BioSig Technologies, Inc.

2019 Annual Report to Stockholders

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2019

Commission File Number 001-38659

BIOSIG TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-4333375**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

54 Wilton Road, 2nd Floor **Westport, CT**	**06880**	**(203) 409-5444**
(Address of principal executive office)	(Zip Code)	(Registrant's telephone number, Including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	BSGM	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act.
Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b–2 of the Exchange Act.

(Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 30, 2019, based on the price at which the common stock was last sold on such date, is $146,426,083. For purposes of this computation, all officers, directors, and 5 percent beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed an admission that such directors, officers, or 5 percent beneficial owners are, in fact, affiliates of the registrant.

As of March 13, 2020, there were 25,965,418 shares of the registrant's common stock outstanding.

Documents Incorporated by Reference:

The registrant incorporates by reference in Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K portions of its Definitive Proxy Statement for the 2020 Annual Meeting of Stockholders, which shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year.

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PART I

Note on Forward-Looking Statements

This Annual Report on Form 10-K (including the section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations) contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Annual Report on Form 10-K. Additionally, statements concerning future matters are forward-looking statements.

Although forward-looking statements in this Annual Report on Form 10-K reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading "Risk Factors" below, as well as those discussed elsewhere in this Annual Report on Form 10-K. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. We file reports with the Securities and Exchange Commission ("SEC"). The SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Annual Report on Form 10-K. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Annual Report on Form 10-K, which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

Unless the context indicates otherwise, references in this Annual Report to "BioSig," the "Company," "we," "our" and "us" mean BioSig Technologies, Inc., and its predecessor entities.

The Company effected a 1-for-2.5 reverse stock split on September 10, 2018. All share and per share information in this Annual Report on Form 10-K has been retroactively adjusted to reflect this reverse stock split.

ITEM 1 – BUSINESS

Corporate Structure

We were formed as BioSig Technologies, Inc., a Nevada corporation, in February 2009 and in April 2011 we merged with our wholly-owned subsidiary, BioSig Technologies, Inc., a Delaware corporation, with the Delaware corporation continuing as the surviving entity.

On November 7, 2018, we formed NeuroClear Technologies, Inc. ("NeuroClear"), a Delaware corporation and majority-owned subsidiary of BioSig Technologies, Inc., for the purpose of pursuing additional applications of the PURE (Precise Uninterrupted Real-time evaluation of Electrograms) EP™ signal processing technology outside of the field of electrophysiology. We own 87.8% of NeuroClear's outstanding shares of common stock as of March 13, 2020. NeuroClear's Business Overview can be found on pages 13-15.

Business Overview

We are a commercial stage medical device company that is commercializing a proprietary biomedical signal processing technology platform to extract information from physiologic signals. Our initial emphasis is on providing intracardiac signal information to electrophysiologists during electrophysiology ("EP") studies and cardiac catheter ablation procedures for atrial fibrillation ("AF") and ventricular tachycardia ("VT"). Cardiac catheter ablation is a procedure that involves delivery of energy through the tip of a catheter that scars or destroys heart tissue in order to correct heart rhythm disturbances. In August 2018, we received 510(k) clearance from the U.S. Food and Drug Administration (the "FDA") to market our PURE (Precise Uninterrupted Real-time evaluation of Electrograms) EP System.

The PURE EP™ System is a proprietary signal acquisition and processing technology. The device is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording and storing of electrocardiographic and intracardiac signals for patients undergoing EP procedures in an EP laboratory under the supervision of licensed healthcare practitioners who are responsible for interpreting the data. The device aims to minimize noise and artifacts from cardiac recordings and acquire high-fidelity cardiac signals. Improving fidelity of acquired cardiac signals may potentially increase the diagnostic value of these signals, thereby possibly improving accuracy and efficiency of the EP studies and related procedures.

Our initial focus is on improving intracardiac signal acquisition and enhancing diagnostic information for catheter ablation procedures for complex and potentially life-threatening arrhythmias like AF, the most common cardiac arrhythmia, and VT, an arrhythmia evidenced by a fast heart rhythm originating from the lower chambers of the heart.

We believe that the PURE EP System and its advanced signal processing tools may contribute to improvements in patient outcomes in connection with catheter ablation due to the following advantages over the EP recording systems currently available on the market:

- acquisition of raw cardiac signals enabled by proprietary system architecture;
- preserved signal fidelity;
- user interface optimized for enhanced visualization; and
- very low noise, maximum frequency bandwidth and wide dynamic range

We believe that these features may allow physicians to better determine precise ablation targets, strategy and end point of procedures with the objective of reducing the need for multiple procedures. The PURE EP System is intended to operate in conjunction with the existing EP lab equipment.

To date, we have conducted a total of twenty-four pre-clinical studies with the PURE EP System, twenty-one of which were conducted at Mayo Clinic in Rochester, Minnesota. We also conducted a pre-clinical study at the Mount Sinai Hospital in New York, NY with an emphasis on the VT model; and two pre-clinical studies at the University of Pennsylvania in preparation for clinical studies to be conducted there. We intend to continue to conduct additional clinical external evaluation at a select number of centers. We also intend to continue additional research studies with our technology at Mayo Clinic.

Leading up to a new Medical Device Regulation that entered into full force in 2020, the European notified bodies were reporting delays in accepting and processing new applications throughout 2019. Given the possibility of issues or delays we may encounter with the adoption of the new process and our focus and priority on commercialization activities in the U.S., we plan to commence audit preparation for the International Organization for Standardization and Medical Device Single Audit Program certification around mid-2020.

We are currently in the process of obtaining and reviewing quotes from various notified bodies for the International Organization for Standardization (“ISO”) 13485:2016 certification. We expect to proceed with the audit to obtain the ISO Certification and CE Mark in 2021.

While we presently do not have any paying customers, we are making all preparations we believe are needed to commence sales of our initial product in the immediate future. We anticipate that our initial customers will be medical centers of excellence and other health care facilities that operate EP labs.

Recent Developments

Clinical Trial

In November 2019, we commenced our first clinical trial for the PURE EP System, titled "Novel Cardiac Signal Processing System for Electrophysiology Procedures (PURE EP 2.0 Study)." Texas Cardiac Arrhythmia Research Foundation (TCARF) in Austin, Texas, is the first institution to conduct patient cases under the clinical trial. On January 16, 2020, we announced that we installed our PURE EP System at Mayo Clinic's Florida campus. Mayo Clinic is the second institution to conduct patient cases under the same clinical trial. Patient enrollments began for the Mayo Clinic mid-January 2020. As of March 13, 2020, 53 patients have been enrolled in the trial.

Registered Direct Offering

On December 31, 2019, we closed a registered direct offering of an aggregate of 231,335 shares of our common stock at an offering price of $6.00 per share, pursuant to a securities purchase agreement, dated December 31, 2019, between us and certain investors. We received gross proceeds of approximately $1.39 million. The net proceeds to us from the transaction, after paying estimated offering expenses, was approximately $1.38 million.

AI-Focused Consulting Agreement

On November 29, 2019 we entered into a consulting agreement with Reified Capital, LLC, a provider of advanced artificial intelligence-focused technical advisory services to the private sector, pursuant to which the parties will collaborate on the development of artificial intelligence solutions in healthcare. The initial focus of this new collaboration is centered on developing machine learning and AI-powered solutions for the PURE EP System.

Mayo Foundation License Agreements

On November 20, 2019, we entered into a patent and know-how license agreement (the "EP Software Agreement") with Mayo Foundation for Medical Education and Research ("Mayo"). The EP Software Agreement grants to us an exclusive worldwide license, with the right to sublicense, within the field of EP software and under certain patent rights as described in the EP Software Agreement (the "Patent Rights"), to make, have made, use, offer for sale, sell and import licensed products and a non-exclusive license to us to use the research and development information, materials, technical data, unpatented inventions, trade secrets, know-how and supportive information of Mayo to develop, make, have made, use, offer for sale, sell, and import licensed products. In connection with the EP Software Agreement, we issued to Mayo an eight-year warrant to purchase 284,455 shares of our common stock at an exercise price of $6.16. This warrant is immediately exercisable and may be exercised on a cashless basis if there is no effective registration statement registering or a current prospectus available for the resale of the shares underlying the warrant. We paid Mayo an upfront consideration of $25,000 and agreed to make earned royalty payments and milestone payments to Mayo pursuant to the EP Software Agreement.

On November 20, 2019, we entered into an amended and restated patent and know-how license agreement (the "Tools Agreement") with Mayo. The Tools Agreement contains terms of license grant substantially identical to the EP Software Agreement, although it is for different patent rights and covers the field of EP systems. In connection with the Tools Agreement, we issued to Mayo an eight-year warrant to purchase 284,455 shares of our common stock at an exercise price of $6.16. This warrant is immediately exercisable and may be exercised on a cashless basis if there is no effective registration statement registering or a current prospectus available for the resale of the shares underlying the warrant. We paid Mayo an upfront consideration of $100,000 and agreed to make earned royalty payments and milestone payments to Mayo pursuant to the Tools Agreement.

On November 20, 2019, our majority-owned subsidiary, NeuroClear Technologies, Inc. ("NeuroClear"), entered into a patent and know-how license agreement (the "NeuroClear Agreement") with Mayo. The NeuroClear Agreement contains terms of license grant substantially identical to the EP Software Agreement and the Tools Agreement, although it relates to different patent rights and covers the field of stimulation and electroporation for hypotension/syncope management, renal and non-renal denervation for hypertension treatment, and for use in treatment of arrhythmias in the autonomic nervous system.

In connection with the NeuroClear Agreement, NeuroClear issued to Mayo an eight-year warrant to purchase 473,772 shares of NeuroClear's common stock at an exercise price of $5.00 per share. This warrant is immediately exercisable and may be exercised on a cashless basis if there is no effective registration statement registering or a current prospectus available for the resale of the shares underlying the warrant. NeuroClear paid Mayo an upfront consideration of $50,000 and agreed to make earned royalty payments and milestone payments to Mayo pursuant to the NeuroClear Agreement.

NeuroClear Financings

NeuroClear was formed in November 2018 initially as our wholly-owned subsidiary for the purpose to pursue additional applications of the PURE EP signal processing technology outside of EP. In August and September of 2019, NeuroClear sold an aggregate of 739,000 shares of its common stock at the purchase price of $5.00 per share, in two private placement transactions, pursuant to securities purchase agreements with certain accredited investors, to fund initial operations. NeuroClear received an aggregate purchase price of $3,695,000 from the two private placements. In subsequent private placements closed from October 21, 2019, through December 19, 2019, NeuroClear sold an aggregate of 157,690 shares of NeuroClear's common stock at $8.35 per share, for an aggregate consideration of $1,316,664, pursuant to a securities purchase agreement with certain accredited investors.

We are party to each of the purchase agreement between NeuroClear and the private placement investors with respect to a provision in each securities purchase agreement which provides that in the event that (i) NeuroClear common stock is not listed on a national securities exchange by October 31, 2020, or (ii) a change of control (as defined in each securities purchase agreement) of NeuroClear occurs, whichever is earlier, at the option of the holder of NeuroClear common stock, each share of NeuroClear common stock may be exchanged into 0.9 of a share of our common stock if the NeuroClear common stock subject to the share exchange was purchased in the August or September 2019 private placements, or 1.1 shares of our common stock if the NeuroClear common stock subject to the share exchange was purchased in the October 2019 private placement.

As of December 31, 2019, we had a majority interest in NeuroClear of 87.8%.

Underwritten Public Offering

On February 25, 2020, we closed a "best efforts" underwritten offering of 2,500,000 shares of our common stock at a price to the public of $4.00 per share. Laidlaw & Company (UK) Ltd. acted as sole book-running manager for the offering.

Our Industry

Pharmacological, or medicine-based, therapies have traditionally been used as initial treatments for cardiac arrhythmias, but they often fail to adequately control the arrhythmia and may have significant side effects. Catheter ablation is now often recommended for an arrhythmia that medicine cannot control. Catheter ablation involves advancing several flexible catheters into the patient's blood vessels, usually either in the femoral vein, internal jugular vein or subclavian vein. The catheters are then advanced towards the heart. Electrical impulses are then used to induce the arrhythmia and local heating or freezing is used to ablate (destroy) the abnormal tissue that is causing it. Catheter ablation for most of arrhythmias has a high success rate. For patients with complex arrhythmias like AF and VT, it is often necessary to perform multiple procedures to achieve success.

Catheter ablation is usually performed by an electrophysiologist (a specially trained cardiologist) in a specialized room in an EP lab. It is estimated that there are about 3,425 EP rooms in the United States and 3,915 EP rooms outside the United States, each typically with an EP recording system costing an average of $160,000. We believe that the current value of the EP recording device market in the U.S. is approximately $548 million, based upon the number of EP labs in U.S. and the average cost of the recording system in each lab

According to the *2018 HRI Global Opportunities in Medical Devices & Diagnostics* report, analysts forecast the global market for EP devices will grow at a 10.4 percent compound annual growth rate, from $4.537 billion in 2017 to $7.445 billion in 2022. In addition, global ablation procedure numbers are predicted to grow from 973,220 in 2017 to 1,455,000 per year in 2022; within this category, complex ablations (AF and VT) to increase 13.5 percent annually from 440,629 in 2017 to 830,390 in 2022.

Catheter Ablation of AF and VT

We believe that the clearer recordings and the very small amplitude of intracardiac signals--high frequency, small amplitude components in midst of large physiologic signals; signals important to characterize critical substrate, such as fractionated atrial and ventricular electrograms; and high-frequency, low-amplitude signals such as the Purkinje potentials—provided by the PURE EP System may improve outcomes during EP studies and ablation procedures for a variety of arrhythmias.

For patients who are candidates for ablation, an EP study is necessary to define the targeted sites for the ablation procedure. Two common, yet complex, conditions for which ablation procedures are performed are AF and VT. Most cardiac arrhythmias are well understood, and ablation simply requires destroying a small area of heart tissue possessing electrical abnormality. In contrast, complex arrhythmias, such as AF and VT, have complex pathophysiology and, because knowledge of their origins and mechanisms are incomplete, ablation treatments for these arrhythmias are largely empirical. Furthermore, the length of these procedures, which typically last from 3-6 hours, exposes the physician and staff to extensive radiation, requiring them to wear heavy lead vests. Consequently, ablating AF and VT has been regarded as being extremely difficult. Therefore, access to these procedures has traditionally been limited to being performed by only especially well-trained cardiologists and high-volume centers.

With advancements in new technologies and techniques, there has been a substantial increase in catheter ablation procedures in the U.S. which has been accompanied by a nationwide increase in complications related to the procedures – low-volume centers had significantly higher complication rates than high-volume hospitals and the changes happened as the complexity of the ablation procedure mix was increasing, with more procedures done for AF and VT ablations (*Mohammadreza S, et al "Catheter ablation of cardiac arrhythmias: utilization and in-hospital complications 2000 to 2013)*. We believe that in the near future, the PURE EP System may have a meaningful impact on assisting ablation strategies for these conditions as it was developed to reveal the very small amplitude of intracardiac signals important for identifying ablation targets.

