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BioSig Unblinding of Clinical Data
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Questioners
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Operator
Hello and welcome to the BioSig Technologies Unblinding of Clinical Data conference call and webcast. At this time, all participants are in a listen-only mode. If anyone should require operator assistance, please press "*0" on your telephone keypad.

A question-and-answer session will follow the formal presentation. For those on the web, you may ask a question at any time by typing it into the "Ask a Question" feature on the left side of your screen. As a reminder, this conference is being recorded.

It's now my pleasure to turn the call over to Andy Ballou, Vice President, Investor Relations. Please go ahead.

Andy Ballou
Thank you, operator, and thank you all for joining us on today's unblinding of clinical data call. Speakers on today's call are Ken Londoner, Founder, Chairman, and CEO of BioSig, and Julie Stephenson, BioSig's head of Clinical Affairs.

Before we begin, I'll remind everyone that this presentation contains forward-looking statements, including statements that address activities, events, or developments that BioSig expects, believes, or anticipates will, or may, occur in the future, such as predictions of financial performance, approvals and launches, by BioSig, of new products, market acceptance of BioSig's products, market, procedure, projections, financial plans, and related documents. Forward-looking statements are based on BioSig's experience and perception of current conditions, trends, expected future developments, and other factors it believes are appropriate under the circumstances and are subject to numerous risks and uncertainties, many of which are beyond BioSig's control.

BioSig does not guarantee any forward-looking statements, and actual results may differ materially from those projected. Unless required by law, BioSig undertakes no obligation to update any forward-looking statement, whether as a result of new information, future events, or otherwise. More detailed information about the company and the risk factors that may affect the realization of forward-looking

statements is set forth in the company's filing with the SEC, including the annual report on Form 10-K and quarterly reports on 10-Q. Investors and security holders are urged to read free-of-charge these documents on the SEC's website, www.SEC.gov. And with that, I'll turn the call over now to Ken Londoner.

Ken Londoner
Thank you, and good day to everyone. Thank you for joining us all on the call. We look forward to describing our critical results to you. For the benefit of those joining the call for the first time and new to BioSig, I'm going to give a brief background on the company.

We were founded in February of 2009, inspired by a physician who was the chair of Harvard cardiology, Dr. Mark Josephson, who introduced myself to the engineers that ultimately ended up designing our technology, and who told me that the quality of electrograms in the industry were causing suboptimal outcomes for the minimally invasive surgical procedure called cardiac ablation. After studying the problem for approximately a year, including patent review, competition, technology assessment, KOL input, all of this, we decided to form the company, and we opened an office in Los Angeles.

We received our 510(k) clearance in 2018. We uplisted to NASDAQ in the fourth quarter of 2018. We made our first commercial installation in November of 2019; and, unfortunately ran into COVID, like every other company. We were out of the market for approximately six months where hospitals were solely focused on treating sick people, and elective procedures were put to the side. We're thankful to see the market opening up completely today.

In terms of where we are today, we are an innovator in cardiac electrophysiology, and we are commercializing what we believe to be a disruptive technology, PURE EP. The global market for electrophysiology is expected to be $12.2 billion by the 2026, an estimated 13.5% compound annual growth rate. The industry is a global one.

We have patents on our technology thoroughly protecting our hardware and software. They're outstanding patents. If anybody'd like to learn more, we're happy to socialize that information. We have FDA clearance. And we've announced our first customers in the first half of this year, and we have more in the pipeline to come.

Today Julie Stephenson, who is our VP of Clinical Affairs, who's been with the company for two years, joined us from Medtronic--great business--she's going to take you through the clinical findings and the trial itself, and then I'll come back and make some comments. Julie, turning it over to you.

Julie Stephenson
Thanks, Ken, and thanks, Andy. Hello, everyone. It is a pleasure to be here today to present the findings from the PURE EP 2.0 study. As Ken mentioned, I'm VP of Clinical Affairs. I've been at BioSig two years, and I come with 20 years of cardiac medical device experience prior to joining

BioSig. I also was fortunate to squeeze in an MBA from the University of Virginia back in 2008. And prior to all of that, I was a critical care nurse for about 10 years with experience in cardiac surgery, cardiac cath lab, and electrophysiology.

