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BioSig
Business Development Update Call
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Presenters
Andrew Ballou – VP Investor Relations
Ken Londoner – Chairman and CEO

Q&A Participants
Yale Jen - Laidlaw & Company
Gary Zwetchkenbaum - Plumtree Consulting
Sanjay Kamani – Private Investor
Fred Leone (PH) - Private Investor
Jeffrey Kaminsky - with JJK Consulting
Tim Moeller (PH) - Private Investor

Operator
Greetings, and welcome to BioSig Business Development Update Call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press star 0 on your telephone keypad. Please note, this conference is being recorded.

I will now turn the conference over to your host, Andy Ballou, Vice President of Investor Relations. Thank you. You may begin.

Andrew Ballou
Good afternoon. Thank you for joining today's business update conference call. On today's call, Kenneth Londoner, Chairman and CEO of BioSig Technologies, will review highlights from the company's third quarter of 2020 and discuss corporate initiatives, including ongoing PURE EP system installations and commercialization outlook.

Before we begin, I'll remind you that this call may contain forward-looking statements. 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. 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. 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, including the company's annual report on Form 10-K and its quarterly reports on Form 10-Q. The company assumes no obligation to publicly update or revise its 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 afternoon and thank you for joining us today. Since we filed our 10-Q on November 5th, we wanted to take this opportunity to update shareholders on our progress with both our core business and our ViralClear subsidiary. On October 26th, as everyone knows, we announced to the market that we were halting our Phase 2 clinical trial for merimepodib, based on the recommendation of the Safety Monitoring Committee. Based on the direction of the BioSig board of directors, management has undertaken two activities with regard to ViralClear.

Number one, wind down the operations of the enterprise, given the results in the Phase 2. And number two was to start opening a dialogue with pharmaceutical or biotech companies that may find the program that we put together of interest to take forward.

I'm pleased to report that on both fronts, we've made good progress. On the wind-down of the activities, we have had clarity and success in talking to the consultants, the vendors, and the people who are supporting the trial. At the beginning of the year when we started 2020, our subsidiary which was called NeuroClear had a cash balance of approximately $4.1 million.

Based on our progress on the wind-down, we believe we will have in excess of that number at the end of the year, and the cash proceeds in the subsidiary will be used to fund the NeuroClear Neurotechnology Program that we had licensed from the Mayo Clinic in November of 2019. And we will have a NeuroClear update at some point in the near future.

In terms of our discussions with pharmaceutical or biotechnology companies, we have had engagement with three organizations. Two are well-known NASDAQ companies, and the third is a private concern. What we're looking for is we're looking for someone who can take merimepodib and all the learnings from the Phase 2 trial, and be able to capitalize and see if they can meet the needs of the pandemic, which was the original reason back in March we decided to get into this business.

Dr. Jerry Zeldis, who was an esteemed member of our board had brought us the opportunity, and we jumped in with full vigor and were able to get well into a Phase 2 trial, and we've learned quite a bit. We do expect to get cytokine data in December, which could offer some of these companies interested in understanding exactly what happened with our trial. And based on the engagements that we've had so far, there is possible additional value we can achieve from these discussions.

Obviously, when we achieve something, we will come back and report back. But as we go into 2021, there will be no further expenditures on ViralClear. The funds that we have in the subsidiary will all go towards value-creating events for our neurotech platform, which is making progress.

On the BioSig side of things, we continue to do quite well since our last update call on September 15th. On the 15th of September, we were only installed in two sites, Texas Cardiac Arrhythmia Institute and Mayo Jacksonville in Florida. Since then, we have achieved four additional installations. We installed at the University of Pennsylvania. We installed at Mass General Hospital in Boston. We installed at Deborah Heart and Lung in New Jersey, and we installed in Overland Hospital in Kansas City. And all of the installations have gone very well.

They are up and running and doing cases at all sites, except Mass General will be starting this Friday. And the results so far been very encouraging. All the physicians who have used the system have given us very strong, positive feedback, and we actually have seen great performance in certain cases where we've had great success.

