

BioSig Technologies Clinical Call September 15, 2020

Presenters

Ken Londoner - Founder, Chairman and CEO Olivier Chaudoir - Senior Director of Marketing Julie Stephenson - Vice President of Clinical Affairs John Kowalski - Vice President of Sales Andrew Ballou - VP Investor Relations

Q&A Participants

Roman Livson - Katalyst Securities Yale Jen - Laidlaw and Company Robert Carlson - Janney Montgomery Scott Gary Zwetchkenbaum - Plum Tree Consulting

Operator

Greetings, and welcome to the BioSig clinical call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. You may submit questions via the web at any time by typing them into the "ask-a-question" field on the left side of your screen. If anyone should require operator or technical assistance during the conference, please press "*0" on your telephone keypad. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Andy Ballou, VP of investor relations. Thank you. You may begin.

Andrew Ballou

Thank you, operator. Welcome to the BioSig Technologies, Inc. conference call and webcast to discuss the unblinding of PURE EP human data. Thank you all for joining us this morning. On today's call from BioSig technologies, we're pleased to have Ken Londoner, Founder, Chairman, and CEO of BioSig technologies; Olivier Chaudoir, Senior Director of Marketing; Julie Stephenson, Vice President of Clinical Affairs; and John Kowalski, Vice President of Sales.

I'll remind everyone that on this call, the presenters may make forward-looking statements. Such statements may be preceded by the words intends, may, will, plans, expects, anticipates, projects, predicts, estimates, aims, believes, hopes, potential, or similar words. Forward-looking statements



are not guarantees of future performance, are based on certain assumptions, and are subject to various known and unknown risks and uncertainties, many of which are beyond the company's control and cannot be predicted or quantified. And consequently, actual results may differ materially from those expressed or implied by such forward-looking statements.

Such risks and uncertainties include, without limitation, risks and uncertainties associated with the geographic, social, and economic impact of COVID-19 on our ability to conduct our business and raise capital in the future when needed, our inability to manufacture our products and product candidates on a commercial scale on our own or in collaboration with third parties, difficulties in obtaining financing or commercially reasonable terms, changes in the size and nature of our competition, loss of one or more key executives or scientists, and difficulties in securing regulatory approval to market our product and product candidates.

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 filings with the Securities and Exchange Commission, SEC, including the company's annual report on Form 10-K and its quarterly reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's website at www.SEC.gov. The company assumes no obligation to publicly update or revise such forward-looking statements as a result of new information, future events or otherwise.

I'll now turn the call over to Ken Londoner.

Ken Londoner

Good morning, everybody, and thanks for joining us today. We will be unblinding data from our very first human clinical trial, and the findings we will discuss. We will also be relating how this data impacts our sales and marketing activities, which have shown some notable pickup in the past several months.

First, I'd like to frame today's discussion through a fundamental and historical context, what I refer to as the medical device innovation cycle. This cycle is tried-and-true. Many of our predecessors have followed the exact same process, and it's characterized by four stages. We started this company because we noted a technical issue in the EP lab that we felt we could, with our engineering skills and capabilities, translate into a meaningful improvement in clinical outcomes. Today's call is historical for us, as we're demonstrating that we've made it to this part in the cycle.

From a historical context, the first stage of our development was called concept feasibility, where our engineers went to Texas Cardiac Arrhythmia Institute and UCLA, and basically were learning from the physician surgeons how to make a prototype that can help solve the issues that they were having. That took us several years.



We took that concept into a first prototype and went into design validation and three clinical studies, where we could fine-tune and improve the innovation that we had. We did that from 2014 through 2017 at Mount Sinai Medical Center in New York and Mayo Clinic. We continued to get favorable results, so we moved forward and ultimately were able to produce FDA approval in the late summer of 2018.

