



+1 (203) 409-5444
info@biosigtech.com

Biosig Technologies, Inc BSGM Shareholder Update Conference Call December 10, 2019

Presenters

Andrew Ballou, VP Investor Relations
Ken Londoner, Chairman, CEO, founder
John Kowalski, Vice President of Sales

Operator

Greetings and welcome to the Biosig Technologies, Inc BSGM Shareholder Update Conference Call. At this time, all participants are in a listen-only mode. A brief 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.

As a reminder, this conference is being recorded. It is now my pleasure to introduce Andy Ballou, VP of Investor Relations. Thank you. Please begin.

Andy Ballou

Thanks very much, Roya, and thank you all for joining Biosig Technologies Shareholder Update Call. I'm Andy Ballou, VP of Investor Relations. I joined the company about six weeks ago after 25 years on the sell side in institutional equity sales and research roles.

On today's call, we'll discuss our 2020 outlook, which is drawn mostly from our November 2019 shareholder letter, a review of our Mayo Clinic deal, announced earlier this month, a review of our MIT AI deal, announced last week, and then that'll be followed by Q&A. We anticipate the prepared remarks will last about 15 minutes with the balance of the hour for Q&A.

Before we go further, I'll read our Safe Harbor disclosure. Today's call may contain forward-looking statements. Such statements may be preceded by the words intend, may, will, plans, expects, anticipants, projects, predicts, estimates, aims, believes, hopes, potential, or similar words.

Forward-looking statements are not guarantees. Our 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 limitations, risks and uncertainties associated with our inability to manufacture our products and product candidates on a commercial scale or in



+1 (203) 409-5444
info@biosigtech.com

collaboration with certain parties, difficulties in obtaining financing on 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 products 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 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 of the SEC's website, www.sec.gov. The company assumes no obligation to publicly update or revise its forward-looking statements for new information, future events, or otherwise.

And, with that, I would now like to turn the call over to Ken Londoner, Biosig's Chairman, CEO, and founder.

Ken Londoner

Good afternoon, everybody. Thank you for participating and joining us this very busy time of year. Thank you for investing in our company. We wanted to provide you a summary of the year 2019 and talk about our positioning for 2020.

It's been a year of excellent progress for the company. One thing I'd like to underscore is that all the commitments we've made, which we've shared in our shareholder communications, we have kept. I encourage you to go to our website and review these letters on www.biosig.com.

We've made all our milestones this year, which is not easy for a small company. But we feel we're positioned for the best year in our 11 year corporate history in 2020.

Next year, 2020, we expect to see our first commercial revenues. We intend on expanding our engineering capabilities and building our product development portfolio and developing additional product to position for market. We're growing both our clinical, commercial, and operational teams, and we have a subsidiary by the name of NeuroClear that's undergoing rapid development.

In the back half of this year, we've added three new board members to the team, including one that some of you may be familiar with, Dr. Jerry Zeldis, who is the original and only Chief Medical Officer of Celgene. We've also added Martha Pease, who is a senior partner at Boston Consulting Group in their digital healthcare technology area, and also Sam Navarro, who is the former head of global investment banking for medical technology at Cowen and who ran a multi-billion dollar healthcare hedge fund.



+1 (203) 409-5444
info@biosigtech.com

In terms of commercialization, we stated in our June 2019 letter that we're successfully bringing PURE EP, our main product, to the market, starting in three leading centers. We've also recently completed our first human clinical trial at TCAI.

In terms of 2020, one thing I'd like to highlight before turning it over to John Kowalski is how we're advancing our industry presence, which we view as great opportunities for all of you to come and learn and participate with us. We will have four major industry events in the first half of 2020, all geared towards driving commercialization.

The first event is called the AF Symposium 2020 in Washington DC. That is going to be January 23rd through the 25th at the Gaylord Center, where we will have a sizable booth and commercial presence on the floor. That's a conference of approximately 5 to 10,000 professionals that are looking at--in the--at normal heart rhythm industry and we expect to have a very well attended booth with KOLs, customers and professionals from our company meeting those folks, and this will be a good opportunity for everybody to come see us.


We also have a Fellows Day, which is where Mayo Clinic is teaching the younger generation of physicians, the electrophysiology fellows, advancing the education of tomorrow's leaders and decision makers. We have been invited to present at this conference. This is in San Antonio on February 20th. We've been invited by the Vice Chairman of the Mayo Clinic. That'll be an excellent forum, because the younger physicians are always interested in new technologies.

The third event is April 2nd, 3rd, and 4th in Austin, Texas, called EP Live. EP stands for electrophysiology. This is the Texas Cardiac Arrhythmia Institute's Bi-annual--every other year, they do a global forum, which is a global broadcast of live cases. So, as they're doing the medical procedures, the surgeries, they're broadcasting this around the world and they also have several hundred people on site to observe this. And, we've been dreaming about being part of this event for over 10 years and now we've been invited this year, which is very exciting to us.

And, last but not least, on May 6th in San Diego, California, is the industry leading event for the year and the leading commercial opportunity of the year called the Heart Rhythm Society Convention and that is going to be a three-day event, as I said, in San Diego, where we will have a larger booth than we had last year. The full commercial team, product demonstrations, new technology demonstrations, and we will be fully in business at that point in time.

I'd like to introduce you to our Vice President of Sales, John Kowalski, who can discuss commercialization and market expansion.

John Kowalski

 54 Wilton Road, 2nd Floor
Westport, CT 06880

www.biosig.com



+1 (203) 409-5444
info@biosigtech.com

Thank you, Ken. Good afternoon, everyone. Thanks for joining us. I joined Biosig Technologies February 1st of this year as the Vice President of Sales. Prior to Biosig, I spent 24 years with Johnson and Johnson in the cardiac electrophysiology division, at a company by the name of Biosense Webster. And, I started with Biosense before the J&J acquisition and was one of the architects in launching the cardo-mapping system. It's approximately a \$300,000 electro-anatomical mapping system, which is used in the electrophysiology market to create a three-dimensional image of the heart's electrical conduction.

And, we built a great business over the years. When I started, we were doing approximately \$5 million in revenues and today, Biosense Webster is doing about \$2.5 billion and it's the fastest growing and one of the most profitable med device businesses within Johnson and Johnson. So, it's really a great privilege and honor to be part of Biosig and stay within the industry, which I'm so passionate about and I have 24 years of experience within.

And I get this question all the time from folks, so I thought I would address it, and that is why did I join? And really, I joined for one primary reason and that is because I believe that the technology that we have can improve procedure outcomes. Today, many of these ablation procedures only have a 50 or 60 percent success rate and they require multiple redo procedures, unfortunately.

The PURE EP system is a signal processing system, which enables the electrophysiologist to more accurately diagnose and treat these complex arrhythmias through improved targeting and visualization of these low amplitude, high frequency signals, which really are not visible today during the procedure. So, very, very excited to be here. I think we've got a great year ahead here and I'm excited to lead the commercial strategy.

If I look at the--talk a little bit about the commercial strategy, I break it down really into three areas of focus, and that's creating world class key opinion leader partnerships, creating value through generating these trusted and compelling clinical data, and then implementing customer focused commercial strategies.

So, around creating partnerships, we're making--we have made great progress in this area and with some of the leading experts in the EP industry, and that's really invaluable. If you think about a company at our stage of evolution, those relationships and those centers that we're working in are just incredibly valuable to the growth of the organization and the development of the technology overall.

As some of you may have seen, we already have a system installed at Texas Cardiac Arrhythmia Institute. It's part of St. David's Hospital in Austin, Texas. TCAI is led by Dr. Natale. Dr. Natale is one

of the top three or four experts in electrophysiology and he has been--he and his team have been using our system now for the last, what's it been, five/six weeks and doing several cases.