AF is the most common heart rhythm disorder in the world and increases the risk for stroke 5-fold. In 2010, there was a reported global prevalence of 33.5 million (20.9 million men and 12.6 million women). In 2017, the Centers for Disease Control and Prevention stated that there are an estimated 2.7-6.1 million Americans suffering with AF, more than 750,000 patients hospitalized annually for the condition, and AF contributes to an estimated 130,000 deaths each year. Despite the fact that physicians have been performing radiofrequency ablations since the 1990s, catheter-based treatment is offered to less than 3% of the AF patient population in the U.S. and Europe. An increasing proportion of diagnosed AF cases are now being treated via ablation, as both physician confidence and the devices used in these procedures improve. A growing amount of positive clinical data has demonstrated the efficacy of AF ablation when compared to the traditional first-line treatment of anti-arrhythmic drugs. The American College of Cardiology Foundation/American Heart Association Task Force reported that catheter-directed ablation of AF represents a substantial achievement that promises better therapy for a large number of patients presently resistant to pharmacological or electrical conversion to sinus rhythm (ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation). Additionally, the 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation findings show new evidence, including data on improved mortality rate, has been published for AF catheter ablation compared with medical therapy in patients with heart failure (HF). However, rates of success and complications may vary for ablation, sometimes considerably.

According to the Heart Rhythm Society, VT is the most dangerous arrhythmia since it may result in ventricular fibrillation, a rapid chaotic heartbeat in the lower chambers of the heart which can often result in sudden cardiac death. Because the fibrillating muscle cannot contract and pump blood to the brain and vital organs, ventricular fibrillation is the number one cause of sudden cardiac death which accounts for approximately 325,000 deaths in the U.S. each year. VT is typically treated with implantable cardioverter defibrillators, or ICDs, or a combination of ablation along with an ICD. Catheter ablation of VT has historically been used primarily for drug refractory ventricular arrhythmias in patients with ICDs. However, advances in electro-anatomical mapping systems, techniques to identify ablation sites during sinus rhythm, and the use of hemodynamic support devices has broadened the applicability of catheter ablation for ventricular arrhythmias. When performed in centers with high procedural volumes, the rates of complications remain relatively low. However, success rates have historically been quite variable and highly dependent on the specific ablation approach adopted. Additionally, catheter ablation has evolved into an important treatment option for patients with scar-related heart disease presenting with VT or VF. An individual's success rate of catheter ablation for VT is determined by the amount of infarct-related scar burden, represented as low-voltage signals; the experience of the team and center will influence outcomes. In patients with recurrent VT or VF despite complete revascularization and optimal medical treatment, radiofrequency catheter ablation should be considered. Recurrent VF episodes may be triggered by PVCs arising from partially injured Purkinje fibers or ventricular myocardium injured by ischemia and/or reperfusion. Precise catheter mapping and successful ablation of triggers for VT or VF, or myocardial substrate sustaining VT or VF, is a complex and demanding procedure according to the *2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC).*

We believe that ablation will continue to become a preferred treatment for AF and VT. This increase in demand for ablation procedures has also increased the demand for technological advances in medical devices essential to ablation procedures. Improvements are needed to help reduce the periprocedural complications and decrease costly lengths of stay in patients undergoing catheter ablation procedures; adding focus to improving outcomes at low volume hospitals and among patients at high risk due to comorbidities.

EP Lab Environment and EP Recording Systems

The EP lab environment and recording systems create significant amounts of noise and artifacts during EP procedures. Current surface and intracardiac recording systems typically consist of large workstations interconnected by a complex set of cables that contribute to significant amounts of noise during signal acquisition. Additional noise and artifacts generated from the EP lab equipment further hamper recordings of small electrophysiological potentials. Preserving spaciotemporal (space and time) characteristics of the signal in a very challenging EP recording environment is a difficult task. To remove noise and artifacts, recorders that are currently on the market offer a family of low pass, high pass and notch filters, but these filters alter signal information context.

The shape and amplitude of electrocardiograms, unipolar and bipolar electrograms, and, consequently, reconstructed endocardial and epicardial maps, are influenced not only by electrophysiological and structural characteristics of the myocardial tissue involved, but with characteristics of the recording system. Amplitude and morphology of electrocardiogram and intracardiac signals are significantly affected by filters used to remove noise. Because of the number of amplitude and interval measurements made during an EP study, it is imperative that the recording system faithfully acquires surface electrocardiogram and intracardiac electrograms. We believe that the recording systems that are currently available on the market are ineffective in preserving the optimal amount of original information contained in the cardiac signals.

In addition, the EP lab consists of sophisticated equipment that requires an electrophysiologist to mentally integrate information from a number of sources during procedures. There are numerous monitors in an EP lab that provide and display this variety of information. An electrophysiologist needs to evaluate the acquired cardiac signals and the patient's responses to any induced arrhythmias during the procedure. However, it can be difficult for an electrophysiologist to synthesize the disparate information produced by the numerous monitors in the lab and calculate the real-time, three-dimensional orientation of the anatomy and the location of the recording and ablation catheters. As the number of EP procedures increase, a variety of diagnostic and therapeutic ablation catheters are becoming more widely available and new highly specialized catheters are being developed. In addition, remote robotic and magnetic navigation systems are being developed to address limitations of dexterity in controlling the catheter tip, especially during complex arrhythmia ablation procedures. We believe that, considering the improvements being made with respect to other equipment used in the EP lab and the continual increase of ablation procedures, the EP recorders currently available on the market are not sufficiently advanced with respect to the quality of their recordings to deliver adequate results. We believe that the PURE EP System will be able to deliver superior quality of recordings that will allow it to successfully integrate with the other advanced equipment found in the EP lab.

The requirement for optimal signal integrity is amplified during ablation treatments of AF and VT. Presently, one of the main objectives of the AF ablation procedure is to precisely identify, ablate and eliminate pulmonary vein potentials and one of the main objectives of the VT procedure is to map the arrhythmia substrate and precisely identify, ablate and eliminate small abnormal potentials. The information provided by recorders is essential for an electrophysiologist to determine ablation strategy during termination of both pulmonary vein potentials and VT. Therefore, it is important that the recording system's noise removal technique does not alter the appearance and fidelity of these potentials. As a result, it is necessary that any new signal processing technology preserves signal fidelity as much as possible during EP recordings; otherwise, the signals that are needed to guide the ablation procedures will be difficult to distinguish due to noise interference.

Our Product

We intend to bring to the EP market our PURE EP System, which received FDA 510(k) market clearance in August 2018. The PURE EP System is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording and storing of electrocardiographic and intracardiac signals for patients undergoing EP procedures in an EP laboratory under the supervision of licensed healthcare practitioners who are responsible for interpreting the data.

Our initial focus is on improving intracardiac signal acquisition and enhancing diagnostic information for catheter ablation procedures for complex and potentially life-threatening arrhythmias like AF, the most common cardiac arrhythmia, and VT, an arrhythmia evidenced by a fast heart rhythm originating from the lower chambers of the heart.

We believe that the PURE EP System and its advanced signal processing tools may contribute to improvements in patient outcomes due to the following advantages over the EP recording systems currently available on the market: acquisition of raw cardiac signals enabled by proprietary system architecture; preserved signal fidelity; user interface optimized for enhance visualization; and very low noise, maximum frequency bandwidth and wide dynamic range.

We believe that these features may allow physicians to better determine precise ablation targets, strategy and end point of procedures with the objective of reducing the need for multiple procedures. PURE EP System is intended to operate in conjunction with the existing EP lab equipment.

Initial Analysis

According to S. J. Asirvatham, MD, et. al. ("Signals and Signal Processing for the Electrophysiologist," *Circ Arrhythm Electrophysiol*. (2011) 4:965-973), recording environments in a typical electrophysiology laboratory presents challenging situations. S. J. Asirvatham, MD, et. al., state, "Successful mapping and ablation in the electrophysiology laboratory is critically dependent on acquiring multiple, low-amplitude, intracardiac signals in the presence of numerous sources of electric noise and interference and displaying these signals in an uncomplicated and clinically relevant fashion, with minimal artifacts. This represents a significant engineering challenge and, in real-life electrophysiology laboratory, is not always successful."

To determine and validate the state of present electrophysiology recording technology in the field, we completed a detailed analysis of the effect of filters used by existing EP recorders to reduce noise on spaciotemporal characteristics of electrocardiograms and intracardiac electrograms. We evaluated the signal quality (amplitude, morphology and duration) of the different recorders, along with the ability of the recorders to reduce noise level and remove baseline wander, which are the cardiac signals that have shifted from the isoelectric line (the base line of the signal tracing). The electrocardiogram and intracardiac signals subjected to the PURE EP System's signal processing showed less baseline wander, noise and artifacts compared to the conventional electrophysiology recorders. Further, spaciotemporal characteristics of signals were greatly distorted by the conventional electrophysiology system, particularly when a notch filter was used, as compared to the recording of the same spaciotemporal characteristics by the PURE EP System.

Proof of Concept Testing

In the second and third quarters of 2013, we performed and finalized testing of our proof of concept unit by initially using an electrocardiogram/intracardiac simulator at our lab, and subsequently by obtaining pre-clinical recordings from the lab at the University of California at Los Angeles. We believe that our proof of concept unit performed well as compared to GE's CardioLab recording system, in that the electrocardiogram and intracardiac signals displayed on our proof of concept unit showed less baseline wander, noise and artifacts compared to signals displayed on GE's CardioLab recording system. Subsequently, we determined the final design of the PURE EP System prototype to use for end-user preference studies, additional pre-clinical studies and research studies.

Prototype Testing

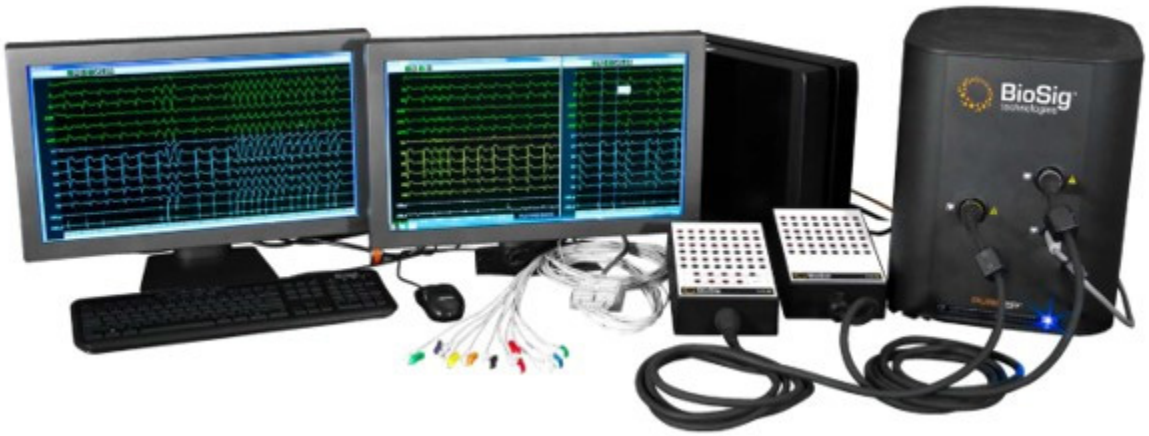
After conducting research of peer-reviewed EP publications (see *Initial Analysis* in Our Products section above), we contacted Samuel J. Asirvatham. M.D. (who we believed to be an expert in the field of signal-based catheter ablation), at Mayo Clinic in Rochester, Minnesota. Since the end of 2014, we have collaborated with Dr. Asirvatham and other physicians affiliated with Mayo Clinic in Rochester, Minnesota and Jacksonville, Florida. We have performed pre-clinical studies at Mayo Clinic since 2015 to validate technology within the PURE EP System prototype. These studies have been designed to determine clinical effectiveness for features within the PURE EP System. Since March 2016, we have published nine manuscripts in collaboration with the physicians from Mayo Clinic evidencing our pre-clinical findings. To date, we have conducted a total of twenty-four pre-clinical studies with the PURE EP System, twenty-one of which were conducted at Mayo Clinic in Rochester, Minnesota. We also conducted a pre-clinical study at the Mount Sinai Hospital in New York, NY with emphasis on the VT model; and two pre-clinical studies at the University of Pennsylvania in preparation for clinical studies to be conducted there.

Clinical Evaluations

On February 18 and February 19, 2019, we conducted the first clinical cases with our PURE EP System. The observational patient cases were performed by Andrea Natale, M.D., F.A.C.C., F.H.R.S., F.E.S.C., Executive Medical Director, Texas Cardiac Arrhythmia Institute at St. David's Medical Center in Austin, TX. On April 16, 2019, we announced the completion of our second set of observational patient cases which were performed at Prisma Health at Greenville Health System in South Carolina which were performed by Andrew Brenyo, MD, FHRS. Dr. Brenyo used the PURE EP System during procedures on patients with ischemic ventricular tachycardias, AF, PVC and atypical flutters. On May 6, 2019, we announced the completion of our third set of observational patient cases at Indiana University under the leadership of Prof. John M. Miller, M.D. and Dr. Mithilesh K. Das, MBBS. Drs. Miller and Das used the PURE EP System during procedures on patients with atypical flutter, atrioventricular nodal reentry tachycardia (AVNRT), AF, SVT, PVC and a rare case of dual septal pathway. And, in August 2019, observational patient cases at Santa Barbara Cottage Hospital in California were performed by Brett Andrew Gidney, M.D. Initial results of the observational patient cases showed improved signal detection and fidelity compared to the data acquired using the existing recording devices in the EP lab.

In November 2019, we commenced our first clinical trial for the PURE EP System, titled, "Novel Cardiac Signal Processing System for Electrophysiology Procedures (PURE EP 2.0 Study)." Texas Cardiac Arrhythmia Research Foundation (TCARF) in Austin, Texas, is the first institution to conduct patient cases under the clinical trial. On January 16, 2020, we announced that we installed our PURE EP System at Mayo Clinic's Florida campus. Mayo Clinic is the second institution to conduct patient cases under the same clinical trial. Patient enrollments began for the Mayo Clinic mid-January 2020. As of March 13, 2020 there have been fifty-three patients enrolled in the clinical trial; and over one hundred patient cases in total have been completed.

The current PURE EP System



Sales, Marketing and Commercialization

We have begun implementing a market development program and plan to commercially launch our PURE EP System in 2020. Our goal is to install PURE EP Systems at several medical centers of excellence (COEs) throughout the U.S. during the first half of 2020 - whereby these systems would be installed on a trial basis for system evaluations, data collection for posters and presentations at cardiology conferences, submissions to peer-reviewed journals, and for potential demonstrations to other physicians to observe the technology.

The physicians who have conducted or observed cases performed with our technology would lead to a potential acquisition of the system - sales of our systems would potentially consist of hardware, software, and a recurring revenue feature through a technical service contract, including software upgrades, and down the line, include the AI aspect.

Our commercial and clinical activities will be led by Vice President of Sales, John Kowalski who spent 24 years at Johnson & Johnson's Biosense Webster division, a global leader and pioneering innovator in the electrophysiology market; Julie Stephenson, MBA, Vice President of Clinical Affairs; and Olivier Chaudoir, Senior Director of Marketing. We believe we will have ample inventory to meet planned commercial placement requirements in 2020, and, in 2021 we believe we will increase our domestic sales efforts and also stage our European commercialization efforts.

We have developed a marketing strategy to introduce and support the PURE EP System. The strategy includes our presence at leading industry events and scientific sessions, both nationally and internationally, for the purposes of physician engagement, PURE EP System's demonstrations and select presentations of advanced R&D product pipeline.

Commercial activity is intended to be strongly supported by growing clinical validation and educational and training programs, including establishing training hubs at our early hospital partners' facilities. With the increased commercialization activity planned, we also plan to continue to grow our clinical account management team to support the initial use of the system and assist with ongoing product training and education, and plan to develop an agile regional sales team to escalate our commercialization efforts.