To give you little bit further indication of our progress, breaking it down by numbers. As of November 11th, BioSig has done 363 total procedures year-to-date on the PURE EP system. 188 of those procedures have been done in Texas Cardiac Arrhythmia Institute, 83 at Mayo Jacksonville, 30 at the University of Pennsylvania, 27 at Deborah Heart and Lung, and 6 at Overland Park in Kansas City. As I said, Mass General will be starting this coming Friday and we have high hopes at that center, too.

In addition to the number of cases, we've touched almost every procedural type that our industry has to offer patients today. We've done 129 persistent AFib cases, 92 paroxysmal AFib cases, 43 PVCs, 10 nonischemic ventricular tachycardias, 4 VTs, 3 ischemic VTs, 10 typical flutters, 7 atypical flutters, 7 atrial tachycardias, 5 AVRNTs, 3 AVRT, and 4 SVT.

Also, we have 28 EP physicians using the system, with Dr. Natale who leads the Texas Cardiac Arrhythmia Institute having used the system 110 cases and has been using it in virtually every one of his cases to date. So, we're very encouraged with the progress that we've had with the installation.

Now, we have two other installations coming up in the next few weeks. We will announce those centers after the installations are done and their hospitals have signed off on our use of their name. On September 15, we promised we would be in 10 centers by the end of the year, and based on the COVID pandemic which is now, everybody knows, really taking off in many parts of the country, two of our installs look like they've been pushed into the first quarter. One is in New York tri-state area and the other is in the state of Ohio.

And despite our best efforts and our entrepreneurial spirit, these two installs just cannot happen in December of this year. But they do want the system, we have signed agreements, and we will be going in just as soon as they allow us in. And as we've seen, patience is a virtue. We installed at Mass General and we had to be very patient to start doing cases in Boston. And despite the pandemic, we're actually starting and we're excited, as we said earlier.

In terms of how we generate support for the commercialization of the systems, it's great to have case studies behind us. As you know, back in September we unblinded the data from the first clinical study for PURE EP, which was geared to assess the quality and the clinical relevance of the PURE EP intracardiac signals when compared to other sources. Patients that were undergoing elective cardiac ablation were included in the blinded study, and we unveiled that data. And that data has since been published.

In early September, the company announced the scientific abstract and poster entitled a Novel Cardiac Signal Processing System for Electrophysiology Procedures, early insights from the PURE EP study, which was made available at the ESC Congress in Italy in late August 2020. Since then, we've published an abstract, and let me just give you a little overview of that.

The background was to demonstrate the value of our intracardiac electrogram data. And we took identical electrographic and intracardiac signal data which were recorded during 15 AF ablation procedures. And we were comparing BioSig's system to that of a traditional recording system and that of a 3-D mapping system. The collected signals underwent blinded controlled evaluation by three independent electrophysiologist reviewers to determine who had the superior signals, and to characterize the superiority of the signals.

The results were clear. In 35.5% of the cases, the reviewers selected BioSig signals where more components were visible. And what we're seeing as we install systems and do cases is that the signals are translating not only as a clinical benefit, but into helping the patients get a better procedure. And we and our marketing team have captured these winning cases and we're using them to highlight and demonstrate that under certain conditions using our technology, the physician can get a better procedural outcome.

And those cases now are being used in sales and marketing materials. They're being used to train our clinical account managers as we go in and install new systems. The information is being shown to the physicians prior to them starting the new cases.

As one example, and we have many, many of these examples, last week in one of the centers that we're installed in, a young adult presented with a very troubling case of AFib. This is an athlete who was having poor heart function. And using our system, the EP physician told us that it was with our technology and the information we provided that he was able to put the patient back into normal sinus rhythm during the ablation procedure. The patient left the hospital same day.
And upon follow-up, the patient is in back to normal heart health. And we will be following that patient to make sure that the ablation was durable and that the AFib doesn't come back. And as we prepare for longer-term evaluation of our system, we're starting to prepare for 2021 clinical activity where we are going to be doing investigator-initiated studies with leaders in our field with protocols that can show both the clinical and procedural value of our system.