We're also planning to install in eight or nine centers, between now and mid-next year. We've already installed at the University of Pennsylvania as well. UPenn, as some of you may know, was one of the leading institutions within the U.S. They have the largest electrophysiology fellowship training program and many world class experts in electrophysiology. We're also planning to install at the Mayo Clinic in Jacksonville next week and we're also working to finalize agreements in six or seven additional centers throughout the U.S.

And, as I mentioned, the goal here in these centers is to partner with the physicians, develop the technology, but also generate clinical data to support our overall value proposition as we go to market. And, then ultimately, it's part of the commercial plan. We'll be converting these accounts and others to sales and through customer friendly acquisition programs, including capital acquisition, rent, rent to own, lease programs, etc.

So, it's an outstanding time to be here. I'm so excited to lead the commercialization. Looking forward to launching the system and generating revenues in 2020. So, thank you and I'll turn it back over to Ken.

Ken Londoner

Just to briefly touch on a couple of other things we wanted to cover today. We recently announced a dramatic expansion of our relationship with the Mayo Clinic in Rochester, Minnesota. We opened an office there in early November, where we're going to house technologists and some business folks to be able to collaborate with the innovator physicians at Mayo, to build our product portfolio.

So, beyond the PURE EP platform, we can then bring additional product into the market. Some of this product that we've licensed from them, we're going to be adding to the patent portfolios that we acquired, so it's tough for us to get into the specifics today. But, suffice it to say, the key to being a long term player in the medical technology business is to develop a portfolio of products as opposed to being a one product or a one platform company.

We've witnessed this over the years of being in this industry and the companies that do that well tend to do quite well for their shareholders. So, we were very pleased that when Mayo approached us to offer us some of their most advanced technology programs, where what we've done is we've licensed the technology, we've taken ownership of the patents, we've committed to developing some of the products a little bit further and putting them into clinical validation manufacturing, and then into commercialization.

And, we've taken three new programs from them: two are in electrophysiology and one is in the neurological area. One project in particular, they've been working on since 2006 and have the prototype developed. We're just going to advance it a little bit longer, breathe a little bit of innovation into that product so we can expand the intellectual property portfolio.

And, then we're hopeful we can be able to take that product into the market in the second half of 2021. Mayo has grown fond of us. We're very fond of them. As John mentioned, we're taking the PURE EP system commercially into Jacksonville, which is one of the three states that Mayo operates in. Mayo, in total, has approximately 20 EP labs that could become commercially viable for us. So, starting in Jacksonville is something we're very excited about. Then we'll also penetrate their other two centers.

In terms of the MIT relationship, the relationship is with a group called Reified Capital. Reified is led by Harvard-and MIT- trained computer scientist and physicist Dr. Alex Wissner-Gross. If you look him up on the internet, he's quite a personality. Alex does work for the Department of Defense in AI, in cybersecurity, and we've signed an exclusive agreement with he and his team to give us exclusive access to him and his folks at MIT and also at the Harvard AI lab, to develop artificial intelligence machine learning tools that we can embed in the PURE EP system and we can actually create a commercial prospect out of.

That project work is already started. We had a kickoff meeting last week with him and our team, and we will be reporting on the progress of that. But, suffice it to say, working with Mayo and working with MIT on getting data from the heart and processing that to increase and enhance decision making on these cardiac ablation surgeries, we think that's going to be a point of distinguishment for us and also give us more revenue opportunity.

So, these are the formidable relationships and it's going to be fun to be sitting in a triangle with these two institutions and by contract, blocking others out of this opportunity. So, for a small little company like us to be able to block out larger companies from the AI opportunity in cardiac ablation with our signal processing expertise, we think is quite outstanding.

One other quick comment. I want to let everybody know that we've received five patents from the U.S. Patent Office to date. We expect more in 2021. One of the most interesting things about our patents, aside from the breadth and our ability to protect our system in total, is that there were no prior art rejections. Meaning, the technology we have is green field. We don't come up against anybody's estates. We don't step on anybody's territory or their toes.



+1 (203) 409-5444
info@biosigtech.com

So, it really reduces the risk of litigation as you see with a lot of small medical technology companies. So, our technology is not only completely protected, but also we didn't have any prior art rejections.

In terms of what we've said in the shareholder letter, as of third quarter 10Q, we had \$12.3 million of cash on hand. One of the things we did over the years is we did small private placements to finance our business with quality individuals and we offered some cash warrants, along with the investment as an inducement, to get them involved early. This happened between 2012 to '17.

And, we have about \$18 million of cash warrants still on the books that expire anywhere between December and within 14 months, they'll all be expired. They're in the hands of mostly friendly people who are long term shareholders and we've been averaging about an 86 percent conversion rate on those warrants.

So, when a warrant comes due to expire, they're pretty much all in the money. We get about an 80 percent conversion where we get the monies in and year to date, we've raised a little over \$8 million on warrant exercises and year to date, we've raised roughly \$21 million to support the growth of our company. So, we feel we're well funded going into next year and we're going to be starting commercialization.

So, with that said, we'd really like to get to your questions. So, Operator, thank you, if you could facilitate that.

Q&A Participants

Gary Zwetchkenbaum – Plum Tree Consulting

Robert Carlson -- Janney Montgomery Scott

Scott Billeadeau -- Walrus Partners

Steven Aiken – Aiken Investment

Lawrence Beroza – Private Investor

Sanjay Kamani – Private Investor

Ted Lou -- Private Investor

Chip Richardson -- Wedbush

Bruce Mulvey – Ameriprise

David Basile – Janney

Jeffery Kamisky – JJ K



+1 (203) 409-5444
info@biosigtech.com

Paul Burnstein – Black Diamond

Michael Rodgers – Boening & Scattergood

Rene Delambert – Private Investor

Eric Anderson –The Hartford Financial

Operator

Thank you. We will now be conducting a question and answer session. 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. And, you'll press Star 2 if you would like to remove your question from the queue.

For participants using speaker equipment, it may be necessary to pick up your handset before pressing the Star keys. Again, it is Star 1 on your telephone keypad and one moment, please, while we pull for questions.

Thank you. Our first question comes from the line of Gary Zwetchkenbaum with BloomTree Consulting. Please proceed.

Gary Zwetchkenbaum

Hi, Ken. Congratulations on the recent announcements from Mayo Clinic and on the collaboration. I just have two questions. One, on the commercialization side, if you can talk a little bit about the program in terms of the number of units that you might have ready and just an idea as to when you think you will be doing sales. In other words, you mentioned the Heart Rhythm Society in May and these other events. Is that an event where you would start being able to sell some of these units? And, I have a question about the Mayo collaboration and the three areas that you're going into, the three new areas.

Ken Londoner

Okay, Gary. With regard to inventory availability, we've made great strides this year. However we don't want to comment specifically on how many units we have for competitive reasons. But, as many who have been longer term shareholders know, we've worked really hard to get up and running and into production with Minnetronix, our manufacturing partner in St. Paul, Minnesota.

And, we now have enough inventory to handle the activities leading up to the Heart Rhythm Society Convention in May 2020. So, inventory is not going to be an issue for us. We are in the process of staffing up the company to be able to install those systems, train the folks in the centers, and get them to the point where we can get them to convert to a revenue generating customer. I'll actually let John touch upon a little bit of that process.

John Kowalski

Yeah, so thanks, Gary. We have the one system installed. The TCAI, we're installing next week in Jacksonville and we'll have an additional six or seven systems which we'll be installing over the next four or five/six months and the plan will be to convert those evaluation systems over to sales over the next several months.