Technology and Development Plan

Our technology team consists of nine engineers and consultants with expertise in digital signal processing, low power analog and digital circuit design, software development, embedded system development, electromechanical design, testing and system integration, and the regulatory requirements for medical devices. We have also entered into collaboration agreements with advisors and medical institutions in the fields of cardiology and electrophysiology, including Mayo Clinic and the Texas Cardiac Arrhythmia Institute in Austin, Texas, where clinical trials are currently underway to define the clinical effectiveness of the system. Currently, we have outsourced manufacturing of the complete PURE EP System to Minnetronix Medical. In addition, we plan to identify a second medical device manufacturer.

We intend to continue additional research studies with our technology at Mayo Clinic. On November 20, 2019, we entered into licensing agreements with Mayo Clinic under newly reached terms to establish a new product pipeline to complement the PURE EP System and develop solutions for novel ways to treat autonomic nervous system disease. The new research and development pipeline contemplated pursuant to these agreements includes hardware, software, and algorithmic solutions to be integrated into the PURE EP platform technology.

On November 29, 2019 we entered into a consulting agreement with Reified, LLC, a provider of advanced artificial intelligence-focused technical advisory services to the private sector, pursuant to which the parties will collaborate on development of artificial intelligence solutions in healthcare. The initial focus of this new collaboration is centered on developing machine learning and AI-powered solutions for the PURE EP System.

We are currently in the process of obtaining and reviewing quotes from various notified bodies for the International Organization for Standardization ("ISO") 13485:2016 certification. We expect to proceed with the audit to obtain the ISO Certification and CE Mark in 2021.

While we presently do not have any paying customers, we are making all preparations we believe are needed to commence sales of our initial product in the immediate future. We anticipate that our initial customers will be medical centers of excellence and other health care facilities that operate electrophysiology labs.

Competition

The EP market is characterized by intense competition and rapid technological advances. There are currently four large companies that share the majority of the EP recording market share. They produce the following electrophysiology recording systems, with an average selling price of approximately $160,000 (source: DRG Medtech 360 Millennium report on EP Devices, issued in June 2019):

- GE Healthcare's family of CardioLab Recording Systems were initially developed in the early 1990s by Prucka Engineering, which was acquired by General Electric Company in 1999.

- The LabSystem PRO EP Recording System was originally designed in the late 1980s by C.R. Bard. C.R. Bard's electrophysiology business was acquired by Boston Scientific Corporation in 2013.

- Siemens AG developed the Axiom Sensis XP in 2002.

- St. Jude Medical, Inc.'s EP-WorkMate Recording System was acquired from EP MedSystems, Inc. in 2008, which had received clearance for the product from the FDA in 2003. In January 2017, Abbott Laboratories acquired St Jude Medical, Inc.

Based upon our analysis of data taken from patent applications filed with the U.S. Patent and Trademark Office ("USPTO") and 510(k) approval applications filed with the FDA, and various publications, we believe that the above recording systems are built on relatively old technologies and all use similar approach in applying hardware and digital filters to remove noise and artifacts. We reasonably believe that such an approach sacrifices cardiac signal fidelity, and in the case of ablation, the filters have a direct impact on the ablation strategy of an electrophysiologist. The method to remove noise and artifacts used by the old recorders could be a contributing factor to the multiple (or repeated) ablation procedures that are frequently required in order to completely cure patients from AF and VT. We intend to market the PURE EP System as an additional information system for the EP lab. We are not currently aware of any other companies that are developing a new ECG and IC recording technology for electrophysiology laboratories.

Suppliers

The PURE EP System contains proprietary hardware and software modules that are assembled into the system. Hardware boards contain components that are available from different distributors. The parts used to manufacture analog and digital boards are readily available from a number of distributors or manufacturers. Presently, Minnetronix Medical in St Paul, Minnesota is manufacturing the complete PURE EP System, and we are evaluating a second medical device manufacturer.

Research and Development Expenses

Research and development expenses for the fiscal years ended December 31, 2019, 2018 were $9,738,819 and $4,368,784, respectively.

NeuroClear Business Overview

NeuroClear is an early stage medical device company that is developing an advanced biomedical signal recording and processing technology platform for high-speed electroneurogram (ENG) recordings based on the core competencies of the PURE EP™ signal processing technology, such as broad dynamic range of recorded signals and low signal-to-noise ratio. Through NeuroClear, we aim to address unmet clinical needs in the global and growing sector of neurological disorders through recordings and analysis of action potentials, the impulses along the membrane of a muscle cell or a nerve cell. These impulses carry valuable clinical information but may be difficult to detect through conventional recording platforms NeuroClear aims to extend the core competencies of BioSig's proprietary technology, which has been validated in pre-clinical studies, which have been conducted by Mayo Clinic, to address what we believe as the two main challenges of bioelectronic medicine devices: achieving accurate and targeted stimulation of specific nerves in a nerve bundle and implementing an effective feedback loop that can self-adjust for the optimal amount and timing of stimulation. We believe that advancements in overcoming these challenges will improve the safety and efficacy of current treatments and contribute to the developments of new therapy lines.

NeuroClear will focus on ENG recordings – methods used to visualize directly recorded electrical activities of neurons in the central nervous system (brain, spinal cord) and/or the peripheral nervous system (nerves, ganglions). ENGs are usually obtained by placing an electrode directly in the neural tissue. ENGs consist of small, high frequency, low amplitude signals, which have been proven hard to detect with conventional signal recording systems.

We believe that the following clinical areas may benefit the most through the advancements in achieving accurate and targeted stimulation and implementation of an effective self-adjusting feedback loop:

• Non-Invasive Vagus Nerve Stimulation("nVNS"): nVNS is stimulation of the vagus nerve, which is a treatment method for treatments of cognitive disorders, AF and chronic pain.

o *Potential Application*: a digital wearable nVNS device, which has a potential to target a range of diseases such as epilepsy, chronic refractory depression, migraine, and obesity.

o We believe that nVNS treatment may also be applicable in both AF and cardiovascular disease by reducing system inflammation.

o One of the key differentiators for our potential product would be the implementation of a feedback loop through a biomedical signal-processing unit, which would self-adjust to provide an appropriate amount of stimulation.

• Deep Brain Stimulation ("DBS"): DBS is a treatment that involves implanting electrodes (leads) within certain areas of the brain to deliver electrical pulses, which has demonstrated improvements in the treatment of movement disorders, such as the Parkinson's disease, tremors and dystonia.

o *Potential Application*: a new high-speed board-based platform for improved accuracy in lead implantation. Precise positioning of the electrodes during the surgical procedure is important in the success of lead implantation, and highly accurate signal readers can aid in the prediction of the activation of axons surrounding the implanted lead.

o We believe that DBS may also be applicable to a substantial number of neurological and psychiatric disorders correlated with dysfunctional circuitry; comparable to a heart pacemaker that uses electric pulses to ultimately regulate brain activity.

o Other applications under our investigation include renal denervation, ADHD, eating disorders, Alzheimer's, addiction, epilepsy, dementia and pain management. Alzheimer's as an application for DBS is currently undergoing clinical trials at several national and international institutions that target the hippocampal outflow pathways by increasing ACh availability, influencing the limbic system, and improving lead placements.

NeuroClear may seek additional research collaborations with other academic centers active in one or more fields of clinical interests described above.

Industry and Market Overview

The global neurostimulation devices market is predicted to grow at 11.2% CAGR during the forecast period with the market size reaching $12.2 billion by 2024. Geographically, North America is the largest neurostimulation devices market, estimated to be $5 billion in 2019, as the region has a high prevalence of chronic diseases and the growing geriatric population. The neurostimulation market is primarily driven by deep brain and spinal cord stimulation. The overall neurostimulation market is expected to grow due to societal factors such as an increase in the geriatric population, as well as the associated increase in the prevalence of chronic diseases.

The segment of the neurostimulation market for central nervous system (CNS), which include nVNS and DBS, is projected to exceed $14.5 billion in 2029 from a market value of $5 billion in 2019.

Non-invasive Vagus Nerve Stimulation

We believe there is a significant opportunity for nVNS based on the potential market size for the treatments for the diseases that nVNS may be applicable. Currently, approximately 1,500 million people worldwide suffer from chronic pain while 1,100 million people worldwide suffer from migraines.

Most of the currently available VNS products have achieved limited commercial success to date. LivaNova currently sells VNS devices that operate in 3 modes, including a non-rechargeable implantable pulse generator (IPG), SenTiva, which uses a limited closed-loop technology and comes with a wrist-worn magnet and a wireless programming wand. Cerbomed has commercialized a transcutaneous auricular VNS device, NEMOS, which consists of a handheld stimulation unit and an ear electrode worn as an earphone. Cerbomed received the European clearance (CE mark) for the VNS treatment of epilepsies and depression in 2010 and for the treatment of pain in 2012. NEMOS has been commercially available in Germany and Austria since 2013 and has expanded to Great Britain, France, and Spain.

The VNS patent domain is currently dominated by U.S. companies such as Medtronic, LivaNova, and Boston Scientific. Medtronic holds certain patents in closed-loop DBS technology, Medtronic currently markets IPGs such as RestoreSensor SureScan MRI, which is indicted for spinal cord stimulation as an aid in the management of chronic, intractable pain of the trunk and/or limbs and which automatically adjusts stimulation based on the patient's needs and preferences in different body positions, and Activa PC, which is a deep brain stimulator, for investigational loop.

We believe that digital health wearable markets present potential opportunities for our technology. We plan to develop technology that can provide a signaling feedback loop designed to deliver appropriate stimulation to the vagus nerve through audio and to seek licensing opportunities with consumer electronic market players.

Deep Brain Stimulation:

Deep brain stimulator market is one of the fastest growing sectors in the neurostimulation market worldwide, growing at 10.7% annually and expected to reach $1.2 billion in worldwide market size by 2022. Globally, 322 million people suffer from depression while 50 million people suffer from epilepsy. Parkinson's disease and essential tremor are FDA-approved indications for DBS, and the deep brain stimulator market is largely dominated by Medtronic, Abbott, and Boston Scientific. These companies have been working on innovations in their electrodes to avoid stimulation of adjacent structures (electric field shaping) which are the root cause of unwanted side effects of DBS. The industry is working on decreasing the size of the implant of the DBS device, which may lead to a skull-mounted implant. Medtronic's Activa systems consist of dual-channel or single channel IPGs. Abbott sells two devices known as the Infinity DBS IPG and Brio Rechargeable IPG. The Infinity DBS IPG is designated to manage movement disorders including Parkinson's disease, essential tremor, and dystonia. It utilizes the Bluetooth technology to communicate with a controller and can receive updates through an application. The system allows for currents to be steered towards target areas while avoiding peripheral stimulation. The Brio Rechargeable IPG delivers constant currents to maintain the desired stimulation level. It has shown clinical efficacy in Parkinson's disease and dystonia. Boston Scientific offers the Vercise directional lead in unison with their Neural Navigator systems ranging from 8 to 16 electrode leads and a directional system.

According to the National Institute of Health, future technical innovation in deep brain stimulators will focus on improving the practicability the device, including extension of battery life, reduced size of the devices and development of a device for delivering more tailored and adaptive stimulation and the integration of wireless technology. Clinically, the main challenge will be meeting the needs of an ageing population worldwide and expanding indications for DBS to circuitopathies other than Parkinson's disease, including depression and Alzheimer disease. Even within established indications such as Parkinson's disease, key questions remain unanswered because biomarkers that predict clinical responses and aid in patient selection and stimulation parameter settings are still largely lacking.

We believe that our technology may help advance clinical response to DBS due to more precise stimulation and improve overall safety of the DBS procedures.

Overview of NeuroClear Business Strategy

NeuroClear's business strategy is to utilize our core signal processing technology to develop superior ENG recording and processing systems and includes the following:

• Develop an ENG signal processing platform to be used in product candidates which qualify for a nerve mapping and stimulation treatments including, but not limited to, deep brain stimulation and vagus nerve stimulation.

• Pursue licensing opportunities and partnerships to leverage our expertise in high-fidelity signal processing for feedback loop systems for development of products for commercial success.

Intellectual Property

Patents

Our success depends in large part on our ability to establish and maintain the proprietary nature of our technology. We filed a patent application with the USPTO in December 2013, "Systems and Methods for the Evaluation of Electrophysiology Systems." In December 2014, we filed this patent application under the Patent Cooperation Treaty (PCT) with the U.S. Receiving Office. This patent application describes a system that can show comparative output of any two cardiac signal systems—such as the PURE EP System as compared to a competitor system. We received notice of allowance on June 5, 2019 and on October 29, 2019, U.S. Patent No. 10,456,057 was issued.

In November 2017, we engaged 3LP Advisors LLC, now Sherpa Technology Group LLC as our intellectual property advisor.

We have also retained Sterne Kessler Goldstein & Fox P.L.L.C., a patent firm based in Washington DC, to help develop and execute a strategy for the development of our patent portfolio. On May 9, 2018 we filed one "omnibus" hardware and software patent application with multiple claim sets, and several multiple feature-set graphical user interface ("GUI") design patents. The omnibus patent application covers the core hardware and software technology associated with our PURE EP System, which technology includes a cardiac signal system that reads cardiac signals and filters such cardiac signals from noise such as non-cardiac signals or other body-generated artifacts. We also filed a second omnibus application in May 2019 capturing innovations in software with Samuel J. Asirvatham, M.D., Mayo Clinic's Vice-Chair of Innovation and Medical Director, Electrophysiology Laboratory, as an inventor. Mayo Clinic's interest in this jointly owned patent application is exclusively licensed to us for all applications.

Our owned patent portfolio now includes five allowed/issued patents. Thirteen additional worldwide utility patent applications are pending covering various aspects of our PURE EP™ System for recording, measuring, calculating and displaying of electrocardiograms during cardiac ablation procedures. We also have 21 allowed/issued worldwide design patents, which cover various features of our display screens and graphical user interface for enhanced visualization of biomedical signals.

BioSig and NeuroClear signed three new patent and know-how license agreements with Mayo Foundation for Medical Education and Research in December 2019. Under the terms of the newly reached agreements, BioSig exclusively licensed additional patents and applications of the Mayo Clinic related to novel ways for ablation therapy and to treat autonomic nervous system disease including hardware, software and algorithmic solutions to be integrated into the PURE EP™ platform technology. BioSig intends to take the licensed intellectual properties and products, which have been developed by Mayo Clinic over the last decade, through FDA approval, manufacturing, and commercialization. The development program will be run under the leadership of Dr. Asirvatham.

Trademarks

Our trademark for "BIOSIG TECHNOLOGIES" was registered on April 25, 2017. Our trademark for "PURE EP" was registered on January 26, 2016. Our trademark for the standard mark, "BIOSIG" was registered January 1, 2019, and our stylized/design trademark mark for the BioSig Technologies' logo was registered February 12, 2019.

On November 5, 2018, we filed a standard mark trademark application for "NEUROCLEAR", and on January 29, 2019, NeuroClear filed a stylized/design trademark application for the NeuroClear logo.

On October 4, 2019, we filed a stylized/design trademark application for "ALLIANCE FOR ADVANCING BIOELECTRONIC MEDICINE."

On October 7, 2019, we filed a standard mark trademark application for "SEE MORE, CLEARLY."