Once we had approval and we were waiting for inventory from our manufacturer, we then did our first in-human clinical experience in February of 2019 at the Texas Cardiac Arrhythmia Institute. And from there, we then went into our first human cases where we installed our first commercial system in November of 2019.

From that point, we've been conducting a clinical trial—this clinical trial we'll be discussing today—to produce data and information that would lend towards the additional targeted commercial release of our system, which we are now into, which the team will be discussing.

Just for those that don't know our company well, the market is quite sizable. The electrophysiology market is approaching \$7.4 billion in size in 2022. It's growing at a double-digit growth rate. It is the fastest growing segment in cardiology, and it is projected to grow for a long period of time. In the U.S., we think there are approximately 3,425 EP rooms that could ultimately take a PURE EP system, so it's a sizable market opportunity for us.

One of the other interesting things is the EP market is characterized by very generous and well-earned reimbursement rates and absolute reimbursement dollars. When COVID hit, and obviously everything kind of shut down in the hospital market for a period of months, as the hospitals are now coming out of that panic-stricken moment in time, they are favoring EP procedures. Because if you look at the bottom left of our slide, you can see that inpatient ablations are being reimbursed at a very handsome rate, relative to other categories of elective procedures.

So the EP labs are very busy. Some are operating at over 100% of their capacity, working through the backlog of patients that needed cardiac ablation treatments that weren't able to get in the first several months after COVID hit.

The other thing I'd point out is on the right side of the chart, the CMS reimbursement changes year-over-year continue to favor ablations and left atrial appendage procedures, which is a subcomponent of the market. And we're almost at double-digit reimbursement rate increases. So our belief is that we will see the EP market come back to full strength. We are seeing that, and hospitals are getting active and busy again.



I'm going to turn the call over to Olivier, who will discuss our technology and our marketing approach.

Olivier Chaudoir

Thank you, Ken. Good morning, everyone, and thank you for attending this call. My name is Olivier Chaudoir. I joined BioSig Technologies a little over a year ago to lead the marketing activities, after having spent 20 years with Johnson & Johnson, amongst which 17 years were in EP in different roles—marketing, business management—in multiple locations across the globe.

I am very excited to be part of BioSig Technologies, given the fundamental need around providing better high-fidelity cardiac signals to the EP community. First, I wanted to give you a brief update on what is making PURE EP so unique in the marketplace. Over the last 20 years, extensive developments were made with regard to mapping technologies. However, very little was done in regard to signal acquisition and signal processing.

PURE EP is addressing critical unmet needs and is designed based on a unique system architecture that is acquiring raw cardiac signals from the patient and converts it into a digital modality. This means that PURE EP is entirely working in the digital domain, providing high- signal fidelity and much more flexibility. Finally, PURE EP is complementing existing EP equipment by providing unique and new information during product procedures. It seamlessly integrates with current technologies and does not disrupt the clinical workflow.

Before moving on to the next section with Julie Stephenson, I'd like to play a short video that will give you a real sense of how PURE EP is used during a procedure, the value that it brings, and how signals acquired by PURE EP are making a difference in diagnosing and treating cardiac arrhythmias. Thank you.

(Video Presentation)

Julie Stephenson

Thanks, Olivier. That video case presentation with Dr. Natale does a great job of showing the PURE EP system in action during a real procedure. I think that's very helpful for all of us to see.

So hello, everyone. This is Julie Stephenson. I'm the vice president of clinical affairs at BioSig Technologies. I've been with BioSig now for about 14 months, and bring to this role greater than 20 years of med device industry experience, working for both Boston Scientific and Medtronic. And prior to my med device industry experience, I was an EP lab nurse. I appreciate the chance to share more information about our recent clinical study results with this group today. So thank you for joining.



I want to start by reviewing the clinical data strategy for the PURE EP System. It's a strategy that is well-defined and will support the commercialization of the PURE EP technology. Step one is validating the superior quality of the PURE EP system, and we've already accomplished this with the ESC 2020 data that we'll be reviewing today. The next step for us in the strategy was to build an infrastructure to harness the growing library of raw procedure data.