So, can't give you exact timelines as to when that will occur, but the conversion will begin in the centers where they're installed, the beginning of next year.

Ken Londoner

And, one point of clarification, Gary. The places we're going into, these hospitals are very large and when we go to install, we're installing one unit to start, obviously getting them up and running. So, in Austin, for example, I believe eight doctors have used the system and we've rotated doctors in to do their surgeries in the room where our system is installed.

As they get up to speed and get comfortable, it would be our objective to place a unit in every operating room where they do these cases. So, the addressable market in these eight to nine centers is multiple units. So, we start with one and we expand from there and the commercial objective is obviously to place a unit in every single one of these rooms.

And, because these are friendly sites and friendly centers, it's going to be our objective to incentivize them to get into multi-unit purchases. But we don't know exactly how each hospital is going to choose to do that, which is why after May, we're going to be expanding to an even bigger number of centers and as we get a little further in, we'll be able to give our shareholders a little bit more clarity. Thank you.

Operator

Thank you. Our next question comes from the line of Robert Carlson with Janney. Please proceed.

Robert Carlson

Hey, guys. Just want to say congratulations for what you've done and the team you've put together. I sort of look at it is as the Red Sox or the Yankees. They didn't win the game until they had a team and the people you have put together are phenomenal.

I just looked back. December 10th, 2018, your stock opened \$3.86. Close today, it's \$6.54. I mean, you're on a fast track, but could you expand a little about the 12-bit system and the 24-bit system? I read something about this and it opened my eyes and maybe other people on the call would like to hear it too.

Ken Londoner

Thank you for the comment, Bob. We appreciate it. So, basically, when we went into the manufacturer in March of 2016 with a prototype, we went through a very long arduous process of converting that prototype into a commercial system that would be appreciated and functional in these large centers.

And, the first generation of product that we received from the manufacturer that was released on your FDA clearance went to three centers in the first quarter, where we got--did first in human use of the system, initial observations, and we got wonderful comments back from the three centers we went into.

I think what you're referring to is we had been working on both hardware and software for about 18 months while we delivered Gen 1 for the first in man. Our Gen 2 system was coming through the pipeline. Gen 2 has the benefit of some hardware improvements and some software enhancements that make it, let's just say, more user friendly.

In terms of the 12-bit to the 24-bit, it's really about the ability to display more information. So, one of the things that the doctors tell us they like about our system is the ability to open up multiple review windows. So, think about being on your PC and you're just popping all sorts of things up on your PC and they can all run real-time, whether it be an Excel spreadsheet or a PowerPoint or an email.

For us, we're running real-time live heart signals and in order to do that, you need a very fast A to D conversion capability and also some other novel technical developments that we've done, so they can see multiple things real-time. And, so the Gen 2 system, we call it Gen 2, it's really the first system that's going into commercial launch, that's going to be our workhorse now for a period of time.

Robert Carlson

And, saying that the competition that's out there now in operating rooms are a 12-bit system, where ours is a 24. And, if my understanding is correct, 12 goes to 13-bits, the amplification doubles. 13 goes to 14, amplification doubles. 14 goes to 15, a double. By the time you're up to 24, your amplification is 4,000 times greater. Is that not correct?

Ken Londoner

I'm going to have John touch upon as to why that's important from a doctor's perspective, John.

John Kowalski

Yeah, so from--that is accurate, your analysis there. And, from a doctor's perspective, it enables them to see signals--again, I mentioned that those very low amplitude, high frequency signals in the heart, which are not visible today with the current recording systems. It is a bit more complicated than just the bit conversion. There's other part of our--the way we acquire the signal, the sampling rate. We sample at 2,000 as opposed to 900 with the other systems. So, we're collecting a lot more data and we're displaying it in different ways.

We're able to display and filter signals on the back end through software. The current recording systems today, they take the signal and it goes through a series of hardware filters and much of the signal fidelity is lost in the process. So, with our technology, we're able to acquire that raw signal and apply our filters, which preserve and improve the fidelity and overall signal characteristics.

Ken Londoner

And, one last comment, Bob--go ahead, I'm sorry.

Robert Carlson

Is the cost of our system compatible to this, to the competition?

Ken Londoner

Are you asking what we're going to charge for it, is it compatible?

Robert Carlson

Yes.

Ken Londoner

We won't get into that kind of discussion, Bob. We believe that our system is more functional and performs better, and it provides them information they've never had before. In Dr. Natale's case, when he used the system for the first time, (John Kowalski was in the operating room) he was able to put the patient back into normal heart rhythm, seeing signals on our system that he couldn't see on his existing system.

We have a mission to basically help everybody understand the value of that. We must have the customers understand that first and by having these very high fidelity capabilities, as we translate this new information to clinical gains and procedural time savings for them, this is where we're going to hit a very good ramp and what's the value of the new technology? I mean, Apple charges--I don't know what the iPhone 11 goes for. It's like what, \$1,000?

Unknown

\$1200.

Ken Londoner

\$1200, where everybody else's phone is being given away. So, a premium technology, we think, will carry a better price, but we have to get into the market to see how the average selling price shakes out.

Robert Carlson

Great, I'll jump off and give somebody else a chance. Thank you, though.

Ken Londoner

Thank you, Bob.

Operator

Thank you. Our next question comes from the line of Scott Billeadeau with Walrus Partners. Please proceed.

Scott Billeadeau

Hi, thanks for taking my question. Just a quick one, and again, you probably don't have numbers, but what--you know, on the commercial strategy, longer term, was this just a classic hardware sale, or is there going to be a hardware with any recurring aspects? Are you going to gather data, and whose data is it? Is it the patients, the hospitals, yours? You know, maybe give us a little--some thoughts there.

Ken Londoner

Yes, thank you for the question. We're looking at generating revenue from all of the above, both hardware, the system itself, software, technical service, and then AI down the road. We will have a recurring revenue program where if the customer signs up for the service agreement, they'll be able to acquire all of our commercially available and launched software, and we're developing a really unique pipeline of software, which will enable additional utility of the system overall.

Scott Billeadeau

Okay, great. And you know certainly, you want to do more with AI with data, but is it your data, is it patient data, hospital data? How--you know, what is it that you can gather? And then obviously build the data to help improve the software, but talk about that a little bit, because sometimes there's--

Ken Londoner

--Sure--.



+1 (203) 409-5444
info@biosigtech.com

Scott Billeadeau

--Yeah--.

Ken Londoner

Let me see if I can be brief about this. In March of 2017, we signed a 10-year collaboration agreement with the Mayo Clinic. They told us at the time of signing that it was the first 10-year agreement they'd ever signed. We didn't understand that or believe it, but it turns out to be true. The second 10-year agreement they signed was about three months ago, with Google. What Google's doing right now for Mayo is they're taking all of their data, and they're moving it up into the cloud, so companies like us can have secure firewall access to it, without the patient information, so we will separate the HIPAA information from the signals. And then our data will be in our system, and we'll have to have some sort of legal and collaborative agreement with the hospital, to be able to utilize that data, so we can enhance decision-making in certain areas of the procedure.

This is now starting to bleed into medicine, we're not the only company doing this. But we're in a pretty unique position, because if you think about Google, their use of Motorola was really to get access to the hardware, to be able to embed their operating systems, and their apps, and all the other things that they want to do on a smartphone. For us, having a system installed in an operating room, under the operating table getting real live heart data that's being processed, and cleaning out all the interference and noise, that's ideal data to be annotated and processed. And this is what we're working on at MIT, to create those data sets in the algorithms to properly identify abnormalities that maybe the human eye misses, because of the complexity of the procedure. And the way we see ultimately charging for that, is as a layered add-on, additional service on top of our offering. And how we charge for that, that could be a monthly subscription fee, that could be a package deal.