So, this is a spoiler alert. I've been asked not to bury the lead, so I'll be starting the call today with the key findings from the study in my first slide and then I'll fill in all the other details and the greater context around the study over the next 10 to 15 minutes during my presentation.

So, here we go. Based on the ratings for each side-by-side signal example, a cumulative total of 204 PURE EP signals out of 218 were rated superior or equivalent in this data set, which equals 93.6%, with 75.2% earning a superior rating. PURE EP signals were statistically rated as superior in three different categories, with a p-value of less than 0.001 in each of those categories.

And those three signal categories are: overall signal quality, with a 92% superior or equivalent rating; ability to discern near field versus far field, with a 96% superior or equivalent rating; and, small, fractionated signals of clinical interest, with a 95% superior or equivalent rating. I'll go into more detail about what these categories mean in future slides.

But first, I want to review with the group the clinical--the overarching clinical data strategy for the PURE EP system. So, this pyramid represents the overarching clinical data strategy. It's the framework that I built almost two years ago to help guide the PURE EP clinical work. The first step in our strategy was to validate the superior quality of the PURE EP signals.

This was accomplished with the PURE EP pilot study that we conducted last year and then was further validated with the findings from the PURE EP 2.0 study, which we're here to review today. The primary goal of the PURE EP 2.0 study was to help clearly define the clinical significance of PURE EP signals.

In parallel to this study, we were also creating an infrastructure to harness the growing database of our PURE EP signals. And currently, we're working to quantify the economic benefits of the PURE EP system. This strategy and our study finding—findings--are already helping BioSig accelerate the commercialization of PURE EP and inform our product pipeline and software modules.

Let's look at the growing database that I just referenced in the strategy. So, beyond the data that we're gathering for our clinical studies, we are also gathering signal data from most of the procedures that we support. So, to date, we have over 1,000 PURE EP procedures from more than 10 hospitals across the United States. And you can see in the larger doughnut there in the center of the slide how that database stacks up as of just a few days ago, July 22nd.

So, 34% of the PURE EP database is comprised of paroxysmal AFib procedures, 29% of the database is persistent AFib procedures, 22% is from VT and PVC procedures, and then 15% represents supraventricular tachycardias. These procedures are similar to the reported procedure mix in most EP

labs across the country, so it's great to see that the PURE EP system is valued in all types of ablation procedures routinely.

This database is already helping support smaller independent investigator studies. It's contributing to the development of additional software modules and AI applications, and it's informing future multicenter clinical studies.

So, this is a really busy slide, but I--it does walk us through the three clinical studies that we have conducted over the last 18 months and it's--it introduces a study that's currently ongoing. And it does show the systematic progress we've made as a company to gather the data needed to support our commercial efforts and to build the foundation for additional clinical studies in the future.

So, on the left side of the slide, in September of 2020 we announced the findings from the PURE EP pilot study, with signals gathered from the first 15 AFib ablation patients, which showed 85% of the time the PURE EP signals were rated superior or equivalent to conventional sources of signals. Today's WebEx is hosted to share the findings from the larger PURE EP 2.0 study, where we had about 100 signal samples from 51 patient procedures, and this study was designed to find the clinical value of those signals.

So, the study expanded--the larger study expanded on the pilot study from last year with more patients across multiple centers and all ablation types, and it was powered for statistical analysis. So, again, the major findings from this study are 93.6% of the PURE EP signal samples were rated superior or equivalent for this data set, and the PURE EP signals were statistically rated as superior in three different signal categories. And we'll go into those categories in a few slides.

But on the right side of this slide, we show another study that's currently ongoing, the Re-Do AFib Ablation Study. It's a single center study to help us explore whether PURE EP signals, when used as the sole source of signals during the procedure, results in different ablation targets and improves procedural efficiency. 50% of the patients in this study will be randomized to PURE EP. 50% were randomized only to the conventional signal system. And the study has already completed enrollment, and we will be conducting the blinded signal analysis sometime in Q3.