Government Regulation

The U.S. government regulates healthcare and related products through various agencies, including but not limited to the following: (i) the U.S. Food and Drug Administration (FDA), which enforces the federal Food, Drug and Cosmetic Act (FDCA) and related laws; (ii) the Centers for Medicare & Medicaid Services (CMS), which administers the Medicare and Medicaid programs; (iii) the Office of Inspector General (OIG), which enforces various laws aimed at curtailing fraudulent or abusive practices, including by way of example, the Anti-Kickback Statute, the Physician Self-Referral Law, commonly referred to as the Stark law, the Civil Monetary Penalty Law (including the beneficiary inducement prohibition) (CMP), and the laws that authorize the OIG to exclude healthcare providers and others from participating in federal healthcare programs; and (iv) the Office of Civil Rights (OCR), which administers the privacy aspects of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All of the aforementioned are agencies within the Department of Health and Human Services (HHS). Healthcare is also provided or regulated, as the case may be, by the Department of Defense through its TRICARE program, the Department of Veterans Affairs, especially through the Veterans Health Care Act of 1992, the Public Health Service within HHS under Public Health Service Act § 340B (42 U.S.C. § 256b), the Department of Justice through the Federal False Claims Act and various criminal statutes, and state governments under the Medicaid and other state sponsored or funded programs. Various states also have state laws equivalent to certain healthcare fraud and abuse laws, including but not limited to state equivalents of the Anti-Kickback Statute and the Stark law, as well as more general state laws regulating all healthcare activities and certain healthcare products, including medical devices.

In addition to being regulated by the FDA, advertising and promotion of certain types of medical devices in the United States is also regulated by the Federal Trade Commission (FTC) and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare laws and consumer protection statutes. Further, competitors can initiate litigation relating to advertising claims under the federal Lanham Act and similar state laws.

FDA Regulation

Our solutions include software and hardware which will be used for patient diagnosis and, accordingly, are subject to regulation by the FDA and other regulatory agencies. FDA regulations govern, among other things, the following activities that we perform and will continue to perform in connection with:

- Product design and development;
- Product testing;
- Product manufacturing;
- Product labeling and packaging;
- Product handling, storage, and installation;
- Pre-market clearance or approval;
- Advertising and promotion; and
- Product sales, distribution, and servicing.

FDA Pre-market Clearance and Approval Processes

The FDA classifies all medical devices into one of three classes based on the risks associated with the medical device and the controls deemed necessary to reasonably ensure the device's safety and effectiveness. Those three classes are:

- Class I devices present a low risk and are not life-sustaining or life-supporting. The majority of Class I devices are subject only to "general controls" (e.g., prohibition against adulteration and misbranding, registration and listing, good manufacturing practices, labeling, and adverse event reporting. General controls are baseline requirements that apply to all classes of medical devices.)

- Class II devices present a moderate risk and are devices for which general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness. Devices in Class II are subject to both general controls and "special controls" (e.g., special labeling, compliance with performance standards, and post market surveillance. Unless exempted, Class II devices typically require FDA clearance before marketing, through the premarket notification (510(k)) process).

- Class III devices present the highest risk. These devices generally are implantable, life-sustaining, life-supporting, or for a use that is of substantial importance in preventing impairment of human health, and/or they present a potential unreasonable risk of illness or injury. Class III devices are devices for which general controls, by themselves, are insufficient and for which there is insufficient information to determine that application of special controls would provide a reasonable assurance of safety and effectiveness. Class III devices are subject to general controls and typically require FDA approval of a premarket approval ("PMA") application before marketing.

Unless it is exempt from premarket review requirements, a medical device must receive marketing authorization from the FDA prior to being commercially marketed, distributed, or sold in interstate commerce in the United States. The most common pathways for obtaining marketing authorizations are 510(k) and PMA. With the enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA), the *de novo* pathway was made available for certain low-to-moderate risk devices that do not qualify for 510(k) clearance due to the absence of a predicate device.

510(k) Clearance Process

The 510(k) review process compares a new device to an existing legally marketed device (or, "predicate device"). "Substantial equivalence" means that the proposed new device: (i) has the same intended use as the predicate device; (ii) has the same or similar technological characteristics as the predicate device; (iii) is as safe and effective as the predicate device, as shown by the supporting information submitted within the 510(k); and (iv) does not raise different questions of safety and effectiveness than the predicate device.

To obtain 510(k) clearance, one must submit a 510(k) containing sufficient information and data to demonstrate that the proposed device is substantially equivalent to a legally marketed predicate device. This data generally includes non-clinical performance testing (e.g., software validation, bench testing electrical safety testing), but may also include clinical data. Typically, it takes approximately three-to-six months for the FDA to complete its review of a 510(k) submission; however, it can take significantly longer and not all 510(k) submissions are accepted by the FDA for review, and not all are cleared following FDA review. During its review of a 510(k), the FDA may request additional information, including clinical data, which may significantly prolong the review process. After completing its review of a 510(k), the FDA may issue an order, in the form of a letter (i) finding the proposed device to be substantially equivalent to the predicate device and stating that the device can be marketed in the U.S., or (ii) finding the proposed device not substantially equivalent to the predicate device and stating that device cannot be marketed in the U.S. We received 510(k) clearance for the PURE EP™ System on August 8, 2018.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require a pre-market approval, which requires more data and is generally a significantly longer process than the 510(k) clearance process. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, it can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or a pre-market approval is obtained.

A device that reaches market through the 510(k) process is not considered to be "approved" by the U.S. Food and Drug Administration. They are generally referred to as "cleared" or "510(k) cleared" devices. Nevertheless, it can be marketed and sold in the U.S.

The Premarket Approval Pathway

The PMA process is the most stringent type of device marketing application required by the FDA. Whether PMA is granted is based on a determination by the FDA that the PMA application contains sufficient valid scientific evidence to ensure that the device is safe and effective for its intended use(s). A PMA application generally includes extensive information about the device including the results of clinical testing conducted on the device and a detailed description of the manufacturing process.

After a PMA application is accepted for review, the FDA begins an in-depth review of the submitted information. FDA regulations provide 180 days to review the PMA application and make a determination; however, in practice, the review time is typically longer (e.g., 1-3 years). During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the data supporting the application and provide recommendations as to whether the data provide a reasonable assurance that the device is safe and effective for its intended use. In addition, the FDA generally will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the quality system regulation (QSR), which imposes comprehensive development, testing, control, documentation and other quality assurance requirements for the design and manufacturing of a medical device.

Based on its review, the FDA may (i) issue an order approving the PMA, (ii) issue a letter stating the PMA is "approvable" (e.g., minor additional information is needed), (iii) issue a letter stating the PMA is "not approvable," or (iv) issue an order denying PMA. A company may not market a device subject to PMA review until the FDA issues an order approving the PMA application. As a condition to approval, the FDA may impose post-approval requirements intended to ensure the continued safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution, and requiring the collection of additional clinical data. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including withdrawal of the approval.

Most modifications to a PMA approved device, including changes to the design, labeling, or manufacturing process, require prior approval before being implemented. Prior approval is obtained through submission of a PMA supplement. The type of information required to support a PMA supplement and the FDA's time for review of a PMA supplement vary depending on the nature of the modification.

We obtained FDA clearance related to the Pure EP System via the 510(k) process in 2018 and we do not anticipate a PMA for it or other devices at this time.

Pervasive and continuing FDA regulation

After a medical device is placed on the market, numerous FDA regulatory requirements apply, including, but not limited to, the following:

- Quality System Regulation (QSR), which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;

- Establishment Registration, which requires establishments involved in the production and distribution of medical devices intended for commercial distribution in the U.S. to register with the FDA;

- Medical Device Listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA;

- Labeling regulations, which prohibit "misbranded" devices from entering the market, as well as mandate the inclusion of certain content in device labels and labeling and prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and

- Medical Device Reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include one or more of the following sanctions:

- Fines, injunctions, and civil penalties;

- Mandatory recall or seizure of our products;

- Administrative detention or banning of our products;

- Operating restrictions, partial suspension or total shutdown of production;

- Refusing our request for 510(k) clearance or pre-market approval of new product versions;

- Revocation of 510(k) clearance or pre-market approvals previously granted; and

- Criminal penalties.

We are subject to unannounced device inspections by the FDA, as well as other regulatory agencies overseeing the implementation of, and compliance with, applicable state public health regulations. These inspections may include our suppliers' facilities.

U.S. Healthcare Laws and Regulations

In the United States, there are several different healthcare fraud and abuse laws, including the federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including but not limited to exclusion from participation in federal healthcare programs. These laws apply to medical device manufacturers, such as us, with respect to our financial relationship with hospitals, physicians, marketers and sales agents, and other potential purchasers or acquirers of our products or those who are in a position to refer or recommend our products. The U.S. government has published regulations that identify exemptions or "safe harbors," which describe various payment and business practices that, although they potentially implicate the federal Anti-Kickback Statute, are not treated as offenses under the statute, and thereby, protected from enforcement actions under the federal Anti-Kickback Statute. To qualify, the activity must fit squarely within the safe harbor. Arrangements that do not meet a safe harbor are not necessarily illegal but will be evaluated on a case-by-case basis. Other provisions of state and federal law impose civil and criminal penalties for presenting, or causing to be presented, to third-party payors for reimbursement claims that are false or fraudulent, or for items or services that were not provided as claimed. False claims allegations under federal, and some state, laws may be brought on behalf of the government by private persons, or "whistleblowers," who could then receive a share of any recovery. In addition, the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. The Physician Self-Referral Law, commonly referred to as the Stark law, is a strict liability statute that prohibits physicians from referring patients to receive certain services defined as "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless a specific exception applies.

International Regulation

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ significantly.

The European Union has adopted legislation, in the form of directives to be implemented in each member state, concerning the regulation of medical devices within the European Union. The directives include, among others, the Medical Device Directive that establishes standards for regulating the design, manufacture, clinical trials, labeling, and vigilance reporting for medical devices. Our PURE EP system may be affected by this legislation. Under the European Union Medical Device Directive, medical devices are classified into four classes, I, IIa, IIb, and III, with class I being the lowest risk and class III being the highest risk. Under the Medical Device Directive, a competent authority is nominated by the government of each member state to monitor and ensure compliance with the Medical Device Directive. The competent authority of each member state then designates a notified body to oversee the conformity assessment procedures set forth in the Medical Device Directive, whereby manufacturers demonstrate that their devices comply with the requirements of the Medical Device Directive and are entitled to bear the CE mark. CE is an abbreviation for Conformité Européenne (or European Conformity) and the CE mark, when placed on a product, indicates compliance with the requirements of the applicable directive. Medical devices properly bearing the CE mark may be commercially distributed throughout the European Union. Failure to obtain the CE mark will preclude us from selling the PURE EP System and related products in the European Union.

Employees

As of March 13, 2020, we had 33 full-time employees. Additionally, we use consultants as needed to perform various specialized services. None of our employees are represented under a collective bargaining agreement.

ITEM 1A – RISK FACTORS

RISK FACTORS

There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. You should carefully consider the risks described below and the other information included in this Annual Report on Form 10-K, including the consolidated financial statements and related notes. If any of the following risks, or any other risks not described below, actually occur, it is likely that our business, financial condition, and/or operating results could be materially adversely affected. The risks and uncertainties described below include forward-looking statements and our actual results may differ from those discussed in these forward-looking statements.

Risks Related to Our Business and Industry

Because we are an early commercialization stage company with one product in commercialization process, we expect to incur substantial additional operating losses.

We are an early commercialization stage company and we expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, regulatory approvals and clinical trial activities increase for our PURE EP System and other product candidates. The amount of our future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any commercial revenue, and, although we expect to generate revenues this year from the commercial sale of our PURE EP System, we may not be able to generate sufficient revenues to fund our operating expenses, if any. Our ability to generate revenue and achieve profitability will depend on, among other things, the following:

- successful completion of the pre-clinical and clinical development of our products;
- obtaining necessary regulatory approvals from the FDA or other regulatory authorities;
- establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and
- raising sufficient funds to finance our activities.

We might not succeed at all, or at any, of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

Our PURE EP System and other product candidates are in continued development and may not be successfully developed or commercialized.

Although our main product candidate, the PURE EP System, received FDA 510(k) clearance from FDA, we are currently conducting clinical trials and may conduct additional clinical trials, which may require substantial further capital expenditure, to establish the safety and efficacy data needed to obtain acceptance by the medical community and coverage by third-party payors. The continued development of the PURE EP System, and/or any other product candidates we may develop, is dependent upon our ability to obtain sufficient additional financing. However, even if we are able to obtain the requisite financing to fund our development program, we cannot assure you that our current or future product candidates will be successfully developed or commercialized. Our failure to develop, manufacture, receive regulatory approval for, or successfully commercialize any of our product candidates could result in the failure of our business and a loss of all of your investment in our company.

We expect to derive our revenue from sales of our PURE EP System and other products we may develop. If we fail to generate revenue from these sources, our results of operations and the value of our business will be materially and adversely affected.

We expect our revenue to be generated from sales of our PURE EP System, which recently became commercially available, and other products we may develop. Future sales of these products, if any, will be subject to, among other things, commercial and market uncertainties that may be outside our control. If we fail to generate our intended revenues from these products, our results of operations and the value of our business and securities would be materially and adversely affected.

We may need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Any additional funds that we obtain may not be on terms favorable to us or our stockholders and may require us to relinquish valuable rights.

Until PURE EP System or another product of ours become commercially viable, we will have to fund all of our operations and capital expenditures from cash on hand, public or private equity offerings, debt financings, bank credit facilities or corporate collaboration and licensing arrangements. We believe that our existing cash on hand will be sufficient to enable us to fund our projected operating requirements for approximately one year and a day. However, we may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We also may decide to raise additional funds before we require them if we are presented with favorable terms for raising capital.

If we seek to sell additional equity or debt securities, obtain a bank credit facility or enter into a corporate collaboration or licensing arrangement, we may not obtain favorable terms for us and/or our stockholders or be able to raise any capital at all, all of which could result in a material adverse effect on our business and results of operations. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Raising additional funds through collaboration or licensing arrangements with third parties may require us to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us or our stockholders. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities, all of which could have an adverse impact on our business and results of operations.

We may be unable to develop our existing or future technology.

Our product, the PURE EP System, may not deliver the levels of accuracy and reliability needed to make it a successful product in the marketplace, and the development of such accuracy and reliability may be indefinitely delayed or may never be achieved. In addition, we may experience delays in the development of our technology for other reasons, including failure to obtain necessary funding and failure to obtain all necessary regulatory approvals. Failure to develop this or other technology could have an adverse material effect on our business, financial condition, results of operations and future prospects.

We have not completed a clinical trial of our product. The results of additional clinical studies may not support the usefulness of our technology.

We have recently commenced our first clinical with PURE EP System, and, to date, we have not completed a clinical trial of our product. Conducting clinical trials is a long, expensive and uncertain process that is subject to delays and failure at any stage. Clinical trials can take months or years. The commencement or completion of any of our clinical trials may be delayed or halted for numerous reasons, including:

- the FDA may not approve a clinical trial protocol or a clinical trial, or may place a clinical trial on hold;
- subjects may not enroll in clinical trials at the rate we expect, or we may not follow up on subjects at the rate we expect;
- subjects may experience unexpected adverse events;
- third-party clinical investigators may not perform our clinical trials consistent with our anticipated schedule or the clinical trial protocols and good clinical practices, or other third-party organizations may not perform data collection and analysis in a timely or accurate manner;
- interim results of any of our clinical trials may be inconclusive or negative;
- regulatory inspections of our clinical trials may require us to undertake corrective action or suspend or terminate the clinical trials if investigators find us to be in violation of regulatory requirements; or
- governmental regulations or administrative actions may change and impose new requirements, particularly with respect to reimbursement.