Right now, we have to build the technology. As we get more and more of these systems installed around the country, we think that'll increase the size and the attractiveness of the data sets we build. And we'll get to a critical point where we have all the commercial agreements in place with the hospitals, they may enjoy some benefit financially from working with us, with the data. But starting with Mayo and expanding to some of these other leading places, we think will put us in a leading position in this field. And you know, in terms of timing, we're going to be working about as fast as we can on this. And we have a pretty good head start because our tech team, both in Los Angeles and in Rochester, Minnesota, will be working on this every week.

Scott Billeadeau

Great, thank you.

Ken Londoner

Hope that answers your question.

Scott Billeadeau

Yep, thank you.

Ken Londoner

My pleasure.

Operator

--Thank you--

Ken Londoner

--Next question?

Operator

Our next question comes from the line of Steven Aiken with Aiken Investments. Please proceed.

Steven Aiken

Yeah, I'd like to echo the congratulations. Great progress, guys, really good progress with the stock. Short question; any update from Europe? If I recall, it was some testing or trials, something going on there in the European area, any kind of an update?

Ken Londoner

Thank you for the question and the comment. I actually have a conference call tomorrow, we are working on our CE mark submission, which is the equivalent of FDA approval in Europe. We've been studying the European market quite intensely over the last three years. We actually have one of our executives based in Geneva, Switzerland, with two other folks over there working on understanding when we get that approval, which I can't really project just yet, Europe put a new method of how they screen these approvals. It used to be pretty easy, and these young MedTech companies would go to Europe first, get a little commercialization there, and come back to the U.S. and try to deal with the FDA. We chose to go the harder route, which is get FDA first, then go to Europe.

You know, we're hopeful we'll get European approval approximately the second half of next year. I don't anticipate it to be any sooner than that. And then we've already been doing some great development work regarding market launch and geographic targeting. For those of you that know Europe, we will choose the places that have the deepest appreciation for our technology that can afford to pay for it.

We have also explored Japan market entry this year. Japan is roughly 10% of the global market for electrophysiology and has been developed since 1993. We hope to make some more progress there next year. We thought we would make dramatic progress this year, and I think our ambition got the better part of us, because as anybody who's worked in Japan, like our friend Mike Allen knows, it takes quite a bit of time to work on market development. But once you succeed, you get a really big focal market. There are seven cities where we can potentially place systems in Japan. We will most likely work with a partner there. So in 2021-22, we expect that you'll start to see international business turn on slowly at first, and then it will be part of our overall revenue ramp.

Steven Aiken

Great. Well thank you so much for the update there, and good work, guys.

Ken Londoner

Thank you, Steven.

Operator

Thank you. Our next question comes from the line of Lawrence Beroza, a private investor.

Lawrence Beroza

Hello. I am an investor and a physician, but I had two questions. First, regarding Biosense division of Johnson & Johnson--I think I know the answer to this, but I just wanted verification. Is that, in any way, in competition with the PURE EP product of Biosig technology? And secondly, the other part of my question is, what I perceive as kind of a decrease in the stock price over the past three or four months. When you go to sleep at night, and you're talking to yourself, what are you saying to yourself about perhaps the reasoning behind the decreasing stock price, over these past several months? Those are my questions.

John Kowalski

Yeah, so this is John, I'll take the first question, and I'll let Ken take the second. This PURE EP signal processing system is not a competitive technology to the cardio mapping system at Biosense Webster, my former employer. In fact, it's a complement, and it makes the procedure and ultimately that technology even better, because it enables, again, the physician to see those low-amplitude high-frequency signals that are just not present on the mapping system or the recording systems in the lab today. So--

Lawrence Beroza

--Wonderful--.

John Kowalski



+1 (203) 409-5444
info@biosigtech.com

--It is a complement, and I look forward to continuing to work with Biosense as we expand our footprint of the technology. Ken?

Ken Londoner

I get the fun question. Dr. Beroza, thank you for joining. So just to maybe do a very quick synopsis, and I think a prior investor, Bob Carlson, had mentioned this. We started Jan 1 in the high \$3.00 range, and we've made all of our commitments to the shareholders. Our stock, after we did our first in-human cases, in February, March, and April, the quality of the comments coming from those lead doctors really captured people's attention. And then we had the big industry conference of the year, it was in May, called the Heart Rhythm Society, which was at the Moscone Center in San Francisco. And we were all there, John was there as well. Our booth was very well attended more so than we expected. Not only did we have physicians and customers at the booth, but we also had sizable number of institutional investors stop by. And on top of that, we were included in the Russell 2000. That all merged together at the same time.

When Donald Trump ratcheted up the talk against China, that was August 5th. We noticed, not just our stock, but many of the small emerging growth life sciences companies, people started to back off of risk-taking in the marketplace. Even though the averages have hit all-time highs, I think many on this call realize that it's in a very concentrated number of stocks, and people had been shying away because of not only the elections coming up, but all this rhetoric over China.

And one thing we've noticed recently is, if a company delivers fundamentals in the sort of emerging market life science category, their stocks can go up quite a bit. And there's been a number of examples here, just in the last several weeks. One of our board members is a lead executive in a company called Sorrento Therapeutics. The stock has more than tripled in about two weeks, from \$1.10 to almost \$4.00, on some positive fundamental news. And I can give you a bunch of other examples, but at the end of the day, the way we look at things is, we're just trying to execute our plan, and we're in a very lucrative marketplace, we're patent-protected, we have a great team. And as we start commercializing and we produce clinical data, that gives John and his commercial team more capability to sell even more product, we think that stock issue will resolve itself, and we expect that to happen in the near term. That's the best we can say.

The other thing--I'll make one other comment. One other comment, Dr. Beroza, if you don't mind--

Lawrence Beroza

--Sure--

Ken Londoner

--Andy Ballou who I've known for many years, has spent a lot of his career talking to large institutions who invest billions and billions of dollars. And that's not a category we've spent a lot of time on because we've been very focused on getting to the commercial market. But we brought him on board to help us better interact with that larger audience. And that audience is kind of looking for the same things many on this call are looking for, which is clarity and commercialization, seeing us continue to honor our commitments. And as we do that, I think everybody on this call will be happy.

Lawrence Beroza

Oh, well thank you. I appreciate the answer, and perhaps that'll help me sleep a little better tonight.

Ken Londoner

Well, one other thing I have to say, Dr. Beroza, and now I'm getting into the weeds here, but as our stock has increased a little over 50% for the year, we've raised \$21 million of capital, put it in very friendly hands, hence the increase in our stock price, and we've also absorbed a two-million-share short position. And I don't want to comment on the short position, only to say that that's selling against stock that is being borrowed, thinking and expecting our company to all of a sudden overnight become like a poor performer. But again, we've made a lot of our milestones--in fact, all of our milestones, and it's our belief that we will continue. If we do continue to do so, there'll be good stock performance for everybody, hopefully next year as well.

Lawrence Beroza

Well, great. Well, I am a believer, and perhaps a little more so now. Thank you very much.

Ken Londoner

Thank you.

John Kowalski

Thank you.

Ken Londoner

Next question?

Operator

Thank you. Our next question comes from the line of Sanjay Kamani, a private investor. Please proceed.

Sanjay Kamani

Yeah, hi, Ken, and John, and the team. Thank you very much for the hard work the team has put, and really appreciate this update. My question is, Ken, you mentioned about the portfolio of the

products, two being in the (INAUDIBLE), one in the EP, if I heard it right. Could you please elaborate on that, and give a little more idea on that?