As of this phone call, we have collected and cataloged signal data from already over 250 PURE EP procedures, and we've built a searchable cloud-based system with tagging functionality to utilize this data for the development of our future clinical modules back to our pipeline, and in our ongoing exploration of AI. We are now squarely focused on understanding the clinical significance of the PURE EP signals. And once we finish doing this, the rest of the pyramid will stack easily.

The PURE EP study was carefully designed to allow BioSig to achieve two important objectives. First, we needed to validate the superior quality of the PURE EP signals when directly compared to existing standard of care sources of cardiac signals. The first publication from the PURE EP study does just that. So we'll go into more detail about those findings in the coming slides.

But in phase two of the study, which we are currently in right now, we will better define the clinical value of the EP signals. We hope to have more data to share about phase two sometime in 2021.

Our primary message for achieving these study objectives is twofold. First, we are collecting matching signal data during each procedure from the PURE EP System, the recording system, and the mapping system. It's important to note that the recording system and the mapping system are the current standard-of-care sources of cardiac signals used today in the EP labs. These systems also serve other important purposes during the procedure, and the PURE EP system runs in parallel.

The recording system also monitors the vital signs, and it stores the electronic medical records. So you can see in the picture there in the middle at the bottom, there's a nurse, and she is responsible for recording everything that's happening during the procedure. The mapping system creates an image of the patient's heart anatomy, and that is used to help show where the catheters are sitting inside the heart.

So once we've collected all of these matching signal samples, this data is collected, randomly arranged, and we subject the signal data sets to a blinded analysis by three leading independent electrophysiologists. So let's take a look at who these folks are.

So in order to ensure high-quality results in our data analysis, we assembled a world-class group of leading electrophysiologists. Dr. Andrea Natale is our principal investigator nationally for the PURE EP 2.0 study, and he's based out of Texas Cardiac Arrhythmia Institute in Austin, Texas. And then the



three independent blinded reviewers of our cardiac signal data sets come from three different academic EP training centers across the country.

Dr. Brad Knight is director of the EP lab at Northwestern in Chicago; Dr. Wendy Tzou is the associate director of the EP lab at the University of Colorado in Denver; and Dr. Pasquale Santangeli is an associate professor of medicine at the University of Pennsylvania. Each of these blinded reviewers received and analyzed the same signal data selected from the first 15 patients enrolled in the PURE EP 2.0 study. We asked them to select the cardiac signal data that they preferred for its diagnostic value, and then to provide a rationale for their preference from a drop-down menu.

So just to be clear, phase one of the PURE EP study involved the first 15 patients enrolled from TCAI or Texas Cardiac Arrhythmia Institute in Austin, Texas. And all of the patients underwent an afib ablation procedure. And then from these 15 patients, 34 signal data sets were randomly selected and arranged for the blinded analysis by our three independent EP reviewers. They rated the overall quality of the signal data and provided a rationale for their preferred signal example in each set.

And now let's talk a little bit about those results. The results from phase one of the PURE EP 2.0 study validates all of BioSig's preclinical findings. It validates the benchtop testing results we've seen, as well as all the positive anecdotal feedback we've received from many EP users prior to this publication. We've heard many times that the PURE EP system generates more signals than can be seen on other systems.

So what the results today provide for us is it quantifies how much of the time we're seeing additional signals. And it showed 36% of the time, the PURE EP system shows more signal components than the conventional system. This result represents potentially thousands of additional intracardiac signals during each procedure.

The two panels in the top right of the slide are one of the signal steps from the study. So I just want to review this with the audience today, because I think it helps explain the significance of this 36%. The panels show identical cardiac beats over a few seconds of time, as displayed on the two systems during the afib ablation procedure. The last panel shows the PURE EP signals, and the right panel shows the conventional signals.