We had a strong group of electrophysiologists who are leading our clinical investigations, conducting our core lab review work, and the blinded panel of electrophysiologists to analyze our signal samples. So, we had three enrolling centers for the PURE EP 2.0 study, the Texas Cardiac Arrhythmia Institute in Austin, Texas, Mayo Clinic in Jacksonville, Florida, and Massachusetts General in Boston.

The panel of blinded EPs came from three prominent academic institutions. They were Brad Knight from Northwestern, Wendy Tzou from the University of Colorado, and Rob Schaller from the University of Pennsylvania. Andrea Natale served as the--our principal investigator, and Amin Al-Ahmad is the first author on the study manuscript. The core lab review work was conducted by

Deepak Padmanabhan and Omar Yasin. And we are very fortunate that we had such esteemed physicians supporting and guiding our work on this.

So, now we're going to dig into the details. So, first, this is another busy slide, but we'll--I'll walk you through it. Let's look at the top of the slide. So, we followed a robust process when we collected the signal samples to ensure the highest quality and integrity in our data. So, once all of the side-by-side signal samples were collected from all the procedures, they underwent a core lab review. And the--that review was designed to identify specific signals of clinical interest in each sample.

Through this process, the core lab reviewers identified signals in four different categories. The first category, in yellow at the--in the table at the top, were small, fractionated signals of clinical importance. These types of signals in patients with cardiac arrhythmias indicate areas of scar and abnormal conduction in the heart, and these types of small, fractionated signals are often the culprit of the tachycardia.

The second category in orange was the ability to discern near-field versus far-field signals. These types of signals are important because physicians, during the procedure, as they're manipulating the catheter inside the heart, they're trying to understand whether that signal is coming from nearby the catheter or further away from the catheter. Is it near-field to the catheter or far-field from the catheter? That's something that they're always trying to discern as they analyze these cardiac signals.

The third category of signals in green is the ability to recover quickly after pacing and cardioversion. So, it's not--it's fairly common during the procedure for the physician to need to pace or cardiovert, and we need the signals to recover quickly after those maneuvers. And so, that was our third category of signals.

And then the fourth in purple is the ability to interpret relevant signals during the ablation treatment itself. Oftentimes, when you come on ablation treatment, there's a lot of electrical noise that's seen on the signals, and ideally we'd like for that noise to be gone so that the physician can assess the impact of that ablation treatment as it's being delivered. So, those were the four categories of clinically significant signals that our core lab reviewers identified.

Now let's look at the bottom of this slide. So, out of that review process, we ended up with 92 signals sets, and a blinded assessment with 235 questions. We subjected that analysis to all three of our blinded reviewers, and we found when we got those results back that 93% of the responses showed consensus across the blinded reviewers. We were really pleased to see this because it indicated that there is a strong consistency across the panel of reviewers.

Based on the ratings for each signal set, we also--and this is something I announced on the first slide, we found 93.6% of the PURE EP signals were rated as superior or equivalent for this data set. But I do want to draw your attention to the table there, bottom right, and just ask you to see the difference between the number of signals rated as superior versus those rated as equivalent. And you can see that

the superior rating occurred four times more than the equivalent rating. So, even though the PURE EP was superior or equivalent, we saw a strong tendency towards a superior rating there.

So, now let's look a little deeper at the statistical analysis. We found, when we looked by signal category, that PURE EP signals were rated statistically superior in three particular categories; overall signal quality, ability to discern near-field versus far-field signals, and the clinical value of the small, fractionated signals, with each of those categories showing a p-value of less than 0.001.

Again, the ability to discern whether a signal is near-field or far-field is important during the procedures because it indicates whether that signal is coming from nearby or further away from the catheter that the physician is using to treat the patient. Small, fractionated signals are clinically important because they indicate areas of scar tissue or abnormal conduction inside the heart, and that can oftentimes be the area where the abnormal heart rhythm is originating.

Then we analyzed the data by procedure type, and we were very pleased to see that the PURE EP signals were rated statistically superior in every type of ablation procedure. Regardless of the type of ablation procedures the patient had, we saw that the PURE EP signals were providing great clinical value, with p-values, again, of less than 0.001 in each of those ablation procedure types. So, this shows that PURE EP is providing important contributions regardless of the cardiac ablation procedure. As you can imagine, we were very pleased to see these results.