Ken Londoner

Sure, to the extent I can give you a little bit more clarity. We're in the process of filing patents in the next 90 days around what we've taken from Mayo. So, basically, if you look at today's landscape, there are four big product categories in our industry. There are mapping systems, there are recording systems, there are catheters or disposable technologies, and then there are other things, you know, accessories and implantables, if you will. We've done a good job staying away from the catheter business, because the catheter business is dominated by J&J, Abbott, and Boston Scientific. So it'd be like fighting with Coke and Pepsi to try to get some shelf space, to get your new beverage on the shelf. So, we have not wanted to take that path. But in terms of software, adding software to our existing system, that's one of the categories we're working with Mayo on, and that we've licensed some technology on. So those are applications that are clinically-focused, that have gone through many years of development at Mayo, and they didn't really have a host or a company to share this technology with because with big companies that are dominating our market, they have their own software's, and they normally want to develop their own advances themselves.

Sometimes they collaborate, but most of the time they do a lot of the work themselves, so we kind of showed up at the right place at the right time. So one area is software, the other area is what we call accessories. There's a lot of different accessories that go along with the installation. And these are recurring revenue type of items, some of them are small tickets, others are a little bit bigger. But in the accessories business, it's high margin, and we're working on taking these accessories rapidly through development and manufacturing so we can--when John and his team are selling PURE EP Systems and software, we can also add to the sale, as we go into 2021 and 2022. John, do you want to add--?

John Kowalski

--Yeah, I think it also--as it relates to the technology itself, the PURE EP system, we're not replacing a current technology. We are--we have the ability to sell our system in every EP lab in the world. In the US alone, there are over 2,000 hospitals that have electrophysiology programs, and within those programs, there's over 4,000 EP labs, and that's just in the US. So the PURE EP system can be implemented and sold into every one of those centers immediately, without replacing a current technology.

Ken Londoner

And we'll be sharing more with you--

Sanjay Kamani

--The mapping--

Ken Londoner

--Go ahead.

Sanjay Kamani

Sorry. The mapping and recording, those two areas, so that is hardware and software, is that right?

Ken Londoner

Mapping and recording is both hardware and software. Correct, yes.

Sanjay Kamani

Okay, okay. Sorry, you were saying something?

Ken Londoner

Thank you. No, I was going to say, with regard to all this new technology, it's our ambition once we get all these patents filed and we get deeper into the planning and execution of this product growth, we will share all this information with the shareholders, and we're hoping to do that sometime midpoint of next year, maybe a little earlier than that. We'll see, it's all based on protecting the technology with patents, which is something we've done a really good job on so far. Thank you, Sanjay.

Sanjay Kamani

Thank you.

Operator

Thank you. Our next question comes from the line Ted Lou with the Valley Financial Group. Please proceed.

Ted Lou

I just wanted to comment that I thought the explanation of being able to see signals that don't show up on ordinary machines was particularly important, made me think of if you have an ordinary hi-fi system, and you play, say, Tchaikovsky's violin concerto, you don't even hear some of the highest notes. And if you have a system with good speakers, and good electronics, it sounds like a lot more beautiful music, which is what I think you're making. Thank you.

Ken Londoner

Thank you, Ted.



+1 (203) 409-5444
info@biosigtech.com

John Kowalski

Thank you. Great analogy.

Operator

Thank you--

Ken Londoner

--Next question, operator?

Operator

Certainly. Our next question comes from the line Chip Richardson with Wedbush. Please proceed.

Chip Richardson

Great job, guys, really appreciate the success you've had. I was just interested in how many new EP labs are going in, and whether you're able to get in on new labs being built? And what is the current use--kind of percentage use, if you have any numbers on that, of how busy the existing labs are, they're used 80% of the time or 40% of the time, kind of thing?

Ken Londoner

Chip, I think John and I are going to split up that question, it's a good one. And it's--sometimes I feel like some of you guys are sitting inside our offices listening to our conversations. In terms of new lab growth, it's about 10 to 13% a year. There are always new labs popping up, because this is one of the highest profit centers in the hospitals. It's one of the most lucrative areas of medical practice. So all the hospitals, as they're dealing with the growth of the aging population, they want to favor building out areas of the hospital where they can actually make money in today's environment.

So with that said, when we hear about a new lab upstart--so some of our early commercialization successes, I think, will be around this topic. We get word that there's a new lab, and then like any of you, we try to jump on that. And the key is to figure out, how do you get written into the architecture of that lab? So think of, if you're building a new office building. Whoever the builder is, you want to know the architect, so if you're selling washing machines, your washing machine's going into the kitchen, so let's say a 3800 apartment complex. So for us, we want to get written into the blueprint of the labs, and when we're able to do that, then a sale gets made.

And a lot of the times, they have budgets to build out these new labs, so it's an easier time. Nothing's easy, but it's--let's say, it's a better category because they have the budget already allocated. So, instead of having to fight for the capital budget for the whole hospital with other companies' x-ray machines, neurology machines, and all the other stuff that gets sold to hospitals, if

they budget's already been allocated, then that's money that we can go after. So, that's going to be one area that I think we'll always be eager to chase. John, do you want to add--?

John Kowalski

--Sure, that's a great opportunity, but the even larger opportunity is the existing 4,000 or so EP labs, in that our system is really kind of plug-and-play. It's a few cables that we run and can integrate with the other systems, so we're not reliant on new construction or new installations as part of that. In terms of your comment around usability, the system can be used for all types of arrhythmias, atrial fibrillation, which I'm sure most of you are familiar with. Afib is about 70-80% of the procedures today, other complex cases, ventricular tachycardia and other arrhythmias. So, there's benefits to seeing improved signal quality in all procedures. And just so you're aware, the large vendors, if you don't--they have often four, five, six electrophysiology labs within their hospital, so there's an opportunity to sell multiple systems in those centers.

Chip Richardson

Uh-huh, and are these large centers also adding new EP labs, or--?

John Kowalski

--Yes, they are. They are. And one of the sale wins I'd like to say is that the electrophysiology ablation procedure is a revenue-generating procedure for the hospitals, with very positive reimbursement trends as well. The reimbursement for afib procedures has grown by 50-60% over the last three, four years. So, very positive trend, and as a result of the revenue-generating aspect within the hospital, they're reinvesting in EP, into new systems and new technologies within that department.

Ken Londoner

I just want to add one brief comment. I'm sorry to interrupt, Chip. Because each patient who elects to have an afib procedure is so lucrative to the hospital, if you think about the big markets in the United States, we call them the NFL cities. In the NFL cities, where you have--depending on the city, four, five, six centers that do the majority of the business. So, one of the things that I think will be attractive for us is, when you have a new technology come into a space like this, where they're all making money, there's like a hidden story about how they compete with one another for room nights, for patient flow.

So we think that will work possibly to our advantage, that if a big center in a big city chooses to elect us and work with us, and they start getting good results and we're supporting them, they may pull market share away from their cross town rival. And that cause the crosstown rival to say, hey, we can't afford to lose these patients, we better get these systems too. And we've seen this with the CyberKnife, we've seen this with the DaVinci robot. So those dynamics work to our advantage, and

being the entrepreneurs that we are, we'll do our best to make sure we get the leaders in each of these big NFL cities into our systems over the next few years.

John Kowalski

Yeah, there's also an opportunity to improve--

Chip Richardson

--That's great.

John Kowalski

There's also an opportunity to improve efficiency of the procedures, as well, if you think about some of these complex ablation procedures can go on for four, five hours, as a result of the challenges with diagnosing the arrhythmia, or targeting certain signals in the heart. So, we believe there's a great opportunity to potentially reduce procedure time, and improve efficiency, and enable these centers to actually do more procedures.

Chip Richardson

Wonderful. Nothing better than having an increasing demand for new technologies, and you guys being able to provide that new technology. Congratulations. Sounds great.