We are just planning our 2021 activities. 2020 was supposed to be our first year of commercial rollout, which we called limited market release. In a limited market release, our goal was to be in 12 to 16 hospitals and some of the top centers in our industry and show that our system had both clinical and procedural value.

Despite the pandemic, as you see by the end of the year, we should be in 8 to 9 centers. And we are showing the value we thought we would show. We just wanted to be in a few more centers.
So, we hope to make up for the lost ground of 2020 by expanding into more centers in 2021. And currently, we're planning on recruiting additional people to our team in sales, marketing, and clinical roles, so we can handle a greater number of centers in the United States.

We do intend, because of the pandemic, to have more of a regional focus in 2021. We believe the markets of the Northeast, Florida, and Texas can keep us very busy in 2021, and we can penetrate a great number of centers while mitigating the traveling we have to do transcontinentally. We think that these places offer us plenty of opportunity, and we will come back to you in the next quarter to give you a specific update on how many centers we expect to be in.

As we noted on the September 15th call, we do expect our first commercial transaction this quarter. And we never know, there may be more than one, but we certainly see visibility now to more commercial transactions based on the success we've had in installing, training, and getting some of these leading physicians up and running.

And we believe we're starting to see the early promise fulfilled of the performance of the technology. We've seen a great number of cases where BioSig and the PURE EP system has been a difference maker. And the KOLs are starting to get excited about our technology.

One thing we just learned is that on December 2nd and 3rd, the Texas Cardiac Arrhythmia Institute is going to host EP Live, which is a unique event in our industry that brings together hundreds of the top EP physicians in Austin, Texas for two days of lice cases and new technologies. We've been informed that this convention is actually going to take place, and that people will be flying in despite the pandemic. There'll be people also dialing into their broadcast network to observe live cases.

And as currently contemplated, it looks like PURE EP will be in approximately 20% of the cases over the two days, which is great visibility for us into future customers and being able to show people the capability of the PURE EP system. We're very proud of being able to present to such a group, and we really thank Dr. Natale and the Texas Cardiac Arrhythmia Institute for including us in such an important biannual presentation.

I'd like to close today by highlighting some of the statistics in our 10-Q published November 5th, and our financial strength now and going into 2021. In the third quarter, BioSig burned approximately $6.2 million, which was evenly split between ViralClear and BioSig PURE EP core medtech business.

So, we burned approximately $3.1 million in the third quarter for PURE EP. We have been seeing on average a burn rate of just south of $1.4 million per month on PURE EP, and that doesn't include any revenues coming into the company. So as we start bringing revenues into the company and we continue to manage our cash burn as we historically have with great care, we believe that the $32.7 million of cash we have on the balance sheet is more than enough to drive us through 2021, and well into 2022.

One other important thing to note is we've already paid for 65 units of commercial inventory. And based on our average selling price, we believe we can pull that revenue in over the next 12 months, thereby bringing our cash burn down even further, and that inventory is already paid for. So, we're optimistic as we go into 2021 from a financial perspective.

With that said, Operator, I'd like to entertain questions. Thank you.

Operator
Thank you. If you would like to ask a question, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star 2 if you would like to remove your question from the queue. And for participants using speaker equipment, it may be necessary to pick up the handset before pressing the star key.

Our first question is from Yale Jen with Laidlaw & Company. Please proceed.

Yale Jen
Good afternoon. Congrats, Ken. I think this is a very good start in terms of the PURE EP advancement. So, here's some quick--a few quick questions. The first one is that in terms of the expense winding down, do you anticipate what kind of burn probably for the fourth quarter of this year? Is that your roughly $5 million for the quarter? And then just probably that would be the base for going into 2021? And then I have some follow-up questions as well.

Ken Londoner
So, Yale, if I understand the question correctly, you're asking for the anticipated burn rate for the fourth quarter for the combined company?

Yale Jen
Yes.