So, now I want to revisit the PURE EP clinical data strategy in my last slide. So, the PURE EP 2.0 study plus the growing database of greater than 1,000 PURE EP procedures have helped us achieve-- the second level of this pyramid. As mentioned earlier in the presentation, BioSig has also completed enrollment in the next clinical study, the Re-Do AFib Ablation Study. This study will provide more data on the clinical significance of PURE EP signals and provide objective data to support the economic benefits of PURE EP. The blinded analysis of those signals will — will take place sometime this Fall. So what do these findings mean for patients suffering from cardiac arrhythmias? At the end of the day, why are these study findings important? Signal data is a critical factor in successfully diagnosing and treating all cardiac arrhythmias. Intracardiac signals are one of the most important inputs driving physician decisions during an ablation procedure.

So with these study results today, we can now say PURE EP represents a new standard in signal acquisition and provides superior physiologic cardiac signals well above the conventional systems on the market. We routinely hear from our physician users that PURE EP makes them more confident and efficient. And this is great news for patients, for doctors, and for the hospitals that they work in. So Ken, so that's what I've got. Do you have anything else you'd like to add?

Ken Londoner
Thank you very much, Julie. And we're going to turn to questions in a moment. First, I wanted to make a comment on our observations about what we see in the market, and a word on the industry.

Obviously, with COVID, you know, and the vaccine coming into view, the industry has opened up quite a bit.

Second quarter results out from the larger corporations note overall momentum across the med tech sector and follows a favorable second quarter commentary from companies like Intuitive Surgical, Johnson and Johnson, Abbott, and others. Abbott said recently that their medical device sales increased almost 20% in the quarter, while Johnson and Johnson noted medical device sales increased 60% in the second quarter driven by procedural volumes and new products.

HCA, which is the largest publicly traded hospital system on the New York Stock Exchange in the country, indicated that hospital procedural volumes are increasing too, which is good news for patients and for companies like BioSig. Hospitals have had an infusion of government monies to help them get through COVID and they have seen, you know, a dramatic improvement in financial results. Obviously, for new product introductions, that's a beneficial backdrop for us to be marketing our product.

We said at the beginning of the year, we gave guidance along the lines that we would expect to be in 20 hospitals by the end of the year under evaluation, and some would convert into paying customers. We're on track, possibly a little ahead of plan, as far as what we expected to do this year. And we're in planning, after the Heart Rhythm Society Convention, we'll be in planning to lay out 2022.

We've been very pleased with procedural volumes. Our clinical account management team, led by Julie and John Kowalski, our head of Sales, has really done a great job getting us onto the different playing fields in the EP labs. If you look at the expanded product adoption slide, you'll see how many procedures we've done as of 7/13/2021. We're now at 1,105 procedures. And at the beginning of the year, we noted we thought we'd do 1000 procedures. We revised that guidance several weeks back to say we think we do 1500. But we continue to see a dramatic increase in product utilization. And from all my years of being in the med tech industry, our internal belief is that increased utilization of the system is a precursor for product adoption.
These folks wouldn't be using the PURE EP system if they didn't see a value in it. And they are being supported by an outstanding clinical management team.

We're also seeing an expanded number of physicians. So it's not just a number of procedures. It's trying to touch as many physicians as possible, and you will continue to see us striving to get new people learned and trained on the system. And in terms of the pipeline for new installations, we see an increase in interest as the word starts to get out. We believe this clinical data will be a benefit, not only in introducing the product to new hospitals, but also in the commercialization process. It

allows our sales teams to refer to clinical output. And we believe this multi-center study done at some of the best hospitals in the United States, with the CRO, fully blinded, is a great step forward for the company.

In terms of going forward, we have the Heart Rhythm Society Convention coming up next week. And there is a slide that shows all of the — all of the experience that an attendee can have at this event. We will be recording these events with television cameras, and we will be posting the presentations up on our website shortly thereafter the Heart Rhythm Society. As you can see, we have two evenings planned out where we have physician leaders there to discuss their experience with the PURE EP system.