Ken Londoner

Thank you, Chip, and have a good afternoon. Next question, please.

Operator

Thank you. Our next question comes from the line of Bruce Mulvey with Ameriprise. Please proceed.

Bruce Mulvey

Gentlemen, I have three quick questions, simple questions. First of all, I don't have heart trouble, but if I did, I would want to go to a hospital that had one of your technologies. Is there a list of the hospitals that have this? Secondly, this is a lot of information for a layman to digest, and so, do you have a website--I'm sure you do, where this information can be found? And third, my last question is, your technology sounds great, it sounds like every doctor who does this is going to want to have it. What is your sense about the appetite for insurance companies to continue to grow and to reimburse the costs of this stuff? Thank you.

Andy Ballou

I'll take the--thank you. I'll take the first easy question. Bruce, you can go to biosig.com, there's a lot of information on that site. John, you want to--?

John Kowalski

--Yeah, and I think in the future there is an opportunity to list the centers, and the partnerships, and the physicians. We did that effectively at Johnson & Johnson, where we actually had kind of a physician list on our site. So in time, I believe that we'll have that available.

Bruce Mulvey

Okay and insurance companies, are they going to--because Medicare is increasingly insolvent, and there's a lot of pressure on that. Are we going to be able to have the costs passed onto the insurance companies to pay for your technology?

Ken Londoner

So, this is one of the hidden beauties of our investment story, one of the reasons I decided to take this journey, is we're not tied to insurance reimbursement costs directly. So, what happens is, the procedure itself is reimbursed by either private insurance, HMO, or the government, and they get a bucket of money. And that money gets allocated to the surgeons, to the support staff, for the disposable products, for the room that the procedures being done and the time in the room. And what's left over after they get their bucket payment is called profit.

And you know, if there's a way they can do the procedure faster, which is something we're working on showing them, they can schedule more procedures. These procedures are being reimbursed roughly \$25,000 by Medicare. And so, if we can even save them 20 minutes, and you multiply that over the course of a day or a week, and they can schedule some additional cases, because there are waiting lines--

Chip Richardson

--I understand.

Ken Londoner

But most of these big centers, we think that'll be appealing. And the industry is interested in that, and of course we're aiming towards improving the outcomes for patients, which'll be a good patient story. We have to do clinical trials to show just how much, and how significant that change is. But we're able to go into these centers now and sell what we have based on the technology itself. Thank you so much. Next question, operator?

Operator

Thank you. Our next question comes from the line of Eric Anderson with The Hartford Financial. Please proceed.

Eric Anderson

Thanks for the update, Ken. I'm excited to hear some of the new technologies that you went over with the Mayo, but I would caution you not to take your eye off the ball, in terms of what you're trying to do first and foremost. But you know, been down this path before with many companies you invested in on the portfolio side, so, just a thought from--

Ken Londoner

Eric, I do like that comment, because that comment was echoed at our Board of Directors meeting-- not recently, but before we did this. One of the things that--one of the reasons we decided to step up with this is, we know we need other things to sell. We don't want to sell other people's products, we want to be innovators, that's number one. Number two, we are adding engineers, not so many, but a couple key people.

We added a gentleman by name of Barry Keenan, who is one of the leaders in this field who came to us. So, we have some really unique capacity in him. And then, last but not least-- you know, we're not precluded in these new developments from working with other partners. So, whether it be a large corporation who wants to co-develop something with us and Mayo, or a manufacturer that wants to be in this business and wants to get into EP, if you consider those two variables where we can get new manufacturers into this hard-to-get-into space, or other companies that want to maybe have-- you know, a partnership of some sort, we think that's compelling and that's why the board allowed us to move forward with these deals at Mayo.

So, you are-- you are correct in your caution, but we think we've covered that.

Operator

Thank you. Our next question comes from the line of Rene Delambert, a private investor. Please proceed.

Rene Delambert

Hi Ken and team, thank you guys so much for all your hard work and an exciting and wonderful call. My question for you is that it sounds like the revenue is going to be fantastic moving forward, but do you anticipate enough revenue to not need more of a raise next year? Or will there probably be required going forward?

Ken Londoner

Well, that's a great question, Rene, and-- you know, one thing that I think we have differentiated ourselves versus other companies is we raise most of our own money. We did use a third-party early in our life cycle, and then we started doing it ourselves and we've been doing a pretty good job building the company off of-- small capital raises. The capital we have on hand, the cash warrants

take care of us for the foreseeable future and-- we're always looking for opportunities to strengthen our balance sheet. Insiders own a considerable amount of equity and we are very thoughtful of how we finance the Company . We are very sensitive to dilution. We only have about 22 million shares outstanding after almost 11 years, which is a very small number and many of those shares are very tightly held for the long term. So, you know, if we do bolster our balance sheet--we'll do it in a manner that's very friendly to shareholders. That's the way we've done it for almost 11 years. We're not going to change now.

Operator

Thank you. Again, if you'd like to ask a question, please press "*" then "1" on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press "*" then "2" if you would like to remove your question from the queue. And for participants using speaker equipment, it may be necessary to setup your handset before pressing the star keys. Thank you. Our next question comes from the line of David Basile with Janney. Please proceed.

David Basile

Yes, good evening. Thank you for your time this evening. I'm kind of curious about Biosig and I've acquired some information from my colleague, Carlson, but I'd like to know about the patient experience in this process of ablation versus an ICD and that market. An ICD or an overnight patient, you go home the next day. How does it work with ablation? And then a second question would be, the fit of the equipment into the surgical setting?

There's space already in these EP labs. You're displacing some technology? Or there's enough room to add on equipment?

Ken Londoner

Yeah, so, the first question around the patient experience, it's a minimally invasive procedure where a catheter is threaded through the femoral vein in the leg and, typically, depending on the complexity of the procedure, a patient could be either outpatient and discharged that day or potentially one night-- overnight in the hospital. It's rare that a patient would be in a hospital more than-- more than one night for an ablation procedure.

In terms of the fit, it's an amplifier system that fits well within the EP lab underneath the patient table, and then there's a computer work station that's next to the other recording and mapping systems in the area, which is called the control room of the EP lab. So, very fit friendly for lack of a better word and easy to install and utilize within the lab.

David Basile

Oh, follow-up question. Yeah, follow-up question on that patient experience, please. And that would be that there are enough doctors that are qualified to do these procedures? Because ICDs are kind of common place these days, aren't they?

Ken Londoner

Yeah, many of the-- well, it's not a replacement for an ICD. So, first of all, the ablation procedure does not typically replace ICDs. Most of the physicians-- actually, many of the physicians who are doing ablations are also doing ICD implants as well as pacemakers.

David Basile

And so, the market then is a conversion, if you will, to ablation versus ICDs? What's the distinction here in qualifying for an ablation-- being a better patient for an ablation versus a defibrillator?

Ken Londoner

Yeah, defibrillators are typically for ventricular arrhythmias, ventricular tachycardia, or episodes of ventricular fibrillation life-threatening arrhythmias where they need to have a precautionary device-- you know, implanted to defibrillate the heart. Although, VT, ventricular tachycardia procedures are being ablated with-- by certain specialty physicians. There are other arrhythmias, specifically atrial fibrillation and other atrial arrhythmias, that are more common for the ablation procedure.

David Basile

So, the size of that market is?

Ken Londoner

The ICD market? Is that your question?

David Basile

Ablation versus ICD? I've kind of got a handle on the ICD market, but I'm trying to understand ablation. Having had a family member go through this recently, I'm just wondering about why ablation versus ICD? Who gets the recommendation here? What patient gets that recommendation? Ablation versus ICD?