Ken Londoner
Yeah. So, what I can share with you is, like I said, we've been seeing on average a burn rate of approximately $1.4 million for PURE EP. We have significantly wound down the operations of ViralClear. So, we don't expect any new invoices or any new billings with regard to ViralClear. So, we've pretty much cut that off and we are clearing out the payables, you know, as best we can.

So, if you take $1.4 million and you multiply it by three, you're probably going to be in the neighborhood. However, as we've said, we expect our first commercial contract in the fourth quarter. And depending on when we collect that receivable, you know, that would reduce--that would be to our favor against the cash burn.

Yale Jen
Okay, great. My next question is that given PURE EP has been used in a number of centers and in a number of procedures, did you guys start to pick up--collect some feedback, in terms both sort of praise of the system as well of any kind of, I guess, maybe kinks you want to--people want to get additional improvement? Any kind of overall general comments?

Ken Londoner
Yale, for some reason I had a little bit of a hard time hearing that question. Were you asking about pricing of the system?

Yale Jen
No, not of pricing the system. I'm just saying, given the system has been used by a large number of EP labs at this moment, been tested at this moment, did you get any feedback from user in terms of both either positive aspect of the system, or maybe additional some improvement they'd like to see, or advancement they'd like to see for the system?

Ken Londoner
No, that's--yeah, I got it. It's a good question. So, when we first went in earlier in the year--and actually, we put our first system into the market in November of last year--we did have a few technical glitches we had to overcome. They were minor in nature, and we overcame them in the April timeframe.

We have gotten some outstanding user feedback, and we have a process for how we digest that. We call that voice of the customer feedback. And some of that is actually being incorporated into a software upgrade that we'll be rolling out in January/ February of next year. Our team is very good at turning feedback into software. We've always been good at that, so the customers I think will be excited to see how responsive we are as a company.

In terms of the centers, every doctor that we worked with is enthusiastic about the product. Several of the physicians have been so moved by our technology that they've actually offered to support us in making different videos that we can use. In fact, today there is a video released out of University of Pennsylvania in the VT Symposium Technology Forum. And we can forward that video along--that link to anybody who would like to see it.

Dr. Santangeli, who's used the system now for a little over five weeks, had an outstanding case several weeks ago where he was excited about the impact that PURE EP could make on a case. And he's given us about a 3, 4-minute video that's now out there for the field to be able to see.

Also, Penn will be making a presentation. They'll be doing a live case at EP Live on December 4th, I believe; you know, using our system, because they're enjoying the way the system is working so far. And we've also gotten videos from Texas Cardiac Arrhythmia Institute, and we have other content coming from Deborah Heart and Lung.

So, we're getting a lot of positive response and we're capturing that, and we're capturing what they're seeing. And we're putting it into visualization software so others can learn what these first physicians are seeing. So, our marketing folks have been doing an outstanding job, and it's absolutely been helping us on the commercial side.

There's been a lot of--you know, the physicians kind of see it right away when they use it; they are very excited about it. And then, of course, our team has to work very hard to convert all of that into commercial traction.

One other thing I want to mention is in the centers that we are installed in, and there's six currently. There'll be eight by the first week of December. Just in the six we're in, if you add up the number of EP labs that they have or the number of units we can sell, we have a potential of 27 units in these six centers. So, some of them are quite large. And we don't know if we'll make 27 sales in these six centers, but we will--we believe we'll be selling product in each one of these centers in 2021. And it just depends on each center on how they want to go.

Right now, at TCAI, they have three systems. And we think that represents pretty much the maximum potential in that site. Maybe there's room for one more, you know. At Mayo in Jacksonville they have one unit, and maximum potential there is two. But Mayo in Rochester, we have the potential for five, and then there's more in Arizona. So that's how we get to 27. And as we add more and more centers, that potential unit number grows. And so, in 2021, we should have a very large addressable market to convert into revenues and, you know, we're optimistic.

Yale Jen
Okay. Maybe the last question here. Again, congrats on that.

Ken Londoner
No, go ahead. Go ahead, one more.

Yale Jen
Okay, which is that you already have about--you mentioned about eight, and that you will have probably 10, 9th and 10th coming first quarter of next quarter online, to using it. And what's currently in the queue in terms of the pipeline further expansion? In other words, further site expansion at this point you can talk about that prepare for 2021.