The first evening is entitled PURE EP: A New Standard in Signal Processing. Dr. Pasquale Santangeli from University of Pennsylvania, Dr. Pedram Kazemian from Deborah Heart Lung in New Jersey, and Dr. Miguel Valderrabano from Houston Methodist will be presenting. We couldn't be happier about that. And then, on Thursday, July 29, we have a dinner called PURE EP Clinical Data to Clinical Applications with Dr. Christopher McLeod from the Mayo Clinic in Jacksonville and Dr. Andrea Natale from Texas Cardiac Arrhythmia presenting.

In addition, we have two scientific presentations on Thursday, July 29. We have a podium presentation of data collected and produced by Dr. Pedram Kazemian on post-ablation bipolar voltage by PURE EP as a marker of lesion assessment. Very important subject within the procedure. And then, Jonathan Salas will be presenting atrial unipolar electrogram filtering to better delineate amplitude and morphology during radio frequency ablation. That is the poster presentation. And he is from the University of Pennsylvania. So with that — with all that said, we would like to open it up to questions. Thank you.

Operator
Thank you. We'll now be conducting a question-and-answer session. If you'd like to verbally be placed in the question queue over the phone, please press “*” “1” on your telephone keypad or, if you’re on the web, you can type your question into the Ask a Question field on the left side of your screen. One moment, please while we poll for questions. Our first question today is coming from Yale Jen from Laidlaw & Company. Your line is live.

Yale Jen
Good afternoon. First, congrats on your outstanding outcomes. It seems like a homerun to me. And so is much broader, in the procedures as well as a higher sort of achieve — success rate. My first question is that, what do you anticipate the potential benefit that the physician could benefit from — from use the PURE EP system in their procedure. Ultimately, whatever benefit the patient could receive, because of using the systems?

Ken Londoner
Julie, I guess I'd let you take that —

Julie Stephenson
I'm happy to take that.

Ken Londoner
Please.

Julie Stephenson
Yep. Thank you, Ken. I'm happy to take that question. So essentially, what are the anticipated benefits to the patient for using this kind of technology? So I, first of all, thank you for the — the comment and the question. There's no doubt that using the PURE EP system and having a higher fidelity, clearer signal, physiologic signal information will serve the patient because the physician conducting the procedure will have a clear line of sight to where that tachycardia could be coming from. And it will also help them be more efficient in their procedures. So if you — if you've got better signal information to guide the procedure, there is some likelihood that it could help the procedure go faster. The physician would be potentially delivering less ablation lesions inside the heart because they can be more specific in their — in their ablation targets. And so I think all of that, then, would translate perhaps into improved outcomes where, in particular, with the patients who have atrial fibrillation, there's a relatively high percentage of patients who need to have redo procedures. So it's — it is our work with this — this next clinical study that — that we've just completed enrollment and that we will have some data to show specifically how PURE EP can impact even procedural outcomes.

Yale Jen
Okay, great.

Julie Stephenson
And if —

Yale Jen
— And maybe — I'm sorry, go ahead.

Julie Stephenson
I just wanted to see if Ken had anything else that he wanted to add to that — to that response.

Ken Londoner
No, that was very good, Julie. Yale, did you have a second follow up?

Yale Jen
Yes, I do. Just a quick one. Basically, you just mentioned about the ongoing study. First of all, when is this study, you may report data, you are analyzing the data in third quarter? Would that be — would the readout be in the second half of this year? And maybe the last question here— you guys are attending the HRS meeting tomorrow, starting tomorrow. For Ken, what would be your anticipation or what do you hope to get from this meeting in terms of maybe increasing the accounts or other sort of benefits? And thanks.

Ken Londoner
Sure. Julie, you want to —

Julie Stephenson
— Yeah, I'll take the —

Ken Londoner
— Take the first — yeah, go ahead.

Julie Stephenson
Yep. So the Re-Do Afib ablation study that — that I mentioned, we've closed enrollment. We are gearing up for the blinded analysis of those signal data in the Fall, sometime late Q3. And then, we would need some time to analyze those data working with the statistician, et cetera. I wouldn't realistically expect results to be shared until sometime early 2022.

Operator
Thank you. As a reminder, if you'd like —

Julie Stephenson
— Ken?