Results of pre-clinical studies do not necessarily predict future clinical trial results and previous clinical trial results may not be repeated in subsequent clinical trials. We may experience delays, cost overruns and project terminations despite achieving promising results in pre-clinical testing or early clinical testing. In addition, the data obtained from clinical trials may be inadequate to support a device's approval or clearance, or to demonstrate safety and efficacy to the extent required to obtain third-party coverage and/or reimbursement. The FDA may disagree with our interpretation of the data from our clinical trials, or may find the clinical trial design, conduct, or results inadequate to demonstrate the safety and effectiveness of the product candidate. The FDA may also require additional pre-clinical studies or clinical trials that could further delay clearance or approval of any product candidates we may develop in the future and/or the PURE EP System to the extent we seek clearance/approval for different indications than that for which it is currently cleared. If we are unsuccessful in receiving FDA clearance approval of a future product candidate, or a product's clearance or approval is withdrawn, we would not be able to commercialize the product(s) in the U.S., which could seriously harm our business. Moreover, we face similar risks in other jurisdictions in which we may sell or propose to sell our products.

The medical device industry is subject to stringent regulation and failure to obtain regulatory approval will prevent commercialization of our products.

Medical devices are subject to extensive and rigorous regulation by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act, by comparable agencies in foreign countries and by other regulatory agencies and governing bodies. Under the Federal Food, Drug, and Cosmetic Act and associated regulations, manufacturers of medical devices must comply with certain regulations that cover the composition, labeling, testing, clinical study, manufacturing, packaging and distribution of medical devices. In addition, medical devices must receive FDA clearance or approval before they can be commercially marketed in the U.S., and the FDA may require testing and surveillance programs to monitor the effects of approved products that have been commercialized and can prevent or limit further marketing of a product based on the results of these post-market evaluation programs. The process of obtaining marketing clearance or approval from the FDA for new products could take a significant period of time, require the expenditure of substantial resources, involve rigorous pre-clinical and clinical testing, require changes to the products and result in limitations on the indicated uses of the product. In addition, if we seek regulatory approval in non-U.S. markets, we will be subject to further regulatory approvals that may require additional costs and resources. There is no assurance that we will obtain necessary regulatory approvals in a timely manner, or at all.

To obtain 510(k) clearance for a medical device, a pre-market notification must be submitted to the FDA demonstrating that the device is "substantially equivalent" to a previously cleared "predicate" device. A new device is substantially equivalent to a predicate device "at least as safe and effective" as the predicate. The FDA considers a device substantially equivalent to a predicate if it has the same intended use as the predicate and has either: (i) the same technological characteristics as the predicate or (ii) different technological characteristics from the predicate, but the information submitted to the FDA does not raise new questions of safety or effectiveness or demonstrates that the device is at least as safe and effective as the predicate.

We received 510(k) clearance to market our current lead product, the PURE EP System in the U.S. However, if we intend to market the PURE EP System for additional medical uses or indications, we may need to submit additional 510(k) applications to the FDA that are supported by satisfactory clinical trial results specifically for the additional indication. Clinical trials necessary to support 510(k) clearance or PMA approval for any future product candidates, or any new indications for use for our PURE EP System, would be expensive and could require the enrollment of large numbers of suitable patients who could be difficult to identify and recruit. Delays or failures in any necessary clinical trials could prevent us from commercializing any modified product or new product candidate and could adversely affect our business, operating results and prospects.

The results of our initial clinical trials may not provide sufficient evidence to allow the FDA to grant us such additional marketing clearances and even additional trials requested by the FDA may not result in our obtaining 510(k) marketing clearance for our product. The failure to obtain FDA marketing clearance for any additional indications for the PURE EP System or any other of our future products would have a material adverse effect on our business.

We, and our third-party manufacturer(s), are, and will be, subject to extensive regulation by the FDA.

In addition to the pre-market regulations, once a device is approved or cleared for the applicable indications for use, numerous FDA regulations apply, including but not limited to those relating to manufacturing, labeling, packaging, advertising, and record keeping. Notably, these regulations apply to us, as well as our contract manufacturer(s). Even if regulatory approval or clearance of a product is obtained, the approval or clearance may be subject to limitations on the uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Any such requirements could reduce our revenues, increase our expenses, and render the product not commercially viable. If we fail to comply with the applicable regulatory requirements, or if previously unknown problems with any approved commercial products, manufacturers, or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other negative consequences, including:

- restrictions on our products, manufacturers or manufacturing processes;
- warning letters and untitled letters;
- civil penalties and criminal prosecutions and penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import or export bans or restrictions;
- voluntary or mandatory product recalls and related publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new products or of supplements to approved applications.

Regulations are constantly changing, and in the future our business may be subject to additional regulations that increase our compliance costs.

We believe we understand the current laws and regulations to which our products will be subject in the future. However, federal, state and foreign laws and regulations relating to the sale of our products are subject to future changes, as are administrative interpretations of regulatory agencies. If we fail to comply with such federal, state or foreign laws or regulations, we may fail to obtain regulatory approval for our products and, if we have already obtained regulatory approval, we could be subject to enforcement actions, including injunctions preventing us from conducting our business, withdrawal of clearances or approvals and civil and criminal penalties. In the event that federal, state, and foreign laws and regulations change, we may incur additional costs to seek government approvals, in addition to the clearance from the FDA in order to sell or market our products. If we are slow or unable to adapt to changes in existing regulatory requirements or the promulgation of new regulatory requirements or policies, we or our licensees may, following approval, lose marketing approval for our products which will impact our ability to conduct business in the future.

The market for our technology and revenue generation avenues for our products may be slow to develop, if at all.

The market for our products may be slower to develop or smaller than estimated or it may be more difficult to build the market than anticipated. The medical community may resist our products or be slower to accept them than we anticipate. Revenues from our products may be delayed or costs may be higher than anticipated which may result in our need for additional funding. We anticipate that our principal route to market will be through commercial distribution partners. These arrangements are generally non-exclusive and have no guaranteed sales volumes or commitments. The partners may be slower to sell our products than anticipated. Any financial, operational or regulatory risks that affect our partners could also affect the sales of our products. In the current economic environment, hospitals and clinical purchasing budgets may exercise greater restraint with respect to purchases, which may result in purchasing decisions being delayed or denied. If any of these situations were to occur this could have a material adverse effect on our business, financial condition, results of operations and future prospects.

Our estimate of the size of our addressable market may prove to be inaccurate.

While our addressable market size estimate for the EP market was made in good faith and is based on assumptions and estimates we believe to be reasonable, this estimate may not be accurate. If our estimates of the size of our addressable market are not accurate, our potential for future growth may be less than we currently anticipate, which could have a material adverse effect on our business, financial condition, and results of operations.

If we seek to market our products in foreign jurisdictions, we may need to obtain regulatory approval in these jurisdictions.

In order to market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval procedures vary among countries (except with respect to the countries that are part of the European Economic Area) and can involve additional clinical testing. The time required to obtain approval may differ from that required to obtain FDA approval. Should we decide to market our products abroad, we may fail to obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority, including obtaining CE Mark approval, does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may be unable to file for, and may not receive, necessary regulatory approvals to commercialize our products in any foreign market, which could adversely affect our business prospects. In addition, a new Medical Device Regulation was published in 2017, which, when it enters into full force in 2020, will include additional premarket and post-market requirements, as well as potential product reclassifications or more stringent commercialization requirements that could delay or otherwise adversely affect our clearances and approvals.

The EP market is highly competitive.

There are a number of groups and organizations, such as healthcare, medical device and software companies in the EP market that may develop a competitive offering to our products. The largest companies in the EP market are GE, Johnson & Johnson, Boston Scientific, Siemens and Abbott. All of these companies have significantly greater resources, experience and name recognition than we possess. There is no assurance that they will not attempt to develop similar or superior products, that they will not be successful in developing such products or that any products they may develop will not have a competitive advantage over our products. Moreover, our product may not be viewed as superior to existing technology or new technology from our competitors and as a result we may not be able to justify expected selling price our product, which may have a material adverse effect on market acceptance of our product. In addition, if we experience delayed regulatory approvals or disputed clinical claims, we may not have a commercial or clinical advantage over competitors' products that we believe we currently possess. Should a superior offering come to market, this could have a material adverse effect on our business, financial condition, results of operations and future prospects.

We rely on key officers, consultants and scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.

We are highly dependent on our officers, consultants and scientific and medical advisors because of their expertise and experience in medical device development. We do not have "key person" life insurance policies for any of our officers. Moreover, if we are unable to obtain additional funding, we will be unable to meet our current and future compensation obligations to such employees and consultants. In light of the foregoing, we are at risk that one or more of our consultants or employees may leave our company for other opportunities where there is no concern about such employers fulfilling their compensation obligations, or for other reasons. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our results of operations.

We may fail to attract and retain qualified personnel.

We expect to rapidly expand our operations and grow our sales, research and development and administrative operations. This expansion is expected to place a significant strain on our management and will require hiring a significant number of qualified personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies, research and academic institutions, government entities and other organizations for qualified personnel in the areas of our activities. Many of these companies, institutions and organizations have greater resources than we do, along with more prestige associated with their names. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our marketing and development activities, and this could have a material adverse effect on our business, financial condition, results of operations and future prospects.

If we do not effectively manage changes in our business, these changes could place a significant strain on our management and operations.

Our ability to grow successfully requires an effective planning and management process. The expansion and growth of our business could place a significant strain on our management systems, infrastructure and other resources. To manage our growth successfully, we must continue to improve and expand our systems and infrastructure in a timely and efficient manner. Our controls, systems, procedures and resources may not be adequate to support a changing and growing company. If our management fails to respond effectively to changes and growth in our business, including acquisitions, there could be a material adverse effect on our business, financial condition, results of operations and future prospects.

Our strategic business plan may not produce the intended growth in revenue and operating income.

Our strategies ultimately include making significant investments in sales and marketing programs to achieve revenue growth and margin improvement targets. If we do not achieve the expected benefits from these investments or otherwise fail to execute on our strategic initiatives, we may not achieve the growth improvement we are targeting and our results of operations may be adversely affected. We may also fail to secure the capital necessary to make these investments, which will hinder our growth.

In addition, as part of our strategy for growth, we may make acquisitions and enter into strategic alliances such as joint ventures and joint development agreements. However, we may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully, and our strategic alliances may not prove to be successful. In this regard, acquisitions involve numerous risks, including difficulties in the integration of the operations, technologies, services and products of the acquired companies and the diversion of management's attention from other business concerns. Although we will endeavor to evaluate the risks inherent in any particular transaction, there can be no assurance that we will properly ascertain all such risks. In addition, acquisitions could result in the incurrence of substantial additional indebtedness and other expenses or in potentially dilutive issuances of equity securities. There can be no assurance that difficulties encountered with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

We currently have limited sales, marketing or distribution operations and will need to expand our expertise in these areas.

We currently have limited sales, marketing or distribution operations. We have begun implementing a market development program and are in the process of building such operations in connection with the commercialization of PURE EP System, and we will need to expand our expertise in sales, marketing and distribution operations for commercial growth. To increase internal sales, distribution and marketing expertise and be able to conduct these operations, we have begun to invest in and will have to invest significant amounts of financial and management resources. In developing these functions ourselves, we could face a number of risks, including:

- we may not be able to attract and build an effective marketing or sales force;
- the cost of establishing, training and providing regulatory oversight for a marketing or sales force may be substantial; and
- there are significant legal and regulatory risks in medical device marketing and sales that we have never faced, and any failure to comply with applicable legal and regulatory requirements for sales, marketing and distribution could result in an enforcement action by the FDA, European regulators or other authorities that could jeopardize our ability to market our planned products or could subject us to substantial liability.

The liability of our directors and officers is limited.

The applicable provisions of the Delaware General Corporation Law and our Amended and Restated Certificate of Incorporation and By-laws limit the liability of our directors to us and our stockholders for monetary damages for breaches of their fiduciary duties, with certain exceptions, and for other specified acts or omissions of such persons. In addition, the applicable provisions of the Delaware General Corporation Law and of our Amended and Restated Certificate of Incorporation and By-laws provide for indemnification of such persons under certain circumstances. In the event we are required to indemnify any of our directors or any other person, our financial strength may be harmed.

Our product development program depends upon third-party researchers, including Mayo, who are outside our control and whose negative performance could materially hinder or delay our pre-clinical testing or clinical trials.

We do not have the ability to conduct all aspects of pre-clinical testing or clinical trials ourselves. We depend upon independent investigators and collaborators, such as commercial third-parties, government, universities and medical institutions, to conduct our pre-clinical and clinical trials under agreements with us. For our first clinical trial for the PURE EP System, titled "Novel Cardiac Signal Processing System for Electrophysiology Procedures (PURE EP 2.0 Study)" which commenced in November 2019, we rely on third parties, including TCARF and Mayo Clinic to conduct the patient cases. In addition, we are party to various license agreements with Mayo, pursuant to which we rely on research and development information, materials, technical data, unpatented inventions, trade secrets, know-how and supportive information of Mayo to develop, make, have made, use, offer for sale, sell, and import licensed products. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. The failure of any of these outside collaborators to perform in an acceptable and timely manner in the future, including in accordance with any applicable regulatory requirements, such as good clinical and laboratory practices, or pre-clinical testing or clinical trial protocols, could cause a delay or otherwise adversely affect our pre-clinical testing or clinical trials, our success in obtaining regulatory approvals and, ultimately, the timely advancement of our development programs. In addition, these collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

Negative publicity or unfavorable media coverage could damage our reputation and harm our operations.

In the event that the marketplace perceives our products as not offering the benefits which we believe they offer, we may receive negative publicity. This publicity may result in litigation and increased regulation and governmental review. If we were to receive such negative publicity or unfavorable media attention, whether warranted or unwarranted, our ability to market our products would be adversely affected. We may be required to change our products and services and become subject to increased regulatory burdens, and we may be required to pay large judgments or fines and incur significant legal expenses. Any combination of these factors could further increase our cost of doing business and adversely affect our financial position, results of operations and cash flows.

If health care providers are unable to obtain sufficient reimbursement or other financial incentives from third-party health care payers related to the use of our products, their adoption and our future product sales will be materially adversely affected.

Widespread adoption of the PURE EP System, and any other products we may develop in the future, by the medical community is unlikely to occur without a financial incentive from third-party payors for the use of these products. Third-party payors include but are not limited to governmental programs such as Medicare and Medicaid, commercial health insurers and private payors, workers' compensation programs, and other organizations. Future regulatory action by CMS or other governmental agencies, or unfavorable clinical data, among other things, may impact coverage and/or reimbursement policies for procedures performed using our products. If healthcare providers are unable to obtain adequate coverage of, or reimbursement for, procedures performed using our products, or if managed care organizations do not receive improved capitated payments due to more accurate patient risk assessment using our products, we may be unable to sell our products at levels that are sufficient to allow us to achieve and maintain profitability, and our business would suffer significantly.

We may face risks associated with future litigation and claims.

We may, in the future, be involved in one or more lawsuits, claims or other proceedings. These suits could concern issues including contract disputes, employment actions, employee benefits, taxes, environmental, health and safety, personal injury and product liability matters. Due to the uncertainties of litigation, we can give no assurance that we will prevail on any claims made against us in any such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity or operating results.