Ken Londoner
So, if I understand you, Yale, site expansion. You know, we haven't given that number yet.

Yale Jen
Additional sites.

Ken Londoner
I'm sorry?

Yale Jen
Additional sites, what I mean, at least that you are contemplating or already have some initial contact, that kind of activities.

Ken Londoner
So, we expect to add to our sales and marketing team. We actually are preparing for quite a decent expansion in 2021, but those numbers haven't been solidified yet. We want to make sure that we are able to handle the demand that's going to get generated by the events like EP Live. That is a big event for us.

And, you know, we also had an outstanding exposure at the VT Symposium. And a lot of these marketing videos that are coming out through different channels like the one I just referenced with Dr. Santangeli at the University of Pennsylvania. You know, these do attract attention. And it wouldn't surprise us to see new inbound inquiries coming in.

We can't quantify that just yet, because it's a little early in the process. But as we get more and more users up on the system--again, the number I mentioned in the presentation, we have 28 EP physicians that have now used our system in human cases. That number is only going to continue to grow. And we've not heard anybody tell us negative things. You know, some have only used it one time, but we're optimistic based on what we've seen. So, the number of places we can go, I mean we haven't even scratched the surface yet.

Yale Jen
Okay, great.

Ken Londoner
Thank you, Yale.

Yale Jen
Thanks a lot. Thanks for the answering, and congrats.

Ken Londoner
Thank you.

Operator
Our next question is from Gary Zwetchkenbaum with Plumtree Consulting. Please proceed.

Gary Zwetchkenbaum
Thank you, Ken. Thank you, Andy and Ken, for taking the time to update us. Ken, you mentioned with the $32 million in the bank, that this is enough money for all of 2021, into 2022. You mentioned you had 65 units that are paid for right now already. I'd like to, if I can, to focus on the--you said there have been more than 360 procedures. You mentioned that 188 were done at TCAI, and if I understand correctly, there are six surgeons there that are doing surgeries during the procedures.

I'd like to get an idea of what the hospitals get. In other words, there's a range in what they charge the patient. There's a particular range of what they get. I'd like to talk about what the hospitals are receiving, how many--I remember you did--September 15, you said they were doing it, at one point at TCAI, 15 surgeries a week. That's bringing in quite a bit of money.

I'd like to hear about that, and the growth. And obviously, that's six centers, eight machines, another two to come. Can you talk about that and the kind of revenue that gives to the hospital, and what we might see from them?

Ken Londoner
Okay, Gary, let me see if I can break that down. So, the Texas Cardiac Arrhythmia Institute is the number one volume center in our industry. They are the number one customer of J&J who leads our industry, and we're thrilled to be there.

At TCAI, we've had quite a number of people using the system. It's actually more than six people who have used the system. But we've become integrated into regular use by those that are doing cases there virtually every day. And it varies between physicians how many cases they do, and they also don't do cases every week in a row.

Dr. Natale under normal conditions travels around the country quite a bit, and also does cases internationally. So when he's there, we are with him and we have two people stationed at TCAI supporting our systems and helping them learn how to bring our system to life and how we bring the most value through all the software and things that we offer. In terms of what they make, I don't have the specific information with TCAI, but the industry averages that we've been able to gather, if a cardiac ablation is done at a center and private insurance pays, we believe the hospital makes roughly $30,000 in operating profit. And so, from an elective procedural process, these are very, very lucrative procedures in the hospital and--you know, with the hits all these centers have taken in the pandemic, they have gotten back the full strength doing these elective procedures, because one people need them. We don't view these procedures as elective. If you have an irregular heartbeat, it's very dangerous, potentially lethal, and they're doing cases now. I can't tell you what the outbreaks of COVID are going to bring, but I think the centers have all learned how to segregate COVID patients from their other patients. And we have heard of none of our centers shutting down.