Ken Londoner

Yeah, so John and I, neither one of us is an EP doc whether we've-- John's been around them for a long time, I've been around them for less. I would tell you, it's really dependent on the patient and the situation. A lot of times, it's really a decision between drug therapy, which are two classes of drugs. One is blood thinners, the other is what regulates the rate and the rhythm of the heart through cell chemistry and the heart wall.

Both of these drugs have known side effects. Some of the side effects are really diminish the quality of life and the disease continues to progress. So, while it might be able to mask some of the symptoms-- you have to be willing to make that decision for yourself or whoever has to make that decision. The opportunity for cardiac ablation in the market itself, of the number of people that are known to have A-fib in the United States, only about 7-8% decide to have cardiac ablation as a first line procedure.

And there's a variety of reasons why that is, we're not like the sole experts on why that is, but what we observe is that, one, the procedure sounds a little nerve-racking. They go in and they do 200-300 burns inside your heart with radio frequency energy. So, they're creating little lesions or scars inside your heart. When the doctor explains that to a potential patient, people get a little squeamish. It's much worse than a colonoscopy. And so, then people say, well, maybe I'll try drugs at first, but the story on drugs isn't that great either.

So, as we make improvements, and others hopefully will bring their own improvements with the cardiac ablation procedure, we believe there's an opportunity for the growth rate of the industry to significantly accelerate. Because in the tradeoff between drugs as the first line of therapy and cardiac ablation, if you can make the cardiac ablation statistics better, then there'd be some more people who choose to have it. Because if they burn in the right places and they catch it early, they can cure the disease with this procedure.

They don't cure the disease with drugs. I hope that helps.

Operator

Thank you. Our next question comes from the line of Michael Rodgers with Boenning & Scattergood. Please proceed.

Michael Rodgers

Good afternoon. Thank you very much for a very informative conference call here. One of my questions was already answered, the burn rate versus your capital that you have on hand and the capital that you've been able to raise in the past that you think you'll be successful in doing in the future.

My second question is the idea, it all goes away at times. We never know if everything is going to go right, might we expect some profitability in the last quarter of 2020?

Ken Londoner

Yeah, that's a-- that's a great-- that's one of my favorite questions because I sit and stare over the numbers and remember where I came from. I was a money manager running growth funds in the

mutual fund industry, and we were obviously very focused on profitability. We never really understood companies that would just burn money with no profit motive. So, I can tell you from a cultural perspective we are profit-minded.

With that said, obviously, we're building up as an organization to be able to meet the initial demands of the marketplace. And in terms of profitability, it's hard to make pronouncements, but our goal is to get towards cash flow break even. And that's really going to be a function of how we do on revenues and average selling price, how that ramps, and our requirements to support that ramp. And then, how we manage the growth of the product portfolio.

Obviously, if we do something in partnership with somebody, we may not have to put up so much money or any money and we can develop a product and gain benefit financially from it. But at the end of the day, philosophically, nothing would make me happier than to cross over to cash flow profitability. A lot of the small med-tech companies that you can look at today, some of them are really good companies.

They're burning money like it's going out of style. They're like little mini we-works, and I don't know where they think they're going to get the money from, especially if the markets get more challenging. You know, our burn rate has always been well controlled inception to date. So, almost 11 years, we've only burned \$50 million dollars approximately. I think it's a little more than that. So, think about that. That's less than \$5 million a year to get to this place.

So, we're very, very judicious about what we spend, although we do want to make investments in our future. So, I think our cash flow break-even point will be distinguishable from all other emerging growth med-tech companies because of what I just said. In terms of cash burn for next year, we haven't given that guidance, but let's just say this time next year if we do our jobs right, our cash burn will be less next year than it is this year. We just don't want to say how much because making that prediction today is going to be-- we don't want to be totally wrong.

Michael Rodgers

Third and final question, Ken, you are a major stockholder in the company. You're the executive chairman and so forth, if you got a call tomorrow morning and someone offered you \$20 a share for your stock, would you feel comfortable going to shareholders and recommending they take that?

Ken Londoner

Well, that's quite a loaded question. My wife has told me that I should never retire and don't come home, so that's part of the answer. But, in seriousness, the true answer is, again, being a former money manager for almost 16 years, we have developed a fully independent board of directors. They are governing the company. Despite my stake in the company, I don't control the vote of the

company. That's in the hands of the shareholders. So, if something like that were to come to pass, I can assure you that it's going to be independently analyzed and judged based on the merits of our plan and our capabilities, versus whatever is shown to us and we'll see how that plays out.

Michael Rodgers

I was hoping you were going to say, Michael, I wouldn't let them steal this company away from me at \$20 a share. It's worth a lot more than that.

Ken Londoner

I've given so much advice to public companies over the years, I-- I just am going to stay neutral on the question because what I believe in is our job is to make money for the shareholders. That's it. We're very shareholder friendly. Everybody in our company owns stock. Everybody's bought stock. And so, we're planning for a nice return for everyone. I don't think the short sellers understand or appreciate that depth of commitment, but in terms of the marketplace we're in, it is a highly inquisitive marketplace.

Every good EP technology that's come along over the last ten years has been acquired for big numbers, so you know, we're in-- almost 11 years into it and we've got great people that have joined the team patents. And if somebody wants to separate us from this technology, they better come-- you know, prepared.

Operator

Thank you. Our next question comes from the line of Lawrence Beroza, private investor. Please proceed.

Lawrence Beroza

Hi, thanks for taking another question from me. This concerns insurance, and regarding insurance reimbursement, it seems like the PURE EP just adds another level of technology to ablations. But right now, I assume that reimbursement from insurance company is the same as doing an ablation without the pure EP versus with the pure EP. But since there's another level of technology being added, it would be reasonable for me to think that the company could approach insurance companies and say, hey, we're doing the pure EP and adding it to the ablation so we expect an increase in reimbursement to the hospitals.

And if that is put into place than the hospitals would have more of an incentive to add the PURE EP to an ablation procedure. Has anyone given any thought to increasing-- to doing that, approaching the insurance companies from that point of view?

Ken Londoner

Yes Dr. Beroza, that's a great question. I'm going to answer it differently than you may expect. I'm sure everybody watches sports on television sees all these commercials on mesothelioma and companies that wronged people medically and all the class action lawsuits that go along with it. When somebody goes to have a cardiac ablation and the procedure fails, we don't know specifically what the legal liabilities are for the hospitals. We don't have those conversations with them.

But any device that can reduce that liability, I think, is a-- another way we can bring value to the hospitals. In addition, many years ago, like 2002-2003, there was a company out of Philadelphia by the name of A Research Technologies. It was Ascent company, traded in the single digits like us, and somehow, somehow, they were able to convince the FDA that their cardiac technology should be used in every drug safety study done for every new drug going into investigation.

They were able to persuade the FDA to mandate that, and their stock went from \$5 to like-- I don't know, some crazy number like \$600. So, as we start collecting clinical data, if the clinical data shows that this should really absolutely be a gold standard, sufficed it to say we'll do everything we can on behalf of the shareholders to make the key stakeholders aware of it and see if we can-- you know, enhance the sales and marketing thrust from that perspective. But in terms additional insurance, I've already met with one of the top insurance companies and we don't have enough time on the call tonight for me to share with you what they had to say.

But really our core focus is communicating the value directly to the hospitals.

Lawrence Beroza

Okay. Alright, thank you.

Operator

Thank you. Our next--

Ken Londoner

Two more-- two more, please, operator. If you don't mind.

Operator

Certainly. Our next question comes from the line of Robert Carlson with Janney, please proceed.