Each line in this image represents different cardiac signal information. The top three lines come from the surface electrodes on the patient's chest, and the other 11 lines are coming from the many electrodes on the three to four catheters inside the heart. So this is obviously very complex information. I understand and appreciate that. And electrophysiologists are trained to interpret and understand all of these signals in detail.



But just to go into this a little bit more, I've drawn a box around a set of lines in the PURE EP sample. And even though we're not electrophysiologists, if you compare them closely, you can appreciate that there is a difference between the two. That there are more signal components seen on the PURE EP example that are not seen on the conventional system. And to our blinded EP reviewers, these additional signal components were important and provided more diagnostic information.

So I think it's also important to say that the independent reviewers did not see more signal components on every randomly selected signal example, but across this data set, more signal components were seen 36% of the time. Again, this represents potentially thousands of additional important diagnostic signals during each procedure that are not currently being seen or appreciated on the conventional systems.

So as I think about an analogy that might help explain this a little better, this is what I came up with. The conventional cardiac signal systems are like an older mobile phone provider that gives a good signal about 64% of the time. But when it's most important to hear what the other person is saying, it drops out. So the PURE EP system is like a better mobile phone provider delivering more complete signal information.

I hope that analogy helps explain the significance of these findings a little better. And then just as a final reminder, the PURE EP study is ongoing. The phase two data are currently being analyzed, and we plan to have additional published results sometime in 2021.

At that, I'd like to hand it over to John Kowalski.

John Kowalski

Thank you, Julie. Good morning, everyone. I joined BioSig Technologies as the vice president of sales in January of last year. Prior to BioSig, I spent 24 years with Johnson & Johnson in their electrophysiology division named Biosense Webster, and was involved in the initial commercial launch of the CARTO mapping system back in 1996.

I'd like to spend a few minutes updating you on our progress and our overall commercial strategy. As Ken mentioned, we are executing a phased rollout of the PURE EP System, which really is a proven formula for success within the medical device industry. Last year as some of you remember, we completed our first in-human cases, as well as the evaluation of our first and second-generation PURE EP systems. We certainly learned a great deal during these initial procedures, and as a result of the customer feedback, we made several very beneficial product enhancements.

This year, in spite of the challenging COVID environment, we advanced to a limited market release of the system. And in 2021, we will expand to an accelerated launch of the technology.



As mentioned, currently, we are in the limited market release phase and focusing on system evaluations with several of the world's expert EP physicians. The goal during this phase is to further develop our clinical and economic evidence, to expand the clinical utility of our system, and to ultimately create positive market awareness and market demand for the PURE EP System.

Our number one goal this year is to install PURE EP systems in 10 leading hospitals by year-end. As many of you know, we installed our first system with Dr. Natale at St. David's in Austin, Texas. And as a result of our success in those first cases with the first system, we installed a second and recently a third system at the request of the physicians as they recognize the benefits of using the PURE EP system to help all of their patients.

As previously announced, we also currently have systems installed at the Mayo Clinic in Jacksonville, Florida, as well as Massachusetts General Hospital in Boston. In addition, we have four hospitals which we will be announcing soon where evaluation contracts are already finalized, and we will be installing in these hospitals over the next 60 days. So it's an exciting time given that our user base will increase from three centers to seven centers by early November.

We're also very close to finalizing agreements with several additional hospitals, which ultimately will enable us to achieve our overall install goal of 10 centers by year-end. After the evaluation period in these top 10 centers, we will be transitioning them over to purchase. We've developed several flexible payment options, including rent-to-own, buy now/pay later, lease options, and other deferred financing options as needed, which will make it easier for customers to acquire the system along with our annual service and our software upgrade offerings.

We're also in the process of creating several centers of excellence training sites where visiting physicians can observe procedures and see firsthand how the PURE EP system can help improve outcomes. And great news. St. David's in Austin has recently agreed to be our first COE site, and they will begin hosting visiting physicians next month.