There are two centers that have asked us to defer installments, until early in the first quarter, but they are not shutting down by any means, they're just dealing with rising COVID cases. In terms of the Medicare/Medicaid reimbursement, if a patient comes through with Medicare/Medicaid, the profit is lower for the hospital, somewhere between $2,500 and $5,000 but it's still a positive for them. So, we think we're in the right area of the hospital, the right department. And we are selling the system, leasing the system or renting the system, and capital budgets vary from center to center. One thing we do when we go into a center is, we have a matrix of how we qualify centers, of where we'd like to go. Right now, we have more places asking for us to come than we have people, and we are hiring, but--you know even still, there's going to be great interest in using a system. But we have a matrix where we have to understand how many labs they have, how long we think it'll take them to get up and running. Our installation contracts are starting to narrow in terms of the time we're allowing these centers to use this system. We're finding that they really immediately see the value in the system and after like three weeks, they see the full value of the system. So, the need for these long evaluation timelines are not as necessary as they were when we first started. So some of these new contracts that'll be coming in the first quarter will be 60 to 90 day evaluation agreements, and our commercial teams will be going in, evaluating before we even install the likelihood of us being able to transfer ownership from BioSig to the hospital, meaning we get paid.

And so that's a factor in our decision making of where we're going and how we're going to do things. But because you know, 2020 was not what we considered the full year we wanted it to be, with the pandemic every business has been affected, we think 2021 will be a year where you see a lot more activity from us. And then we all assume 2022, we're thinking the pandemic's going to be gone and we'll be going at full strength. So, we see ourselves ramping from this year into next and the good news from this call is the initial sites that are using the system are seeing value, a lot of value in the system. We've not had one center that hasn't said that to us. So, thank you Gary. Next question please?

Operator
As a reminder, it's star one on your telephone keypad if you would like to ask a question. Our next question is from. Sanjay Kamani, Private Investor. Please proceed?

Sanjay Kamani
Yeah, hi again, thank you for the updates and about--specially about the BioSig projects and plans. I'm wondering about the ViralClear investments, so the people who invested directly into the ViralClear, how that investment is going to be handled and I'm wondering--you know, how the investment's going to be--if there is any plan for that?

Ken Londoner
Thank you, Sanjay. So those that invested in the ViralClear own their percentage of the subsidiary BioSig, currently own 69.5% of the subsidiary. Right now, in that subsidiary at the end of the year there will be cash which will be used to drive our Mayo Clinic projects forward on all the neurotech that we've been developing for years. We are looking to find ways to bring value through--placing the VX-497 program, in someone else's hands, and we'll have to see how that plays out. So, the ViralClear investors will own a stake in our neurotech program. We are going to do another call, we didn't want to do it today, where we can take everybody though our NeuroClear program. We have advanced the NeuroClear assets considerably this year, and we haven't talked much about it because most of the discussion was focused on the ViralClear program, but we had a team advancing that technology, and we do think that in 2021 there will be several value events for the neurotech assets.

But to get into it now, we don't have the time and I'm more than happy to answer it for you. So, you will own a stake in that in terms of monetizing that stake, we as a leadership team are working on that plan for 2021. And we understand the investment was made in ViralClear asset and just like all of our other shareholders, we're going to be working hard to create value and we understand that that's our obligation. So that's the best I can share with you right now.

Operator
Our next question is from Fred Leone (PH), private investor. Please proceed.

Fred Leone
Ken, good afternoon thanks for having this call and thanks for taking my question. I've got a quick question regarding the revenue of the unit itself. Is there revenue besides that revenue for the unit, is there an ongoing software cost per unit that each of these centers are going to have to pay on a monthly basis?

Ken Londoner
Thanks for the question Freddy, thanks for your investment. We are selling the hardware, we actually have plans that we offer these hospitals and we have a, what we call a "Service contract" which will include installation, training, clinical support, access to any software upgrades when they come. And we are going to be getting a contract in place for that. So, they'll buy the hardware and then they'll buy the service contract, and we're marketing each differently. There are also accessories that get sold--you know we have special wires and connectors and things of that nature.