Robert Carlson

Yeah, just one quick follow-up. We've heard a lot about Biosig and the pure EP, but what about the subsidiary of NeuroClear, and maybe you can just fast-forward and give us an idea of what the NeuroClear's forecast are? What they may be doing? What medical needs they may come with, etcetera?

Ken Londoner

Fair question. Thank you for bringing it up. So, we formed the NeuroClear subsidiary in June of 2018. We got board approval to segregate the accounting for NeuroClear. We got board approval to raise capital for the subsidiary and we raised \$3.7 million on September 5 at a valuation of \$40 million dollars. There are certain things going on a NeuroClear that preclude me from talking about it in detail.

We're working on some important developments that we hope to be able to bring to your attention in the near term, but in terms of the longer-term circumstance there, NeuroClear is focused, not on heart signals, but on nerve signals. So, the electrical impulses that ride down our nervous system, but the central nervous system and the peripheral nervous system, that will help some of the therapeutic developers like our friends at Mayo. With our signals, they hope to develop different ways of treating diseases that currently either don't have a great solution, or-- or have a drug solution that they think they can compete with the device.

So, one-- one example of that today, if anybody looks at Inspire Medical Systems for sleep apnea. They implant a little device sub-clavically near your shoulder. They attach some wires to your tongue and it eliminates sleep apnea without you having to wear a CPAP machine. And they rolled this out to the market, the market has accepted it. It's all bioelectronic medicine and signal processing. We may, at some point, be able to speak to them about enhancing their signal capabilities. But you know, they're rapidly being adopted and there are many other little companies that are doing the same thing in other areas of the body.

At NeuroClear we're focused in the area of hypertension, which is high blood pressure. Hypertension is a very large disease in the United States. 75 million people, 40% of which don't respond to drugs at all, and that's the population that we're working on with Mayo to see with our signals and some of their tools and know how, can we add value that they can see a way to do something better? If we hit on something like that, that would be inside NeuroClear. That would be a very big deal and we could bring that to market at NeuroClear, or we could find a partner to bring that to market with.

That's one area of development. The other area that we're focused on are some of the central nervous system diseases where drugs really don't do a great job. So, depression, right now the SSRI class of drugs have heavy, heavy duty side effects from many-- you probably know some of them. And then, there are some device companies working on depression through the use of magnetics in helmets. We're looking at a different type of approach with Mayo, and our goal is to be in the animal lab with this system next year trying to see these initial proof points and getting data that says with our signals, we can do better.

If we see that, then we can go into rapid prototyping, manufacturing, and then put a-- put a commercial plan together. That's generally speaking what's going on with NeuroClear, and you'll definitely be hearing a lot more from us in the first and the second quarter of next year. We're-- one of the reasons we opened the office in Rochester was to support all of the technical and development activities for NeuroClear.

Robert Carlson

Ken, thank you.

Operator

Thank you.

Ken Londoner

Last question.

Operator

Our final question will come from the line of Paul Burnstein with Black Diamond. Please proceed.

Paul Burnstein

Hi, Ken. I got on a little late, but at least I can get one question. It looks like you're moving ahead. You have a lot of technology and I'm just curious, is that actually slowing down the sales cycle because you keep bringing out new things or people read about new things and-- you know, you don't have any sales yet. So, the key thing from my perspective is the company has to start getting sales. And then, you start getting into the game, so I'm just wondering what the major questions are from the potential buyers when they're looking at this technology, the PURE EP system?

And are a lot more questions-- meaning should I hold off and wait on this for something better? Or-- you know, what are they coming back with? And I think we met in August and you were starting a sales cycle, and I'm just curious of whether the sales cycle is going to be longer or shorter with all of the other things you guys have been working on?

Ken Londoner

Thank you, Paul. If you want to take a hard look at this, I recommend you go back and read our June and November 2019 shareholder letters at www.biosigtech.com where we said what we were going to do and have executed exactly that. We highlighted what the process is to put product into the commercial market and we're right on track with our plans. And in terms of commercial selling, the way it works in our industry, Paul, is to have to use the system for a period of three months or more before they're willing to commit to a commercial contract.

We're in all these hospitals with formal contracts. The contracts say they can use the system for free under certain terms and conditions with our support. Our installation, our people, our training, etcetera. And then, at the end of that period, they'll have a choice to make to purchase the system through the way John suggested, which is either an outright purchase, a rent-to-own, or a lease, or we would pull the system out of the hospital and go elsewhere. We have selected the first eight or nine centers based on their-- our belief that they would be willing to commercially enter a contract with us to produce revenues.

So, we've been transparent about that process in our communications and we have been getting great feedback on our first installations. It's an optimistic look and—but we're not going to talk about each center and when it's going to happen. We believe that next year will be our first full year of commercial revenues, and then 2021 should be a bigger year of commercial revenues, and the year after that should be bigger than that. The market is, as John said, over 4,000 locations. And we think our challenge is going to be managing demand and keeping these folks happy upon install when they buy the system, as opposed to is there any commercial interest.

So, if you think there's no commercial interest, I'd encourage you to maybe do a site visit with us at some point. Thank you.

Operator

Thank you. Our last question will come from the line of Jeffery Kaminsky with JJK. Please proceed.

Jeffery Kaminsky

Thanks, guys, for taking the question at the end of your great call. At the beginning of the call presentation, you mentioned something about some clinical trials, and then in answering one of the questions not that long ago, you also referred to some clinical trials. But could you help me understand your-- I know you have or you've mentioned that you have evaluation systems for your EP and Mayo, etcetera, etcetera. Are the clinical trials being held at these centers, so as these new hospitals are starting to use the device, they are also collecting the data?

And if that is the case or whatever is the case, when do you expect that the data from these clinical trials will be available to help market and sell these devices? Obviously, the data is going to be critical moving forward.

Ken Londoner

Thank you for the question. We stated in our November shareholder letter that we were going to start our first trial-- our first clinical trial at TCAI, which we put a link in our shareholder letter. If you go to that letter on our website and you click on the link, it'll send you to the USFDA database called

clinicaltrials.gov and you'll be able to see the protocol that we've been using to collect human data. So, we started that trial in early November. Our goal was to collect as much data as possible by the Thanksgiving Holiday so we could-- and we worked with a contract research organization.

So, this was a randomized blinded human trial at TCAI in one center, and the protocol was developed in conjunction with our scientific advisors and our goal was to collect the data and submit a manuscript to the heart rhythm society. We had a deadline of December 9th, so we made the deadline. We cannot talk about anything else related to that. The data will be available for public review around the heart rhythm society convention, which if the data is good, it will help our commercialization efforts.

Now, we're going to continue to do clinical work going into 2020. So, we're going to build upon our experience that we had over the last month at other leading centers that we're going into. So, instead of a single center trial randomized blinded with samples, we're planning to do multi-center trials with market leaders around a protocol that we will also put up on clinicaltrials.gov so you can see the end points. And this is all the way medical devices get marketed today.

I would say in our industry, electrophysiology, we're taking a very ambitious approach. A lot of the bigger companies, they're doing trials but they're doing small trials relative to the size of their organizations, where we're doing more trials at about the same size as the J&J website and we're a very small company. So, we know that data is going to drive adoption beyond what it already is today, and you know, you'll just have to stay tuned for the second quarter to see what the results are all about.

Jeffery Kamisky

Terrific. Thanks for the answer.

Ken Londoner


You're welcome. Well, thank you, everybody. We appreciate your interest and look forward to seeing some of you in January down at the AF Symposium in Washington, D.C. and we appreciate your support.

Operator

Thank you. This concludes the teleconference. You may disconnect your lines at this time and thank you for your participation.



+1 (203) 409-5444
info@biosigtech.com

 54 Wilton Road, 2nd Floor
Westport, CT 06880

www.biosig.com