



Novel EP Recording Device that Eliminates the Noise associated with Diagnostic Cardiac Electrophysiology and Ablation Procedures allowing for more Timely Intervention of Arrhythmia



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“We have a novel technology that has the potential to disrupt the marketplace and there are few opportunities to invest in these types of companies, particularly in the cardiac electrophysiology space because most companies go the venture capital route and the ability for a private investor to invest in those companies does not exist because the VCs put in all the money. We are a publicly traded company and anyone can buy our stock on the market. It offers an opportunity to get involved in a high-growth marketplace with a potential to continue grow and improve and potentially save patients lives.”- Gregory D. Cash

CEOCFO: Mr. Cash, would you tell us how you got started with BioSig Technologies?

Mr. Cash: I have been with BioSig for two years. I have spent my entire career in the medical device industry primarily in cardiovascular medical devices. Most of those markets have seen the growth of their products and product segments slow down to low single-digit growth. One of the things that attracted me about BioSig is they participate in the cardiac electrophysiology segment. Cardiac electrophysiology, in addition to being a big market, it is in excess of \$4 billion per year in terms of revenue, is growing at double digits in terms of devices as well as the new patient population. That is one of the things that attracted me. One of the other things is the technology is very novel and potentially disruptive, so that is something that additionally caught my interest.

CEOCFO: BioSig is focused on improving the quality of cardiac recording. How are you approaching that?

Mr. Cash: Most of the products that are on the market today have been out for quite a while and some of them for almost thirty years. There is a lot of room for improvement in the actual hardware itself. The signals that need to be acquired and analyzed in order to treat complex arrhythmias, are very small. The environments in which these devices are used can be very noisy from an electrical standpoint so it makes it difficult to see some of the target signals. If you take an arrhythmia like Atrial Fibrillation for example, which is the largest arrhythmia in terms of incidence rate there is in the market, the primary approach for treating that arrhythmia is using an anatomical approach because the signals are too small to be seen with existing equipment. This anatomical approach has a few issues in terms of the outcomes not being as good as the clinicians might

want. In other words, the recurrence rates are quite high. If a patient has persistent or permanent Atrial Fibrillation (AF), they have almost a one in two chance of requiring a repeat procedure. Our system, which is under development at this point in time, is able to pick up signals that the existing systems cannot see and we also have a way to deal with noise by the way that we distribute our signal processing. In addition to seeing clearer more high fidelity signals, we virtually have eliminated the noise associated with a diagnostic cardiac electrophysiology procedure.

CEO CFO: *What are the ultimate dangers of arrhythmia?*

Mr. Cash: When we talk about complex arrhythmias, the two we are talking about are Atrial Fibrillation and Ventricular Tachycardia leading to Ventricular Fibrillation. Atrial Fibrillation in and of itself is not a life-threatening arrhythmia. There are some risks that go along with it. For example, if you have Atrial Fibrillation you are more prone to forming clots in the atrium that could result in a stroke, so managing the stroke aspect of Atrial Fibrillation is very important. That being said, it is more of a lifestyle and how you feel type arrhythmia. In other words, when you have Atrial Fibrillation, the two upper chambers of the heart are not contracting and therefore are not contributing to the oxygenated blood flow that is being pushed throughout the body. You can live without the contribution of the atria however it is going to affect how you feel; you might be short of breath, you might get tired easily upon exertion or just in general. So it is more of a quality of life issue. Ventricular Tachycardia on the other hand, if not rapidly reversed will lead to Ventricular Fibrillation and if that is not converted it will lead quickly to death. Ventricular Tachyarrhythmias are more life-threatening than AFib.

CEO CFO: *Would you tell us a bit about your diagnostic device the PURE EP™ System?*

Mr. Cash: Our PURE EP™ System, as I alluded to earlier, is designed to improve the clarity of cardiac signals available for EP studies and cardiac catheter ablations. PURE EP is a surface electrocardiogram in conjunction with an intracardiac multi-channel recording and analysis system. It is designed to help physicians make clinical decisions in real-time by acquiring and displaying high fidelity cardiac signals. It is used in the cardiac electrophysiology lab. When a patient has an arrhythmia they are generally referred to a cardiac electrophysiologist who will do this study in the hospital. In some settings it will also lead to a treatment procedure called a cardiac ablation. Cardiac ablation is the application of energy, either radiofrequency energy or cold to kill the cells in the area of the heart that are causing the arrhythmia.