Operator
Please go ahead. Forgive me,

Julie Stephenson
No, no. Ken —

Ken Londoner
— So the answer to your second part of your question, Heart Rhythm Society is a very large event. We have a comprehensive lineup of different meetings from scientific data, podium, and poster presentations. We have demonstrations to future customers, existing customers, and other constituencies in our booth. We'll have a full demo on the floor, and we will have customers coming through inquiring about how PURE EP works. We'll be giving them a demonstration taking them through the data. And we expect a pretty full turnout based on all the behind the scenes and outreach that we've done.

Andrew Ballou
Great. So thank you. Operator, I'll read a couple here from the webcast questions that have been written in. So in signal assessment, is there a threshold that hospitals would want in order to consider switching to/adding PURE EP? It would seem that anything over 50% would mean hospitals should buy PURE EP. And I think, Julie, if you could take a shot at that, that would be great.

Julie Stephenson
Very good. So yeah, so thank you for the question. I would — I think it's difficult to — to speak specifically to what that threshold is, you know, as it relates to hospitals making purchases of new equipment. But there's no doubt from these findings that pure EP represents the new standard in signal acquisition and processing in the electrophysiology space. So I think once these results get disseminated across the space, and I think the Heart Rhythm Society represents a great opportunity for the company to disseminate these results to a larger group of EP users, and potential EP users, that there will be, I anticipate, a growing demand for this technology.

But it's — it's difficult to know. The hospital purchasing process is complex, as probably many of you recognize and, you know, this would represent an additional piece of equipment that would need to be purchased. But I have no doubt that these results do represent vthe new standard and signal acquisition in the electrophysiology space. I hope that answers the question.

Andrew Ballou
That does. Great. Thank you, Julie. We have another one coming in from the webcast. This is for you, Ken. What do these trial results mean for commercialization?

Ken Londoner
Thank you. In order to commercialize, you have to convince the physician that the technology is a value to them in their practice. So they need user experience. That's the reason we do the installations and the trials. But then, the hospital administration needs to see data. They need to be able to check the box in their administrative review of the value of PURE EP that there is clinical data.

And I believe today's results give us the opportunity to check that box when we're in commercial conversations. And this data, to remind everybody, is going to be published in a leading medical journal. And as that gets published and it gets presented and socialized at not only this Heart Rhythm Society but other industry events, I believe that'll only support our commercial opportunities. Next question.

Operator
As a reminder, if you'd like to be placed into question queue, please press “*” “1” on your telephone keypad, or you can type your question into the Ask a Question field on the left side of your screen. One moment, please while we poll for questions.

Andrew Ballou
Operator, while we’re polling for questions, I've got another one here from the webcast. And this one, I think, goes to Julie. Can you say with confidence that the small, fractionated signals that the PURE EP detects hold the key to curing an arrhythmia?

Julie Stephenson
Yes. So Andy, thanks for the question. So these small, fractionated signals, as I mentioned, represent areas of scar tissue inside the heart and slow abnormal conduction. And these very small, highly fractionated signals --until PURE EP was invented--were very difficult to acquire and see in the conventional systems. I'm talking about signals with an amplitude of less than 0.05 millivolts. And we're seeing these types of signals more routinely on the PURE EP system that haven't really been able to be appreciated on the conventional technology.

And what we're discovering is that these — these signals that we're seeing, when we treat Re-dos tend to lead the physicians to the origin of those tachycardia. So I do think it is an important finding for us. And we — we do have additional research work where we really want to dig into the small, fractionated signals in more detail and look by ablation type and arrhythmia type to really help the EPs understand those signals in more detail and describe them in the future. But yeah, it's a very important finding for us, for sure.

Andrew Ballou
Thank you.

Operator
Thank you. We’ve reached the end of our question answer session. I'd like to turn the floor back over to Ken for any further or closing comments.

Ken Londoner
Thank you, everybody, for your time today. We look forward to seeing a number of you at the Heart Rhythm Society. Don't forget we have a dinner on Wednesday with physicians and customers speaking to the technology. We also have a dinner on Thursday evening as well. We look forward to answering your questions. That's the Heart Rhythm Society. Thank you.

Operator
Thank you. That does conclude today's teleconference and webcast. You may disconnect your line at this time and have a wonderful day. We thank you for your participation today.