We're also preparing to expand the launch next year, and thus we're investing in building our team. We're planning to add additional clinical account managers, sales managers, and other commercial support resources as needed. We are planning to showcase our technology at several upcoming industry conferences: the VT Symposium next month sponsored by Mount Sinai in New York and the University of Pennsylvania; we'll be at the EP Live conference in Austin at St. David's in December; and then next year again at the AFIB Symposium in New York City; and then also at the Heart Rhythm Society meeting which is the largest industry event in July in Boston next year.

So with that, thank you for listening. Thank you for your support. And at this point, I'd like to turn it back over to the Operator who can open it up for questions. Thank you.



Operator

Thank you. At this time we will be conducting a question and answer session. As a reminder you may type your questions into the "ask a question" field on the left side of your screen. If you would like to verbally ask a question, please press "*1" on your telephone keypad. A confirmation tone will indicate your line is in the question queue. One moment please, while we poll for your questions.

Andy Ballou

Operator, while we're waiting for questions to poll, I'll take one from the webcast. And this is for the team. Can you give us some context around the number of patients in the study? Fifteen seems like a small number. Also, how were the signals selected?

Julie Stephenson

Hi Andy, this is Julie. I'll take that question. Thank you very much. Yeah, so I think it's important to note that in consultation with Dr. Natale and his team around this phase one of the PURE EP study, it was noted that we didn't need a lot of patients. And the reason behind that is that literally, there are, as I said, thousands of cardiac signals that stream across the screen during each procedure. And so from 15 patients, we were making 20 to 25 signal annotations throughout the procedure and then working with those EPs to make some decisions about, you know, which of those signals to include in the study for potential randomization.

So the reality is during each procedure we have access to countless signal examples. Which means that we don't have to enroll that many patients in order to get a robust result. Thank you for the question.

Andy Ballou

Thank you. Operator we'll take a question from the line now.

Operator

Thank you. Our first question from the phone comes from Roman Livson of Katalyst Securities. Please proceed with your question.

Roman Livson

Yeah so good morning. Congratulations on the great results. I have two questions. First of all, armed with that information on 36% of cases, what will the clinician do differently? How would the procedure change from the current standard? That's number one. And number two, one of the known lingering side effects of COVID is heart arrhythmia. Was wondering if there's any synergy of that for BioSig. Thank you.



Julie Stephenson

This is Julie, I can start with those questions. So 36% of the time they're seeing additional signal data that they're not currently able to appreciate on the conventional system. And even in the video example that Olivier shared at the start of our presentation today, it shows a real-life case where Dr. Natale was able to more quickly identify the target area for that arrhythmia, that cardiac arrhythmia, and deliver treatment.

So even though, as I said on the phone today, I don't have the hard data that support PURE EP expediting procedure time and perhaps even procedure efficacy, it is our plan to continue to analyze future PURE EP study data and try to get at those particular answers. But you can see just anecdotally that if they have more diagnostic information during their procedure that it could benefit them by getting to the exact site inside the heart that needs to be treated more quickly.

And then you--so I guess I'll open it up to the team to see if there was any other comment on that topic before we answer his second question related to COVID.

Ken Londoner

Julie, you can answer the question--

Olivier Chaudoir

--This is--yeah. This is Olivier. I agree with what you said absolutely and what was shown on the video is a good illustration of, you know, that usual information that we can get--that we're getting with the PURE EP System. Those are, you know, complex electrograms that have a lot of diagnostic value and meaning, and we're seeing a lot of those cases and will see more, you know, as we are activating more accounts. But yeah, 36% of the time, seeing more signals and critical signals is significant. So I'm very confident that, you know, this will play a major role and will have a significant impact on how procedures are being conducted moving forward.

Julie Stephenson

And then as it relates--

Roman Livson

--So it wouldn't--it would improve clinical outcomes for a number of patients that won't have to undergo the procedure again. Would that be the main consequence, the main benefit?