CEO CFO: *Is the test administered by a technician?*

Mr. Cash: There is usually a technician who is operating the recording and analysis system but the placement of the catheters and the actual ablation procedures are being done by a physician.

CEO CFO: *Is the physician the one interpreting the data?*

Mr. Cash: There is usually a technician operating our system however the data that is acquired from it in terms of intracardiac electrograms and surface electrocardiograms, are being displayed in the procedure room. The physician is looking at those signals and using that as a basis on which to diagnose and treat the arrhythmia.

CEO CFO: *Where are you in the development process of PURE EP?*

Mr. Cash: We started a development process with a third-party. They are in the process of developing the device for us, the reason we did that

was primarily to save time. They also are likely to be our contract manufacturer. Since they will be manufacturing the device, it makes for a fairly easy transfer from their own product development team to their manufacturing team. We are smack dab in the middle of the development process so at some point when the device is near its final form, we will do verification and validation testing and make a submission to the FDA in the form of a 510k application. When you are doing a 510k with a device like ours, which is classified as a Class II device, you need to prove that it is safe and substantially equivalent to product that is in the marketplace so there is no requirement to do human clinical trials, which speeds the process up and also takes risk out of the exercise. We expect some time in the first half of next year to be in a position to submit our 510k application to the FDA. You cannot predict how long they are going to take to prove a product but we are projecting somewhere between two and six months. By this time next year we should be in the process of either commercializing or preparing for the sale of our PURE EP system.

CEOCFO: *Are you as well as the company in this for the long-term?*

Mr. Cash: I have spent my entire career dealing with complex medical devices, getting them through development, positioning them in the marketplace and developing markets for them so I am fully prepared to see this through to the end, as is the company. That being said, this is a market that has been dominated by large strategic companies who do not have a good track record of late in terms of innovation. Because this is a large fast-growing market, they tend to snap up new technologies as they come onto the market. We are the only standalone publically held company in this marketplace and there are only a handful of other companies out there. We are going to do what is best for our shareholders and I am not saying that we are going to be acquired but we are prepared to go either way. If an offer comes in that represents the best shareholder value, we are obviously going to evaluate and make a decision based on that, if not we will go the distance and continue as a standalone cardiac electrophysiology company. If we were to do that, we would be the only one out there.

CEOCFO: *Do you have the funding you need presently to get through the next year or will you have to reach out to investors?*

Mr. Cash: We are doing a lot of the fundraising ourselves. We work with an investment bank but do not currently have a fundraising activity underway. We closed one at the end of May and brought a little more cash in after that because there were investors that wanted to invest. We have raised money as we needed it without a great deal of difficulty. Because of the way we have financed the company, we sort of have control of our own destiny. The senior management and the board own in excess of 50% of the company and we have never taken any venture capital. We did that on purpose so we could maximize shareholder value in terms of their investment as well as to get products to the marketplace that help improve patients quality of life and potentially save lives.

CEOCFO: *What would you like to say to the business, investment and healthcare communities, in closings?*

Mr. Cash: The company is participating in a large market. It is a \$4 billion plus market for cardiac electrophysiology devices. The population for patients with cardiac arrhythmias is growing in excess of 10%. The market for electrophysiology products is growing at 12.5 % compound annual growth rate and both are predicted to continue to increase. We

have a novel technology that has the potential to disrupt the marketplace and there are few opportunities to invest in these types of companies, particularly in the cardiac electrophysiology space because most companies go the venture capital route and the ability for a private investor to invest in those companies does not exist because the VCs put in all the money. We are a publicly traded company and anyone can buy our stock on the market. It offers an opportunity to get involved in a high-growth marketplace with a potential to continue grow and improve and potentially save patients lives.



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