The risk that we may be sued on product liability claims is inherent in the development and commercialization of medical devices. Specifically, we believe we will be subject to product liability claims or product recalls, particularly in the event of false positive or false negative reports, because we plan to develop and manufacture medical diagnostic products. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Product liability claims could be asserted directly by consumers, health-care providers or others. We have obtained product liability insurance coverage; however such insurance may not provide full coverage for our current or future clinical trials, products to be sold, and other aspects of our business. A product recall or a successful product liability claim or claims that exceed our planned insurance coverage could have a material adverse effect on us. In addition, insurance coverage is becoming increasingly expensive and we may not be able to maintain current coverage, or expand our insurance coverage to include future clinical trials or the sale of new products or existing products in new territories, at a reasonable cost or in sufficient amounts to protect against losses due to product liability or at all. A successful product liability claim or series of claims brought against us could result in judgments, fines, damages and liabilities that could have a material adverse effect on our business, financial condition and results of operations. In the event of an award against us during a time when we have no available insurance or insufficient insurance, we may sustain significant losses of our operating capital. We may incur significant expense investigating and defending these claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations, as well as impair our reputation in the medical and investment communities.

Our business is subject to cybersecurity risks.

Our operations are increasingly dependent on information technologies and services. Threats to information technology systems associated with cybersecurity risks and cyber incidents or attacks continue to grow, and include, among other things, storms and natural disasters, terrorist attacks, utility outages, theft, viruses, phishing, malware, design defects, human error, and complications encountered as existing systems are maintained, repaired, replaced, or upgraded. Risks associated with these threats include, among other things:

- theft or misappropriation of funds;
- loss, corruption, or misappropriation of intellectual property, or other proprietary, confidential or personally identifiable information (including supplier, or employee data);
- disruption or impairment of our and our business operations and safety procedures;
- damage to our reputation with our potential customers and the market;
- exposure to litigation;
- increased costs to prevent, respond to or mitigate cybersecurity events.

Although we utilize various procedures and controls to mitigate our exposure to such risk, cybersecurity attacks and other cyber events are evolving and unpredictable. Moreover, we have no control over the information technology systems of our suppliers, and others with which our systems may connect and communicate. As a result, the occurrence of a cyber incident could go unnoticed for a period time.

We do not presently maintain insurance coverage to protect against cybersecurity risks. If we procure such coverage in the future, we cannot ensure that it will be sufficient to cover any particular losses we may experience as a result of such cyberattacks. Any cyber incident could have a material adverse effect on our business, financial condition and results of operations.

We may be subject, directly or indirectly, to U.S. federal and state health care fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.

While we have achieved regulatory approval to market our PURE EP System, our operations may be, directly or indirectly, subject to various U.S. federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, federal False Claims Act, and federal Foreign Corrupt Practices Act. These laws may impact, among other things, our proposed sales, and marketing and education programs. In addition, we may be subject to patient privacy regulations by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to, the following.

- The federal Anti-Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program, such as the Medicare and Medicaid programs.

- The federal physician self-referral law, commonly referred to as the Stark Law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition.

- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits may be filed under the federal False Claims Act by the government or by an individual on behalf of the government (known as "qui tam" actions). Such individuals, commonly known as "relators" or "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement.

- The federal transparency requirements under the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, including the provision known as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) to record any information related to payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, and to report this data annually to CMS for subsequent public disclosure. Manufacturers must also disclose investment interests held by physicians and their family members.

- The federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies.

- Federal criminal statutes created through the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information.

- Other federal and state fraud and abuse laws, prohibitions on self-referral and kickbacks, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, transparency, reporting, and disclosure requirements, which may extend to services reimbursable by any third-party payer, including private insurers.

- State and federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that could potentially harm consumers.

Additionally, we may be subject to state equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. Several states impose marketing restrictions or require medical device companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements, and if we fail to comply with an applicable state law requirement we could be subject to penalties.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. In addition, healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the False Claims Act as well, as under the false claims laws of several states.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our existing or future business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Any such actions instituted against us could have a significant adverse impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are successful in defending against such actions, we may nonetheless be subject to substantial costs, reputational harm and adverse effects on our ability to operate our business. In addition, the approval and commercialization of any of our products outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of our employees, agents, or the physicians or other providers or entities with whom we expect to do business are found to have violated applicable laws, we may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, or, if we are not subject to such actions, we may suffer reputational harm for conducting business with persons or entities found, or accused of being, in violation of such laws. Any such events could adversely affect our ability to operate our business and our results of operations.

In addition, to the extent we commence commercial operations overseas, we will be subject to the federal Foreign Corrupt Practices Act and other countries' anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The federal Foreign Corrupt Practices Act prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the federal Foreign Corrupt Practices Act and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and results of operations.

We could be adversely affected if healthcare legislation or reform measures substantially change the market for medical care or healthcare coverage in the U.S., negatively affecting our business or revenue for PURE EP or future products.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, commonly referred to as the "Healthcare Reform Law," includes a number of rules regarding health insurance, the provision of healthcare, conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients, and other healthcare policy reforms. Through the law-making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the U.S., including changes made to extend medical benefits to certain Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and medical devices, and imposing additional taxes, fees, and rebate obligations on medical device companies). This legislation was one of the most comprehensive and significant reforms ever experienced by the U.S. in the healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law's provisions were designed to encourage providers to find cost savings in their clinical operations. Medical devices represent a significant portion of the cost of providing care. This environment has caused changes in the purchasing habits of consumers and providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding medical devices. This attention may result in our products we may commercialize or promote, including our current commercial products, being chosen less frequently or the pricing being substantially lowered. At this stage, it is difficult to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us.

These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare, Medicaid, and the State Children's Health Insurance Program), creation of government-sponsored healthcare insurance sources, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for prescription devices, including our current commercial products, those we and our development or commercialization partners are currently developing or those that we may commercialize or promote in the future. If reimbursement for our approved medical devices, products we currently commercialize or promote, or any product we may commercialize or promote is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our reputation, business, financial condition or results of operations.

Extending medical benefits to those who currently lack coverage will likely result in substantial costs to the U.S. federal government, which may force significant additional changes to the healthcare system in the U.S. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care and increased enforcement activities. Cost of care could be reduced further by decreasing the level of reimbursement for medical services or products (including those products currently being developed by us or our development or commercialization partners or any product we may commercialize or promote, including our current commercial products), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for, any medical device or any product we may commercialize or promote, including our current commercial products, or for which we receive marketing approval in the future, could have a material adverse effect on our reputation, business, financial condition or results of operations.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, and they continue to litigate various aspects of the legislation. On July 26, 2012, the U.S. Supreme Court generally upheld the provisions of the Healthcare Reform Law at issue as constitutional. However, the U.S. Supreme Court held that the legislation improperly required the states to expand their Medicaid programs to cover more individuals. As a result, the states have a choice as to whether they will expand the number of individuals covered by their respective state Medicaid programs. Some states have not expanded their Medicaid programs and have chosen to develop other cost-saving and coverage measures to provide care to currently uninsured individuals. Many of these efforts to date have included the institution of Medicaid-managed care programs. The manner in which these cost-saving and coverage measures are implemented could have a material adverse effect on our reputation, business, financial condition or results of operations.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the Healthcare Reform Law and judicial challenges continue, and may increase in light of the current administration and legislative environment. We cannot predict the impact on our business of future legislative and legal challenges to the Healthcare Reform Law or other changes to the current laws and regulations. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for medical devices affected by the legislation. From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing coverage, reimbursement, and marketing of pharmaceutical products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

Since taking office, President Trump has continued to support the repeal of all or portions of the Healthcare Reform Law. President Trump has also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Healthcare Reform Law and in which he directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the Healthcare Reform Law to the maximum extent permitted by law. Congress has enacted legislation that repeals certain portions of the Healthcare Reform Law, including but not limited to the Tax Cuts and Jobs Act, passed in December 2017, which included a provision that eliminates the penalty under the Healthcare Reform Law's individual mandate, effective January 1, 2019, as well as the Bipartisan Budget Act of 2018, passed in February 2018, which, among other things, repealed the Independent Payment Advisory Board (which was established by the Healthcare Reform Law and was intended to reduce the rate of growth in Medicare spending). There have also been more recent examples of judicial challenges, such as federal judges attempting to invalidate the entire Healthcare Reform Law based on the individual mandate. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold.

The recent coronavirus outbreak may adversely affect our business.

In December 2019, a strain of coronavirus was reported to have surfaced in Wuhan, China, and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions and other public health safety measures in China, the U.S., Italy and other affected countries. The continued outbreak and spreading of the coronavirus may adversely impact our business plan as our clinical studies may be delayed as hospitals in the impacted regions may shift their resources to patients affected by the disease. The various precautionary measures taken by many governmental authorities around the world in order to limit the spread of the coronavirus could also have an adverse effect on the global markets and global economy, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. Therefore, the coronavirus could disrupt production and cause delays in the supply and delivery of products used in our operations, may affect our operation, including the conduct of clinical studies, or the ability of regulatory bodies to grant approvals or supervise our candidates and products, may further divert the attention and efforts of the medical community to coping with the coronavirus and disrupt the marketplace in which we operate and may have a material adverse effects on our operations. The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. The development of the coronavirus outbreak could materially disrupt our business and operations, slow down the overall economy, curtail consumer spending, interrupt our sources of supply, and make it hard to adequately staff our operations.

Risks Related to Our Intellectual Property

If we do not obtain protection for our intellectual property rights, our competitors may be able to take advantage of our research and development efforts to develop competing products.

We intend to rely on a combination of patents, trade secrets, and nondisclosure and non-competition agreements to protect our proprietary intellectual property. We have filed two patent applications with the U.S. Patent and Trademark Office, and we have filed one of these patent applications under the Patent Cooperation Treaty (PCT) with the U.S. Receiving Office and plan to also file the other one in the PCT and with the U.S. Receiving Office. We plan to file additional patent applications in the U.S. and in other countries as we deem appropriate for our products. Our applications have and will include claims intended to provide market exclusivity for certain commercial aspects of the products, including the methods of production, the methods of usage and the commercial packaging of the products. However, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- if and when such patents will be issued, and, if granted, whether patents will be challenged and held invalid or unenforceable;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly regardless of outcome.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, it is our policy to require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Given the fact that we may pose a competitive threat, competitors, especially large and well-capitalized companies that own or control patents relating to electrophysiology recording systems, may successfully challenge our current and planned patent applications, produce similar products or products that do not infringe our future patents, or produce products in countries where we have not applied for patent protection or that do not respect our patents.

If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of our intellectual property may be greatly reduced. Patent protection and other intellectual property protection are important to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

If we infringe upon the rights of third parties, we could be prevented from selling products and forced to pay damages and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may be required to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate;
- redesign our product candidates or processes to avoid infringement;
- cease usage of the subject matter claimed in the patents held by others;
- pay damages; and/or
- defend litigation or administrative proceedings which may be costly regardless of outcome, and which could result in a substantial diversion of our financial and management resources.

Any of these events could substantially harm our earnings, financial condition and operations.

We depend on our collaboration with Mayo Clinic for the research and development of additional advanced features of PURE EP™ System. If this collaboration is not successful, we may not be able to realize the market potential of such features, and may not have rights to use any such developed advanced features.

On March 15, 2017, we entered into a know-how license agreement with Mayo Foundation for Medical Education and Research ("Mayo Clinic"), effective December 2, 2016, and as amended whereby we were granted an exclusive license, with the right to sublicense, certain know how and patent applications in the fields of signal processing, physiologic recording, electrophysiology recording, electrophysiology software and autonomics to develop, make and offer for sale. The agreement expires ten years from the effective date. In furtherance of this collaboration, we subsequently entered into four additional agreements whereby we were granted exclusive licenses, with the right to sublicense additional Mayo Clinic patents and know-how. Pursuant to these agreements, Mayo Clinic retains ownership of the licensed intellectual property and any developed intellectual property. Mayo Clinic also retains the right to prosecute and enforce the developed intellectual property. If our agreements with Mayo Clinic terminate, our access to technology and intellectual property licensed to us by Mayo Clinic may be restricted or terminate entirely, which may delay our continued development of such advanced features utilizing the Mayo Clinic's technology or intellectual property or require us to stop development of those product candidates completely. Additional risks posed by this collaboration include:

- Mayo Clinic may not properly obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our advanced features or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity, and enforceability of our intellectual property;
- Mayo Clinic may own or co-own intellectual property covering our advanced features that results from our collaboration with them, and in such cases, we may not have the exclusive right or any right to commercialize such intellectual property or such product candidates or research programs; or
- We may be prevented from enforcing or defending any intellectual property that we contribute to or that arises out of the collaboration, if Mayo Clinic refuses to cooperate with such action.

Our collaboration with Mayo Clinic is made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between Mayo Clinic and the U.S. government. Additionally, to the extent there is any conflict between our agreements with Mayo Clinic and applicable laws or regulations, applicable laws and regulations will prevail. Some, and possibly all, of the developed intellectual property rights relating to our advanced features may have been developed in the course of research funded by the U.S. government. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980. Government rights in certain inventions developed under a government-funded program include a nonexclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us, or an assignee or exclusive licensee to such inventions, to grant licenses to any of these inventions to a third party if the U.S. government determines that adequate steps have not been taken to commercialize the invention, that government action is necessary to meet public health or safety needs, that government action is necessary to meet requirements for public use under federal regulations, or that the right to use or sell such inventions is exclusively licensed to an entity within the U.S. and substantially manufactured outside the U.S. without the U.S. government's prior approval. Additionally, we may be restricted from granting exclusive licenses for the right to use or sell our inventions created pursuant to such agreements unless the licensee agrees to additional restrictions (e.g., manufacturing substantially all of the invention in the U.S.). The U.S. government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title in any country in which a patent application is not filed within specified time limits. Additionally, certain inventions are subject to transfer restrictions during the term of these agreements and for a period thereafter, including sales of products or components, transfers to foreign subsidiaries for the purpose of the relevant agreements, and transfers to certain foreign third parties. If any of our intellectual property becomes subject to any of the rights or remedies available to the U.S. government or third parties pursuant to the Bayh-Dole Act of 1980, this could impair the value of our intellectual property and could adversely affect our business. The U.S. government has not exercised any of these rights or provided us with any notice of its intent to exercise any of these rights with respect to any of the intellectual property licensed to us by Mayo Clinic. We are not aware of any instance in which the U.S. government has ever exercised any such rights with respect to any technologies or other intellectual property developed under funding agreements with the U.S. government.

Risks Related to our Common Stock

The market price for our common stock may fluctuate significantly, which could result in substantial losses by our investors.

The stock market in general, and Nasdaq in particular, as well as biotechnology companies, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of small companies. The market price of our common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- announcements of technological innovations, new products or product enhancements by us or others;
- actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in our business, operations or prospects;
- announcements of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments by us or our competitors;
- conditions or trends in the biotechnology industry;
- changes in the economic performance or market valuations of other biotechnology companies;
- general market conditions or domestic or international macroeconomic and geopolitical factors unrelated to our performance or financial condition;
- purchase or sale of our common stock by stockholders, including executives and directors;
- volatility and limitations in trading volumes of our common stock;
- changes in our capital structure or dividend policy, future issuances of securities, sales or distributions of large blocks of our common stock by stockholders;

- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- changes in earnings estimates or recommendations by security analysts, if our common stock is covered by analysts;
- the addition or departure of key personnel;
- disputes and litigation related to intellectual property rights, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our common stock and result in substantial losses by our investors.