Julie Stephenson

It's a little premature for us to be making those claims now. But we do have an analysis of additional data that hopefully will help us answer those questions more clearly and be able to make those



claims. But anecdotally that is what we're, you know, hoping and hearing from physicians that we're working with currently. I hope that helps.

And then as it relates to the COVID patients they, you know, there are some patients suffering from long term cardiac conditions, and naturally some of those patients will need to be treated by electrophysiologists. So there is some potential opportunity for the PURE EP technology to help treat those types of patients long term.

Roman Livson

Thank you.

Olivier Chaudoir

Thank you.

Julie Stephenson

Mm-hm.

Andy Ballou

Thanks Roman, thanks Julie. We're going to take one from the webcast now from Anthony Amato. How do you plan on ramping sales for EP? BioSig employees or an established sales organization established in the market? Ken will answer that.

Ken Londoner

Thank you Anthony. In terms of ramping, like I said earlier in the presentation, there's a tried and true formula that all publicly-traded and even private med-tech companies undergo. Getting this data is a critical component to the selling process. And getting the support of physicians at leading centers is also part of that as well as going to conferences, publishing papers, et cetera.

Because of what we've been able to achieve with the team at Texas Cardiac Arrhythmia Institute which was done in less than a year from the time we showed up there, we now have the advocacy of that center, as well as Mayo Clinic, and hopefully soon to be other centers of excellence. Once we have that, we're able to then start moving the sales process to the next level.

As John Kowalski said, that would be hiring additional sales resources which we'll be talking more about towards the end of the year. We're in the market hiring now. You know, we don't disclose who we hire when we hire, but that team is expanding, which will help us meet the needs of this year. And then ramping into next year.

One other question that goes along with this is, how do you convert these types of activities to revenues? And that conversion cycle in the early days does take time because you have to ramp up



these centers and get them to the point where we've gotten to, which is excellent. As we start getting more and more proof points, the evaluation periods are going to shrink. We have some deals in the pipeline where the evaluation period is 30 days. And after the evaluation period's over, assuming we reach the same point that we've reached in these first two centers, then the conversion comes in where we work on a commercial transaction.

So the pipeline will be loaded up with 10 centers and then many more going into 2021. And that's really the beginning of the sales ramp for the company.

Andy Ballou

Thanks Ken. Operator, we'll take another from the telephone line now please.

Operator

Thank you. Our next questions come from the line of Yale Jen with Laidlaw and Company. Please proceed with your questions.

Yale Jen

Good morning first, and congrats on very encouraging data here. My first question is that in terms of 36% additional signals--was this number significant from a practitioner's perspective, as well as what type of patient or procedures that would enable to have additional signal being seen. What's the patient characteristic, or other aspect of the patient might be? And I have a follow up.

Julie Stephenson

So this is Julie Stephenson. So the 36% I guess it's important to note that the results were not powered for significance but, you know, we did see 36% of the time our independent reviewers responded that they preferred the PURE EP signal sample because it provided more components-signal component--than what was seen on the alternative signal sample.

So as it relates to the types of procedures that the PURE EP system is being used for, we're currently participating in all types of ablation procedures. Afib ablations, VT ablations, PVC ablation procedures. Any type of ablation procedure the PURE EP technology can be used, and is being used in those centers where we're currently installed.

In phase two of the study, which we are currently involved in right now and enrolling in, we are enrolling all of those different types of ablation patients. And it will be a multi-center analysis. We'll have many more signals, and a more robust analysis will happen with our blinded reviewers in phase two.



Yale Jen

Okay great. And maybe just one follow up. Yes, that's great insight here. And maybe just one question for Ken that how would you see the purchasing environment of the hospital on this point going forward, and do you anticipate any revenue could be realized this year or most likely be in 2021? And thanks.