So, we have these all in a package and when we get a purchase order, all of the elements are detailed out in what the hospital's committing to. So yeah, there are two lines of business if you will. And so ultimately, as we get this business launched, the hardware is the razor, and the software will

be the blades. And we have a lot of software to deliver the industry. We have a very robust product development pipeline we've been building for years. And next year, we're working right now to determine how much software we want to release because we have so much. And you know, the industry can only absorb so much. So, we're ahead of the curve in terms of the products that we've created and they're all clinically valuable. So, you know that's going to serve us well as we go deeper into commercialization. Thanks for your question, Fred.

Fred Lione
Of course, no problem.

Operator
Our next question is from Jeffrey Kaminsky, with JJK Consulting, please proceed?

Jeffrey Kaminsky
Hi, good afternoon Ken and thank you for taking my question. Kind of a follow-up to the last question, I'm just trying to put pen to paper here. You had mentioned the sale of hardware and then an annual software upgrade, or a software fee that goes with it. Could you give us a sense of actual dollars here? In past discussion you had said that you were entertaining a rent to buy model, or a lease model. Now you're discussing the purchase of the hardware. And then as a follow-up, the software and the upgrades and the maintenance that you'd described, what will that cost? In other words, if I've got it installed, I like it, I'm using it and I want it, what am I paying for on the onset and what am I paying every year? In other words, what revenue is the device going to generate?

Ken Londoner
Thank you for the question. So, we--because of the pandemic, we're trying to be as flexible as possible to be able to get an installed base. Because off the installed base of the hardware, we have the ability each year to come back and sell additional software. And this is a business model that's well accepted. Our friends at Biosense Webster, who pioneered this market have done an outstanding job showing us the way in the industry by being able to put hardware into the market and then consistently bringing additional software value. And that software is sold in two ways, it's sold in a package where they get the basics, which are installation, training, basic systems upgrades, these are operating software upgrades, we have our own operating software with the system. So, as we find improvements, feature improvements by buying the software package, they get the upgrades automatically and then we sell modules. Modules are specific softwares, almost like if you think about when you buy an Apple computer or a Dell, you will pay extra for Microsoft and all the Windows, PowerPoint, Excel, et cetera. You pay the separate fee for that.

So, we will also have another fee for specific software modules. So, if you want to think of the model, the base is the hardware, then you have the operating software and that annual fee that

they pay. And then on top of that, we will have distinctive modules that we create, or we already have created, that can help them do more in their procedure that are in addition to the core base system. And then lastly, and we have highlighted this in the past, we've been working very diligently this year on our artificial intelligence offerings and we've filed quite a few patents in this arena. And we would like to bring one AI module to market next year, if we can. Again though, there's only so much the market can digest for us. Our corporate strategy is to use the full basis of 2021 to grow as large an installed base as we can get, where we will get paid for that installed base.

And then that will be another building block towards an even bigger base in 2022. So, it's base hardware, software modules, and AI offerings on top of that. In terms of the specific pricing, because we think we may have some competition on the call, we try not to get into that so much at this point. But the average selling price, the value we're offering the system is in the ballpark of what you're paying for these types of technologies. And you know, you guys will see as our future goes along, you'll probably be able to back into what we're able to get. So, thank you for the question.

Operator
Our next question is from Tim Moeller (PH), private investor, please proceed. Tim your line is live.

Unknown Speaker
Sorry about that. Afternoon, Ken.

Ken Londoner
Hi Tim.

Tim Miller
So, obviously you have 300 plus patients, the blind study has demonstrated the superiority of the signal. Any color in terms of the efficacy of using the PURE EP System versus standard of care in terms of the duration of the procedure versus historical norms?

Ken Londoner
Yeah, that's a great question. And we're just in the beginnings of detailing out the efficacy. But these videos that I've referred to, and we can send you the ones that we've produced, in each case, this is a case where they additional information that our system provides have given the EP physician new ablation targets that they would not have had before. And by selecting and following the information to those targets and burning in those locations, in the atrium or even the ventricles, they've been able to . . .

Operator
Okay, you are back in you may continue.

