when patients are going about their normal daily lives the ECGs that are gathered are often quite noisy. Unfortunately the noise confounds current software that processes the ECGs to extract information, causing inaccuracies that can lead to errors in reporting and diagnosis. Other software can remove noise but compromises certain diagnostic information along the way. For example, a paper published in a peer-reviewed cardiology journal, based upon research led by a physician from Columbia University, showed that about 95% of arrhythmias reported by a commonly used device were actually not arrhythmias but were "false positive" events caused by noise and other factors. A cardiac monitoring center industry has grown up around receiving these signals from patients via the cellular network and creating reports that document arrhythmias for the treating physician. Current practices and technology rely on human intervention whereby monitoring center staff manually scrutinize ECG strips received from patients and correct mistakes made by the software so the report that the physician receives contains accurate information. This process is labor intensive and prone to error. Our software removes most of the noise in these ECGs and greatly reduces the number of errors in identifying arrhythmias. This results in a significant reduction in labor and improves the quality of reporting. We anticipate that our technology will result in a faster diagnosis at a lower cost. What we bring to the table is a more efficient and much less costly process for moving from patient data to information in the physician's report, while at the same time improving the quality of reported information.

CEOCFO: *Would you tell us about your recent National Institutes of Health grant to pursue the wearable technology?*
Mr. Brockway: That grant was awarded to develop a small device for monitoring cardiac arrhythmias that patients can wear as they go about their normal daily activities. What is unique about it is that it implements what we refer to as our MultiDomain Signal Processing, or MDSP™, real-time processing technology that removes noise from the electrocardiograms and identifies arrhythmias. Compared to current devices, ours will do this more accurately and deliver the information to the clinic or monitoring center in a way that greatly reduces the cost of monitoring these patients. Since the technology is also extremely power efficient, the device can be quite small, so it is less cumbersome and less intrusive for the patient compared to current devices. Therefore, the patient is more likely to comply and actually wear the device.

CEOCFO: *Where were the technical challenges in putting this together?*
Mr. Brockway: Probably the most difficult challenge, beyond the creative insight to come up with the basic approach, was the incredible complexities in the math needed to implement the technology in a way that not only removes most of the noise but also preserves the diagnostic information in the ECG. The technique was developed by VivaQuant's founder, a PhD mathematician, and uses a totally unique approach compared to current ECG processing technologies. I have been involved in this field since grad school and if you had asked me six or eight years ago if this could be done I would say it would be impossible. She found a way of implementing this noise removal technique in a way that overcame significant hurdles in the mathematics to make it a reality.

CEOCFO: *Where are you in the development process?*
Mr. Brockway: We have commercialized our technology for preclinical and clinical research for assessing drug safety and have licensed it to a multinational sports apparel manufacturer. We have an ongoing service business that utilizes the technology, which is doing quite well. Our strategy has been to gain lots of experience as early as possible in order to understand how well the technology performs in the real world. Now that we have a great history of experience with the technology on a very large data set, we are confident that it's ready to go mainstream. We are currently developing a wearable device and are about to file an FDA 510 K to gain market approval for software to process ECGs from cardiac patients.

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CEOCFO: *What have you learned since it has been in use? Have you changed or tweaked anything?*
Mr. Brockway: One of the strategies that we pursued is to commercialize the product as early as possible. In the medical device business that is very difficult to do. Therefore, we looked outside the medical device business to the unregulated preclinical research market where there is a need to analyze noisy ECGs from research models in drug and biomedical research studies. Not only did that bring in cash, but it also gave us tremendous real world experience. It allowed us to understand the technology's limitations and find ways to improve and make the algorithm more efficient. Probably the biggest thing that we learned along the way is how the technology performs in the real world and how to take advantage of what it does really well in order to structure the software to facilitate efficient work flow when processing large volumes of data.

CEOCFO: *How far will the funding that you have now take you? Are you seeking additional funding or investments?*
Mr. Brockway: We are not seeking additional funding right now. We did have a capital raise last summer. Between the capital on hand, cash flows from our service business, preclinical software sales, and the NIH grant, we will be able to rollout the software product currently being submitted to the FDA as well as complete development of the wearable device. We could likely avoid another capital raise, but we will keep our eyes open as we see how the opportunities unfold. We may elect to raise additional capital to accelerate growth in the future.

CEOCFO: *What are some of the lessons learned from your previous ventures?*
Mr. Brockway: What past experience has taught me more than anything else is probably about how to best utilize scarce resources in a startup. There are many ways to get a startup off the ground. One of them is to go out and spend a lot of time raising capital and then building a substantial team, an approach that is very expensive and dilutive to the founders. Once you've taken their capital, providing information to those investors can be a huge resource burden as well. In the last startup I was involved in, raising capital was a big part of my job and also took the precious time of other key people. It's very time consuming and often distracts the best talent from moving the technology to market and taking care of customers. At VivaQuant, we do a lot of planning relating to how and where investment and other capital is sourced but we also spend creative time on how we can efficiently utilize the capital we have. We are focused hard on the customer, product, and the technology and how we can bring this to market as quickly as possible while efficiently utilizing resources. One of our strategies is to build VivaQuant as a virtual company. We staff key areas where the job requirements are unique to us or deep market or technology knowledge is required. We mostly engage people that enjoy a fast-paced and somewhat chaotic environment, bring a broad base of skills to the table, and get enjoyment out of doing whatever it takes to move the company forward. In areas that don't fit this description we use contractors and consultants to keep our fixed costs under control. This way we can flex with the ups and downs of resource needs and can focus the majority of our resources on tasks that build unique value and fuel growth.

CEOCFO: *VivaQuant is located in the Minneapolis, St Paul area, where there is the highest concentration of med tech firms in the world. Why is that important?*

Mr. Brockway: The infrastructure and the talented work force in this area are critical to our growth strategy. This is key, for example, to our strategy of building a virtual company. There are a lot of very talented contractors, consultants, and service providers here that we can tap into for expertise. We also have a state government and local trade associations that promote favorable policies for growth of med tech firms. The University of Minnesota and the Mayo Clinic are also nearby if there is a need for very specialized expertise. It would be much more difficult to execute on our growth strategy in many other metropolitan areas. There are just a lot of resources and a lot of infrastructure to support med tech in the Minneapolis, St Paul area.

CEOCFO: *Why does VivaQuant standout?*

Mr. Brockway: We have a technology that allows us to address a large established market with reimbursement in place where there is a significant unmet need for efficiency and improved quality of information. Something like four million U.S. patients see a physician every year for cardiac arrhythmia monitoring and are prescribed some kind of remote monitoring device. We also have a great patent portfolio with ten issued patents that provide solid protection on a unique technology that addresses a significant unmet need. Longer term, we believe that our ability to remove noise without losing diagnostic information will facilitate the development of non-invasive approaches for improved management of patients suffering from heart failure and ischemic heart disease. It's really exciting to be involved in something where we have the potential to provide significant benefit to patients while reducing the cost and improving the quality of healthcare. It is just a lot of fun and very motivating and rewarding to be involved in something like this.

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