Further, the stock market in general, and the market for technology companies in particular, has experienced extreme price and volume fluctuations in the past. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock.

Price volatility of our common stock might be worse if the trading volume of our common stock is low. In the past, following periods of market volatility, stockholders have often instituted securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and attention of management from our business, even if we are successful. Future sales of our common stock could also reduce the market price of such stock.

Moreover, the liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but by delays in the timing of transactions and reduction in security analysts' and the media's coverage of us, if any. These factors may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our common stock. In addition, without a large float, our common stock is less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate its investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future.

Although our shares of common stock have been listed on the Nasdaq Capital Market since September 2018, we currently have a limited trading volume, which results in higher price volatility for, and reduced liquidity of, our common stock.

Although our shares of common stock have been listed on the Nasdaq Capital Market since September 2018, trading volume in our common stock has been limited and an active trading market for our shares of common stock may never develop or be maintained. The absence of an active trading market increases price volatility and reduces the liquidity of our common stock. As long as this condition continues, the sale of a significant number of shares of common stock at any particular time could be difficult to achieve at the market prices prevailing immediately before such shares are offered.

If we cannot continue to satisfy the continuing listing criteria of the Nasdaq Capital Market, the exchange may subsequently delist our common stock.

Nasdaq requires us to meet certain financial, public float, bid price and liquidity standards on an ongoing basis in order to continue the listing of our common stock. Generally, we must maintain a minimum amount of stockholders equity and a minimum number of holders of our securities. If we fail to meet any of the continuing listing requirements, our common stock may be subject to delisting. If our common stock is delisted and we are not able to list our common stock on another national securities exchange, we expect our securities would be quoted on an over-the-counter market. If this were to occur, our stockholders could face significant material adverse consequences, including limited availability of market quotations for our common stock and reduced liquidity for the trading of our securities. In addition, we could experience a decreased ability to issue additional securities and obtain additional financing in the future. There can be no assurance that an active trading market for our common stock will develop or be sustained.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market, it could create a circumstance commonly referred to as an "overhang," in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, also could make more difficult our ability to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

Our stockholders may experience substantial dilution as a result of the conversion of outstanding convertible preferred stock, the exercise of options or warrants to purchase shares of our common stock, or upon exchange of the shares of NeuroClear common stock into shares of our common stock.

As of March 13, 2020, we have outstanding options to purchase 3,678,896 shares of common stock and have reserved 1,594,718 shares of our common stock for further issuances pursuant to our 2012 Equity Incentive Plan. In addition, as of March 13, 2020, we may be required to issue 94,421 shares of our common stock for issuance upon conversion of outstanding convertible Series C preferred stock which includes accrued dividends as of March 10, 2020 and 2,521,438 shares of our common stock for issuance upon exercise of outstanding warrants. Should all of these shares be issued, you would experience dilution in ownership of our common stock and the price of our common stock will decrease unless the value of our company increases by a corresponding amount.

Moreover, in the event that NeuroClear common stock is not listed on a national securities exchange by October 31, 2020, or a change of control (as defined in the securities purchase agreement for NeuroClear financings) of NeuroClear occurs and the investors who participated in the NeuroClear private placements completed in August through December of 2019, elects to exchange their shares of NeuroClear common stock to our shares of common stock, subject to certain conditions as set forth in the respective securities purchase agreement, you would experience dilution in ownership of our common stock. Such investors' shares of NeuroClear common stock may be exchanged into up to 838,559 shares of our common stock.

The interests of our controlling stockholders may not coincide with yours and such controlling stockholders may make decisions with which you may disagree.

As of March 13, 2020, three of our stockholders beneficially owned over 19.92% of our common stock. As a result, these stockholders may be able to influence the outcome of matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in control of our company and make some future transactions more difficult or impossible without the support of our controlling stockholders. The interests of our controlling stockholders may not coincide with our interests or the interests of other stockholders.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have new research coverage by securities and industry analysts. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

We are subject to financial reporting and other requirements that place significant demands on our resources.

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. Any failure to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price. Moreover, effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed.

We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock. In addition, because we were an emerging growth company, our independent registered public accounting firm had not been required previously to provide an attestation report as to our internal control over financial reporting.

As disclosed in "Item 9A – Controls and Procedures," we have identified a material weakness in our internal control over financial reporting related to the segregation of duties in the initiating and recording of transactions, which lead to our principal executive officer and our principal financial officer concluding that the disclosure controls and procedures were not effective in ensuring that: (i) information required to be disclosed by us in reports that we file or furnish to the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms and (ii) material information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for accurate and timely decisions regarding required disclosure.

A "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Management has evaluated, and continues to evaluate, avenues for mitigating our internal controls weaknesses. The management has during the year ended December 31, 2019, hired a controller and upgraded our financial systems to establish a better system of maintaining appropriate segregation of duties and improve the oversight in the initiating and recording of transactions as part of the preparation of reliable financial statements and to avoid a potential misstatement that could result due to the deficient controls or the absence of sufficient other mitigating controls. In addition, we engaged outside experts to review, document and recommend improvements to our internal control policies and procedures. These improvements continue into 2020.

However, we had not yet completed our improvements, and we cannot assure you that additional remedial measures added in 2020 will fully remediate the material weakness described above or that in the future additional material weaknesses will not exist, reoccur or otherwise be discovered, a risk that may be increased in light of the our current plan to grow our business. If our remediation measures of these material weakness described in "Item 9A – Controls and Procedures" is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock. Any failure to report our financial results on an accurate and timely basis could also result in sanctions, lawsuits, delisting of our shares from the Nasdaq Capital Market or other adverse consequences that would materially harm our business.

Delaware law and our Amended and Restated Certificate of Incorporation and By-laws contain anti-takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable.

Our board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our stockholders. In addition, we are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless (i) prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; (ii) the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 could delay or prohibit mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

The terms of our Series C Preferred Stock prohibit us from paying dividends in the future on our common stock. As a result, any return on investment may be limited to the value of our common stock.

The terms of our Series C Preferred Stock prohibit us from paying dividends in the future on our common stock, absent consent from the holders representing a super-majority of the outstanding shares of our Series C Preferred Stock and a certain investor. Because we will likely not pay dividends, our common stock may be less valuable because a return on an investment in our common stock will only occur if our stock price appreciates.

Risks Related to our Series C Preferred Stock

Our Series C Preferred Stock contains covenants that could limit our financing options and liquidity position, which would limit our ability to grow our business.

Covenants in the certificate of designation for our Series C Preferred Stock impose operating and financial restrictions on us. These restrictions prohibit or limit our ability to, among other things:

- incur additional indebtedness;
- permit liens on assets;
- repay, repurchase or otherwise acquire more than a de minimis number of shares of capital stock;
- pay cash dividends to our stockholders; and
- engage in transactions with affiliates.

These restrictions may limit our ability to obtain financing, withstand downturns in our business or take advantage of business opportunities. Moreover, debt financing we may seek may contain terms that include more restrictive covenants, may require repayment on an accelerated schedule or may impose other obligations that limit our ability to grow our business, acquire needed assets, or take other actions we might otherwise consider appropriate or desirable.

In addition, the certificate of designation for our Series C Preferred Stock requires us to redeem shares of our Series C Preferred Stock, at each holder's option and for an amount greater than their stated value, upon the occurrence of certain events, including our being subject to a judgment of greater than $100,000 or our initiation of bankruptcy proceedings.

The holders of our Series C Preferred Stock are entitled to receive a dividend, which may be increased if we do not comply with certain covenants.

The holders of the Series C Preferred Stock are entitled to a 9% annual dividend on the $1,000 per share stated value of our Series C Preferred Stock, which is payable in cash or, subject to the satisfaction of certain conditions, in pay-in-kind shares. The dividend may be increased to a 18% annual dividend if we fail to comply with certain covenants, including our being subject to a judgment of greater than $100,000 or our initiation of bankruptcy proceedings. As a result of the payment of dividends related to our Series C Preferred Stock, we may be obligated to pay significant sums of money or issue a significant number of shares of our common stock, which could negatively affect our operations or result in the dilution of the holders of our common stock, respectively.

The terms of our Series C Preferred Stock contain anti-dilution provisions that may result in the reduction of the conversion prices in the future.

The terms of our Series C Preferred Stock contain anti-dilution provisions, which provisions require the lowering of the conversion price to the purchase price of future offerings. If in the future we issue securities for less than the conversion of our Series C Preferred Stock then in effect, we will be required to further reduce the relevant conversion prices. We may find it more difficult to raise additional equity capital while our Series C Preferred Stock are outstanding.

ITEM 1B – UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2 – PROPERTIES

We maintain our principal executive office at 54 Wilton Road, Westport, Connecticut, where we sublease approximately 4,343 square feet of office space. This lease runs until October 30, 2021, with monthly payments of $18,277 per month from May 1, 2019 through April 30, 2020, $18,639 per month from May 1, 2020 through April 30, 2021 and $19,001 from May 1, 2021 through October 31, 2021, inclusive of a fixed utility charge. In connection with the lease, we paid a security deposit of $68,764, of which $34,382 represents the last two months of the term. There is no option to extend the lease past its initial term.

In addition, we maintain our engineering offices at 12424 Wilshire Boulevard, Los Angeles, California, where we lease approximately 4,000 square feet of office space. This lease runs until June 30, 2021, with monthly payments of $14,731 from July 1, 2018 with escalating payments to $16,033 through June 30, 2021. In connection with the lease of our office space in Los Angeles, we are obligated to lease parking spaces at an aggregate approximate cost of $1,800 per month, subject to annual increase. In addition, we entered into a lease for storage space within the building that commenced on September 1, 2019 and expires on June 30, 2021. Our monthly lease payments with respect to such storage space is approximately $223 per month escalating to $250.00 per month beginning September 1, 2020. We have an option to extend the Los Angeles lease for an additional 3-year term.

On October 1, 2019, we entered into a lease agreement for approximately 1,400 square feet of office space in Rochester Minnesota commencing November 1, 2019 and expiring on October 31, 2021 at an initial rate of $3,411 per month with escalating payments to $3,513 through October 31, 2021. This lease agreement includes an option to extend the lease for two additional periods of two years each past its initial term.

We believe we may need to expand our current facilities to meet our future needs.

Future minimum lease payments under these three agreements are as follows:

Year Ending December 31,	
2020	455,124
2021	321,386
	$ 776,510

ITEM 3 – LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

There are no material proceedings in which any of our directors, officers or affiliates or any registered or beneficial shareholder of more than 5% of our common stock is an adverse party or has a material interest adverse to our interest.

ITEM 4 – MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5 – MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market for Common Stock

On October 29, 2014, our common stock commenced trading on OTCQB under the symbol "BSGM" and on September 21, 2018 we commenced trading on the Nasdaq Capital Market exchange under the same ticker symbol. Prior to October 29, 2014, there was no established trading price for our common stock. The last reported sales price of our common stock on the Nasdaq Capital Market on March 12, 2020, was $2.905 per share.

Holders of Record

As of March 13, 2020, there were approximately 332 holders of our common stock, as determined by counting our record holders and the number of participants reflected in a security position listing provided to us by the Depository Trust Company. Because the "DTC participants" are brokers and other institutions holding shares of our common stock on behalf of their customers, we do not know the actual number of unique shareholders represented by these record holders.

Dividends

We have never paid cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future but intend to retain our capital resources for reinvestment in our business

ITEM 6 – SELECTED FINANCIAL DATA

Not applicable

ITEM 7 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and the related notes thereto that are included in this Form 10-K. In addition to historical information, the following discussion and analysis includes forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly in the section entitled "Risk Factors." See "Special Note Regarding Forward-Looking Statements."

Overview

We are a commercial stage medical device company that is commercializing a proprietary biomedical signal processing technology platform to extract information from physiologic signals. Our initial emphasis is on providing intracardiac signal information to electrophysiologists during electrophysiology ("EP") studies and cardiac catheter ablation procedures for atrial fibrillation ("AF") and ventricular tachycardia ("VT"). Cardiac catheter ablation is a procedure that involves delivery of energy through the tip of a catheter that scars or destroys heart tissue in order to correct heart rhythm disturbances. In August 2018, we received 510(k) clearance from the U.S. Food and Drug Administration (the "FDA") to market our PURE (Precise Uninterrupted Real-time evaluation of Electrograms) EP System.

The PURE EP™ System is a proprietary signal acquisition and processing technology. The device is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording and storing of electrocardiographic and intracardiac signals for patients undergoing EP procedures in an EP laboratory under the supervision of licensed healthcare practitioners who are responsible for interpreting the data. The device aims to minimize noise and artifacts from cardiac recordings and acquire high-fidelity cardiac signals. Improving fidelity of acquired cardiac signals may potentially increase the diagnostic value of these signals, thereby possibly improving accuracy and efficiency of the EP studies and related procedures.

Our initial focus is on improving intracardiac signal acquisition and enhancing diagnostic information for catheter ablation procedures for complex and potentially life-threatening arrhythmias like AF, the most common cardiac arrhythmia, and VT, an arrhythmia evidenced by a fast heart rhythm originating from the lower chambers of the heart.

We believe that the PURE EP System and its advanced signal processing tools may contribute to improvements in patient outcomes in connection with catheter ablation due to the following advantages over the EP recording systems currently available on the market: acquisition of raw cardiac signals enabled by proprietary system architecture; preserved signal fidelity; user interface optimized for enhanced visualization; and very low noise, maximum frequency bandwidth and wide dynamic range

We believe that these features may allow physicians to better determine precise ablation targets, strategy and end point of procedures with the objective of reducing the need for multiple procedures. The PURE EP System is intended to operate in conjunction with the existing EP lab equipment.

We have not generated any revenue to date and consequently our operations are subject to all risks inherent in the establishment of a new business enterprise.

Critical Accounting Policies and Estimates

The following discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with generally accepted accounting principles in the U.S. The preparation of financial statements in accordance with generally accepted accounting principles in the U.S. requires us to make estimates and assumptions that affect the amounts reported in our financial statements. The financial statements include estimates based on currently available information and our judgment as to the outcome of future conditions and circumstances. Significant estimates in these financial statements include allowance for doubtful accounts and accruals for inventory claims. Changes in the status of certain facts or circumstances could result in material changes to the estimates used in the preparation of the financial statements and actual results could differ from the estimates and assumptions.

Among the significant judgments made by management in the preparation of our financial statements are the following:

Research and Development.

We account for research and development costs in accordance with the Accounting Standards Codification subtopic 730-10, Research and Development ("ASC 730-10"). Under ASC 730-10, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and developments costs are expensed when the contracted work has been performed or as milestone results have been achieved. Company-sponsored research and development costs related to both present and future products are expensed in the period incurred.

Stock-Based Compensation.

All stock-based payments to employees and to nonemployee directors for their services as directors consisted of grants of restricted stock and stock options, which are measured at fair value on the grant date and recognized in the statements of operations as compensation expense over the relevant vesting period. Restricted stock payments and stock-based payments to nonemployees are recognized as an expense over the period of performance. Such payments are measured at fair value at the earlier of the date a performance commitment is reached or the date performance is completed. In addition, for awards that vest immediately and are non-forfeitable, the measurement date is the date the award is issued.

On October 29, 2014, our common stock commenced trading on OTCQB under the symbol "BSGM" and on September 21, 2018 our common stock commenced trading on the Nasdaq Capital Market exchange under the same ticker symbol. Fair value is typically determined by the closing price of our common stock on the date of the award.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include the recoverability and useful lives of long-lived assets, the fair value of the Company's stock, stock-based compensation, fair values relating to warrant and other derivative liabilities and the valuation allowance related to deferred tax assets. Actual results may differ from these estimates.