Ken Londoner
Sorry about that Tim, we just lost the call. What I was saying is the information that we've providing and these new ablation targets that they're seeing are either able to put the patient back into normal sinus rhythm or help them complete the procedure on a more timely basis. So, the more of this we see, the more excited they get, we get excited as well and we believe ultimately this will translate into system acquisition. In terms of what we're leaning in the field from all of this experience, we are working on a plan to do what's called, "Investigator Initiated Clinical Trials," so these are things that they're seeing and they--because they have this new tool, they think that we can demonstrate efficacy in a certain subsegment of patients, with these patient categories, where they're going to come to us with protocols and we are going to fund these protocols and they'll do multicenter randomized, blinded studies that are initiated by the investigator.

So, we will provide the PURE EP system, they will provide the protocol and they will go out and recruit the patients under IRB approval and we will get that information back. We have many, many ideas and we have many categories that we want to study, unipolar signals, pulmonary vein isolation improvements, tissue viability and so on and so forth. These are all areas where we can make improvements through our technology and in the way, things are done. And it's pretty exciting, pretty exciting stuff. But we will get back to you on the next call, with regard to our clinical trial. By the way, the second leg of our PURE EP study, the one that was unblinded is under way, and we expect to have data from the study. It's basically a continuation from the first data that was published. We did 15 patients, we're going to try to get up to 100 patients in the second leg of that study, and that data we're hoping to unblind by the Heart Rhythm Society Meeting in July of next year.

Tim Moeller
I appreciate that. Obviously exciting in terms of the technological advancement. Given that comment from a procedural standpoint, is there efficiency here in terms of time of the procedure, i. e. that being shorter given the clarity of the signal? And then in terms of, obviously you've able to attack the arrhythmia in terms, is there a lower recurrence rate of the arrhythmia coming back, or is the data still too young?

Ken Londoner
Yeah, the data's still too young to measure recurrence, although in working with TCAI given how busy a center that it is and also Penn (PH)--you know we're discussing registries where we can follow these patients and follow them through the databases of these large teaching and operating facilities. So, there's going to be focus there, absolutely. In terms of the data and how it comes out, we're going to have an abundance of data and we're going to have an abundance of evidence for the industry. We already have more than we ever expected this year. It just hasn't been visible to the investor community. Like I said, today, there was a video that came out from the University of

Pennsylvania. We've only been in that center I believe, for about six weeks. So the fact that they'd be willing to make a video highlighting a great case and the value of our system--you know this is the hard work of our team, the hard work of the physicians that are using the system and it's early days, but the early feedback that's coming in is encouraging, very encouraging to us.

It's what keeps us going, you know, it's what keeps us all very excited. And It's early days, we--because we've seen consistency in each center, I mean the system, our clinical account managers who are in there with the system and the physician, they're all doing an outstanding job. This is an excellent team we have, and we look forward to growing that team. As that team grows, we'll be able to go on to more and more centers and we believe we'll probably have consistency of experience. And then at some point, we're going to have quite a backlog of places that want us to come in there and install systems. So, we're working hard to get to that point. And of course, there's a conversion in how long it takes from a hospital to get the system to conversion. In a pandemic we have to see, but the place we're going to we're choosing very selectively, based on their propensity to become commercially paying customers. So, I just want to remind you of that.

Conclusion

And in summary, thank you everybody for joining us today. I wanted to just remind everyone we've closed out the quarter with the strongest balance sheet in our history. We've installed systems in six centers, and we'll be adding many more going forward. The strong physician feedback we have regarding PURE EP and the cases that we've been seeing are creating some excitement and some momentum that you will see the benefits of this quarter and going forward. The clinical information we've already gathered is creating our ability to focus on these physicians, when we outreach to them. And last point I'll make is, although we halted the trial for merimepodib, for safety, there is a subcommittee of the board looking for potential partners that might be interested in acquiring or licensing MMPD and VX-222. And we are having those conversations now, and as we learn more there, we will report back to everybody. But you know, we think the outlook is bright for us, and thank you for your support everyone.

Operator

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