Ken Londoner

So good questions, Yale, thank you. The environment was pretty much closed down in April and May, but these elective procedures as I pointed out early in the presentation, are some of the highest reimbursed procedures for the hospitals. Hospitals exist based on elective procedures economically, so they have to get back to these procedures. At the Mayo Clinic, for example, we're told that they're at 120% of capacity, meaning they're doing extra cases burning off the back logs to basically help the patients first and foremost get the procedures that were deferred and also economically recover.

So we're seeing a much more active marketplace. And John stating that we have four contracts that we're soon to announce for evaluation, and then more right after, that shows a thawing for us as a company. In terms of revenues, we do expect revenues this year. And as soon as we achieve them, we will announce those contracts to the investors.

Yale Jen

Congrats on the progress.

Andy Ballou

Thank you, Yale. Operator, we'll take another from the line now.

Operator

Thank you. Our next question comes from the line of Robert Carlson, Janney Montgomery Scott. Please proceed with your questions.

Robert Carlson

Hey guys, congratulations on the presentation. It was extremely professional and well done. But in the presentation Ken, you mentioned there were 3,400 EP rooms presently or as our opportunity. What--how many EP rooms are we currently installed in just for comparison?

Ken Londoner

Julie do you want to take that or John?



Julie Stephenson

Sure--

John Kowalski

--So we are currently installed in three centers. We have three systems in three labs at St. David's in Austin, Texas, we have a system at the Mayo Clinic in Jacksonville, and one system in Boston at Mass General. So five current labs that are using our technology, and as mentioned we will have seven additional sites by year end. Four sites--four additional sites with multiple units over the next 60 days.

Robert Carlson

So we currently have five, we're installing in seven. So by year end we will have 12.

John Kowalski

In that range; probably 12 to 15. I anticipate that some of these new centers where we signed and will be signing contracts will be installing multiple systems. I think it's important to mention that some of these larger hospitals have five and six labs where they're doing procedures. So typically as we have done in Austin, we'll start with one system. We would add a second, third, fourth, and then transition those evaluations into purchases of multiple systems within the hospital.

Robert Carlson

Well congratulations and again for us Bostonians congratulations on Mass General.

John Kowalski

Thank you.

Ken Londoner

Thanks Robert.

Andy Ballou

Operator, we'll take a question now from the webcast. The next question comes from Tom Ringe. Dr. Natale discussed a complex case and how PURE EP helped there. Does PURE EP help in the low complexity cases as well? Julie.

Julie Stephenson

Thank you Andy and thank you Tom for the question. So we enrolled--even in those 15 patients there were, you know, paroxysmal afib patients, persistent afib patients, and about half of them were re-do afib patients. So just in this initial publication, we do have a wide range of complexity among the procedures that were enrolled for this first data set.



We are routinely doing paroxysmal afib procedures, which is, you know, a relatively low complexity procedure that's done--nationally just about every EP is doing paroxysmal afib cases, and we are participating in those cases in the centers where we're installed now each week. And we do have good feedback coming from physicians who are participating in those types of procedures as well that the PURE EP system is providing additional signals and helping to guide their procedures.

So that's anecdotal data, but of course, we will have more data coming in phase two that really covers the full gamut of all types of ablation procedures.

Andy Ballou

Thank you, Julie. Operator, we'll take another one quickly here from the webcast. This one comes from David Cohen. Given the significantly larger quantity of signals, would this materially increase the time to complete the procedure? Secondly, how might this affect ROI for the providers if reimbursement doesn't change? Julie maybe--

Julie Stephenson

--I can take that one as well. Yep.

Andy Ballou

Thank you.

Julie Stephenson

So David, thank you for the question. No, I think it's actually quite the contrary. If they're--if they've got full visibility of the--all the cardiac signals to help guide their treatment decisions, it actually could potentially help shorten the procedure time because they're able to get to the targeted areas that are really triggering that arrhythmia sooner.

So, you know, I think that's the other way of looking at these additional signals: that it's actually helping to guide them more clearly and efficiently to the target site of that arrhythmia. And then was there a second piece to that question? Let me see. I've lost sight of it. I hope I answered that full question. Andy?

Andy Ballou

Oh, sorry Julie. Yeah, that was it. Operator, if you--if we could take one more from the phone at this point.



Operator

Thank you. Our next questions come from the line of Gary Zwetchkenbaum of Plum Tree Consulting. Please proceed with your question.

Gary Zwetchkenbaum

Thank you. Congratulations Ken and the BioSig team on the unblinding of data and the fact that you will have revenues this year and especially that you'll be in 12 to 15 by year end. My question is for John Kowalski and also for Ken. Can you tell us about the current cost and price range of the PURE EP system? And is there any recurring revenue stream? And then also what is the current evaluation period for the installed systems before a hospital has to purchase the PURE EP? I know Ken made a comment about recent ones being as short as 30 days. So John, please let me know.

Ken Londoner

Well John let me take--

John Kowalski

--Sure. Sure. Yeah--

Ken Londoner

--John if you don't mind, let me go first. Gary we don't share cost information. I assume there's some competition on this call. But John can talk about the other elements of your question.

Gary Zwetchkenbaum

Thank you.

John Kowalski

Okay yeah, thanks Gary for the call. So recording and mapping systems that are purchased for the EP lab typically range in price from \$100,000 to \$175,000 each. We do not compete with these systems. We're a signal processing system. However, our pricing will in fact be in this range as hospitals are used to buying equipment in that price range. We will also have a recurring revenue stream of both service and software. Service typically ranges around approximately 20% of the total hardware cost, and software upgrade packages in the EP industry range typically from \$30,000 to \$100,000 per year really depending on the, you know, the anticipated value of that new software that we will be launching and the number of upgrades that we anticipate, you know, each year.

In terms of the evaluation period, the terms of the evaluation do vary. They vary from 30 days, which several of the new ones will be at to up to 180 days. And there's several factors that go into determining that term. Often it's, you know, the number of physicians who we need to train. In



some hospitals there's three physicians. In other hospitals like Texas Cardiac Arrhythmia's there's 15 attending physicians who we'd like to be able to, you know, use the system multiple times. We also, you know, have clinical study partnerships with some of these centers so we want to align the term of the evaluation with our objectives and goals and with that clinical research agreement. And then we also work to understand the, you know, the capital budget process and timelines within the hospital, and align the evaluation period to that so we can transition from evaluation to purchase.

Gary Zwetchkenbaum

So a sale of a system with hardware, software, and recurring revenue service contract can be over \$250 and somewhere in that range as a--

John Kowalski

--It could be. And we would also be offering bundle deals for multiple systems. As mentioned there will be opportunities to sell four, five, six systems in one hospital. So.

Gary Zwetchkenbaum

Can you talk about the number of surgeries that have been done at these five centers and kind of, like, what the hospital charges for a surgery like this? I know you mentioned that in Texas they--he had done--Dr. Natale had done 13, 14 of these procedures in a week. Any feeling on what the hospital charges and what that brings in?

John Kowalski

In terms of reimbursement, there's a range of I believe it's \$23,000 to \$55,000 based on Medicare reimbursement. And then, Julie, in terms of number of procedures do you want to take that question?

Julie Stephenson

Yes. So as of today we have over 250 PURE EP procedures across our three centers.

Andy Ballou

Thank you. Thank you Julie, thanks Gary. Operator, if we could take the last question.

Operator

There are no further questions via the phone at this time.

Andy Ballou

Great. Well thank you all for joining us on today's call. Please visit our website www.BioSig.com for further information, and please don't hesitate to reach out to us. Thanks and have a good day.



Operator

Thank you. This does conclude today's conference. You may disconnect your lines at this time. Thank you for your participation and have a great day.