Derivative Instrument Liability

We account for derivative instruments in accordance with ASC 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of hedging relationship designation. Accounting for changes in fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged. On December 31, 2019 and 2018, the Company did not have any derivative instruments that were designated as hedges.

On December 31, 2019, we had outstanding preferred stock and on December 31, 2018, we also had warrants that contained embedded derivatives. These embedded derivatives include certain conversion features and reset provisions.

Income Taxes.

Deferred income tax assets and liabilities are determined based on the estimated future tax effects of net operating loss and credit carryforwards and temporary differences between the tax basis of assets and liabilities and their respective financial reporting amounts measured at the current enacted tax rates. We record an estimated valuation allowance on our deferred income tax assets if it is not more likely than not that these deferred income tax assets will be realized. We recognize a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement.

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, such as the progress of our research and development efforts and the timing and outcome of regulatory submissions. Due to these uncertainties, accurate predictions of future operations are difficult or impossible to make.

Twelve Months Ended December 31, 2019 Compared to Twelve Months Ended December 31, 2018

Revenues and Cost of Goods Sold. We had no revenues or cost of goods sold during the twelve months ended December 31, 2019 and 2018.

Research and Development Expenses. Research and development expenses for the twelve months ended December 31, 2019 were $9,738,819, an increase of $5,370,035 or 123%, from $4,368,784 for the twelve months ended December 31, 2018. This increase is primarily due 2019 increases in payroll due to staff increases and accelerated design work. In addition, we issued warrants with a fair value of $3,162,342 and cash of $175,000 to acquire research and development services (see discussion below), net, with reduction in consulting work.

Research and development expenses were comprised of the following:

	2019	2018
Salaries and equity compensation	$ 3,488,321	$ 1,972,721
Consulting expenses	696,287	987,972
Clinical studies and design work	1,944,607	1,249,370
Acquired research and development	3,337,342	-
Travel, supplies, other	272,262	158,721
Total	$ 9,738,819	$ 4,368,784

Stock-based compensation for research and development personnel was $1,920,060 and $1,056,571 for the year ended December 31, 2019 and 2018, respectively.

During the year ended December 31, 2019, we and NeuroClear entered into patent and know how agreements pursuant which we paid Mayo Foundation for Medical Education and Research ("Mayo") whereby we and NeuroClear paid Mayo an aggregate of $175,000 and warrants with an estimated fair value of $3,162,342.

General and Administrative Expenses. General and administrative expenses for the twelve months ended December 31, 2019 were $24,810,712, an increase of $11,929,685, or 93%, from $12,881,027 incurred in the twelve months ended December 31, 2018. This increase is primarily due to increase in equity-based and other compensation, increases in professional services, consulting fees and travel, meals and entertainment costs.

Payroll related expenses (including equity compensation) increased to $17,882,004 in the twelve months ended December 31, 2019 from $8,199,609 for the twelve months ended December 31, 2018, an increase of $9,682,395, or 118%. This increase is due to the value of the stock-based compensation increasing to $13,923,678 in 2019, as a result of the vesting of stock and stock options issued to board members, officers and employees, as compared to $5,544,018 of stock-based compensation in 2018, along with added additional personnel in 2019.

Professional services for the twelve months ended December 31, 2019 totaled $1,004,139, an increase of $359,701, or 56%, over the $644,438 recognized for the twelve months ended December 31, 2018. Of professional services, legal fees totaled $902,139 for the twelve months ended December 31, 2019, an increase of $359,351, or 66%, from $542,788 incurred for the twelve months ended December 31, 2018. The significant increase in legal fees in 2019 is due to extensive legal work in developing and registering patents. Accounting fees incurred in the twelve months ended December 31, 2019 amounted to $102,000, an increase of $350, or 0%, from $101,650 incurred for the same period in 2018.

Consulting fees totaled $3,341,768 for the twelve months ended December 31, 2019, an increase of $943,129 or 39%, from $2,398,639 for the twelve months ended December 31, 2018. The increase primarily relates to our fund raising and investor relations to support our increased efforts in market research and potential investor identification and key consultants in connection with our commercialization efforts.

Travel, meals and entertainment costs for the twelve months ended December 31, 2019 were $704,565, an increase of $215,043, or 44%, from $489,522 incurred during the twelve months ended December 31, 2018. During 2019, more travel was required than in 2018 due to our commercialization and fund-raising efforts.

Rent for the twelve months ended December 31, 2019 totaled $413,763, an increase of $208,088, or 101%, from $205,675 incurred during the same period in 2019. In 2019, our significant increase was the result of our new sublease of our corporate headquarters in Connecticut and lease of facilities in Minnesota along with escalation increases of our existing leases in 2019.

Depreciation and Amortization Expense. Depreciation and amortization expense for the twelve months ended 2019 totaled $54,349 as compared to $12,403 incurred during the same period in 2018. The increase is due primarily to additional equipment purchased and amortization of our patent development costs in 2019.

Interest Income. Interest income for the twelve months ended December 31, 2019 totaled $132,751 as compared to $10,897 earned during the twelve months ended December 31, 2018. The increase in 2019 was due larger cash balances and better rates in our interest-bearing accounts.

Preferred Stock Dividend. Preferred stock dividend for the year ended December 31, 2019 totaled $25,163, a decrease of $859,573, or 97% from $884,736 incurred during the year ended December 31, 2018. Preferred stock dividends are primarily related to the issuance of our Series C, D and E Preferred Stock from 2013 through 2018. The significant decrease in 2019 as compared to 2018 is the result of 2018 conversions of the Series D and E Preferred Stock and the payment, upon conversion, of a required minimum dividend of $405 and $315, respectively, per share of Series D and E Preferred Stock for the first three years of issuance.

Noncontrolling Interest. In 2019, NeuroClear sold shares of its common stock to fund its initial operations. As of December 31, 2019, we had a majority interest in NeuroClear of 87.8%. The proportionate loss attributed to noncontrolling interests for the year ended December 31, 2019 was $415,849 as compared to $0 for 2018.

Net Loss Available to BioSig Technologies, Inc. Net loss available to common stockholders for the twelve months ended December 31, 2019 was $34,079,991, compared to a net loss of $18,136,053 for the twelve months ended December 31, 2018, an increase of $15,943,938 or 88%. The primary reasons for the increase, as described above, are the increases in research and development costs, general and administrative and preferred stock dividends from 2018 to 2019.

Liquidity and Capital Resources

We had an accumulated deficit as of December 31, 2019 of approximately $105 million, as well as a net loss of approximately $34 million and negative operating cash flows. We expect to continue incurring losses and negative cash flows from operations until our products (primarily PURE EP System) reach commercial profitability. We believe that our existing cash on hand will be sufficient to enable us to fund our projected operating requirements for approximately one year and a day. However, we may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We also may decide to raise additional funds before we require them if we are presented with favorable terms for raising capital.

Our plans include the continued commercialization of PURE EP System and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that we will be successful in obtaining the level of financing needed for our operations. If we are unsuccessful in commercializing our products and raising capital, we may need to reduce activities, curtail or cease operations.

Equity Financing

On March 12, 2019, we consummated one closing under the Securities Purchase Agreement by and among certain accredited investors (as defined by Rule 501 under the Securities Act of 1933, as amended), pursuant to which we issued 2,155,127 shares of our common stock for aggregate consideration of $8,619,278, net of $1,230 in expenses. The securities sold in this offering were not registered under the Securities Act of 1933, as amended, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act of 1933, as amended, provided by Section 4(2) and Regulation D (Rule 506) under the Securities Act of 1933, as amended.

From August 5, 2019 through September 5, 2019, NeuroClear Technologies, Inc and us entered into Securities Purchase Agreements with certain accredited investors, pursuant to which NeuroClear agreed to sell an aggregate of 739,000 shares of NeuroClear' s common stock, par value $0.001 per share, at $5.00 per share, for an aggregate purchase price of $3,695,000. We are a party to the Securities Purchase Agreements with respect to a provision in each such agreement, which provides that in the event that (i) the NeuroClear common stock is not listed on a national securities exchange by October 31, 2020, or (ii) a change of control (as defined in the applicable Securities Purchase Agreement) of NeuroClear occurs, whichever is earlier, at the option of the holder of NeuroClear common stock, each share of NeuroClear common stock may be exchanged into 0.9 of a share of common stock of the Company.

The NeuroClear private placement and the potential exchange of NeuroClear's common stock into the Company's common stock are not registered under the Securities Act of 1933, as amended (the "***Securities Act***"), or the securities laws of any state, and the shares of NeuroClear common stock and the shares of the Company's common stock issuable upon the potential exchange of NeuroClear's common stock into the Company's common stock will be offered and sold, in reliance on the exemption from registration under the Securities Act, provided by Section 4(a)(2) and Regulation D (Rule 506) under the Securities Act. Each Investor represented that it is an accredited investor (as defined by Rule 501 under the Securities Act).

From October 21, 2019 through December 19, 2019, NeuroClear Technologies, Inc and us entered into Securities Purchase Agreements with certain accredited investors, pursuant to which NeuroClear agreed to sell an aggregate of 157,690 shares of NeuroClear' s common stock, par value $0.001 per share, at $8.35 per share, for an aggregate purchase price of $1,316,664. We are a party to the Securities Purchase Agreements with respect to a provision in each such agreement, which provides that in the event that (i) the NeuroClear common stock is not listed on a national securities exchange by October 31, 2020, or (ii) a change of control (as defined in the applicable Securities Purchase Agreement) of NeuroClear occurs, whichever is earlier, at the option of the holder of NeuroClear common stock, each share of NeuroClear common stock may be exchanged into 1.1 of a share of common stock of the Company.

The NeuroClear private placement and the potential exchange of NeuroClear's common stock into the Company's common stock are not registered under the Securities Act of 1933, as amended (the "***Securities Act***"), or the securities laws of any state, and the shares of NeuroClear common stock and the shares of the Company's common stock issuable upon the potential exchange of NeuroClear's common stock into the Company's common stock will be offered and sold, in reliance on the exemption from registration under the Securities Act, provided by Section 4(a)(2) and Regulation D (Rule 506) under the Securities Act. Each Investor represented that it is an accredited investor (as defined by Rule 501 under the Securities Act).

On December 31, 2019, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain investors for the sale by us of 231,335 shares of our common stock, par value $0.001 per share, at a purchase price of $6.00 per share. The proceeds for the sale of the shares was $1,387,910, net of $100 in expenses. The closing of the sale of the shares under the Purchase Agreement occurred on December 31, 2019.

The shares were offered and sold by us pursuant to an effective shelf registration statement on Form S-3, which was filed with the Securities and Exchange Commission on March 22, 2019, and subsequently declared effective on March 29, 2019 (File No. 333-230448), and a related prospectus.

On February 21, 2020, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Laidlaw & Company (UK) Ltd. (the "Underwriter"), relating to an underwritten public offering of 2,500,000 shares of the Company's common stock, at the public offering price of $4.00 per share. At closing on February 25, 2020, the Company received net proceeds of approximately $9,100,000, after deducting the underwriting discount and other offering expenses of approximately $100,000.

Twelve Months Ended December 31, 2019 Compared to Twelve Months Ended December 31, 2018

As of December 31, 2019, we had a working capital of $10,797,951, comprised of cash of $12,108,582, inventory of $577,690 and prepaid expenses of $141,221, which was offset by $1,488,776 of accounts payable and accrued expenses, accrued dividends on preferred stock issuances of $128,478 and short term lease liabilities of $412,288. For the twelve months ended December 31, 2019, cash provided by financing activities totaled $23,427,338, comprised of proceeds from the sale of our common stock of $10,007,188, sale of subsidiary stock to non-controlling interests of $5,011,309 and proceeds from the exercise of options and warrants of $8,408,841. In the comparable period in 2018, $9,139,721 was raised through the sale of our common stock and convertible securities, $1,492,969 from the sale of our Series E Preferred stock and proceeds of $2,832,997 from the exercise of options and warrants. At December 31, 2019, we had cash of $12,108,582 compared to $4,450,160 at December 31, 2018. Our cash is held in bank deposit accounts. At December 31, 2019 and 2018, we had no convertible debentures outstanding.

Cash used in operations for the twelve months ended December 31, 2019 and 2018 was $15,482,982 and $10,255,427, respectively, which represent cash outlays for research and development and general and administrative expenses in such periods. Increase in cash outlays principally resulted from increased research and development and general and administrative expenses due to the continued development of our operations.

Cash used in investing activities for the twelve months ended December 31, 2019 was $285,934, compared to $307,679 for the twelve months ended December 31, 2018. During the twelve months ended December 31, 2019, we incurred $111,591 in patent and trademark costs and $177,092 purchases of office furniture and computer equipment, net with proceeds from disposal of equipment of $2,749. For the twelve months ended December 31, 2018, we purchased office furniture and computer equipment of $38,033 and incurred 269,646 in patent and trademark costs.

Our Series C Preferred Stock contains triggering events which would, among other things, require redemption (i) in cash, at the greater of (a) 120% of the stated value of $1,000 or (b) the product of (I) the variable weighted average price of our common stock on the trading day immediately preceding the date of the triggering event and (II) the stated value divided by the then conversion price or (ii) in shares of our common stock, equal to a number of shares equal to the amount set forth in (i) above divided by 75%. As of December 31, 2019, the aggregate stated value of our Series C Preferred Stock was $215,000. The triggering events include our being subject to a judgment of greater than $100,000 or our initiation of bankruptcy proceedings. If any of the triggering events contained in our Series C Preferred Stock occur, the holders of our Series C Preferred Stock may demand redemption, an obligation we may not have the ability to meet at the time of such demand. We will be required to pay interest on any amounts remaining unpaid after the required redemption of our Series C Preferred Stock, at a rate equal to the lesser of 18% per annum or the maximum rate permitted by applicable law.

We expect to incur losses from operations for the near future. We expect to incur increasing marketing and commercialization expenses related to our PURE EP system in addition to additional research and development costs, including expenses related to clinical trials. We expect that our general and administrative expenses will increase in the future as we expand our business development, add infrastructure and incur additional costs related to be a public company, including incremental audit fees, investor relations programs and increased professional services.

Our future capital requirements will depend on a number of factors, including the progress of our research and development of product candidates, the timing and outcome of regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing and our success in developing markets for our product candidates. We believe our existing cash will be sufficient to fund our operating expenses and capital equipment requirements for the next year and a day.

Future financing may include the issuance of equity or debt securities, obtaining credit facilities, or other financing mechanisms. Even if we are able to raise the funds required, it is possible that we could incur unexpected costs and expenses or experience unexpected cash requirements that would force us to seek alternative financing. Furthermore, if we issue additional equity or debt securities, existing holders of our securities may experience additional dilution or the new equity securities may have rights, preferences or privileges senior to those of existing holders of our securities.

If additional financing is not available or is not available on acceptable terms, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

There were various updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to a have a material impact on the Company’s consolidated financial position, results of operations or cash flows.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8 – FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

BIOSIG TECHNOLOGIES, INC.

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
of BioSig Technologies, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of BioSig Technologies, Inc. (the Company) as of December 31, 2019 and 2018, and the related statements of operations, stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 13, 2020, expressed an adverse opinion.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Liggett & Webb, P.A.

We have served as the Company's auditor since 2013.

New York, NY
March 13, 2020

BIOSIG TECHNOLOGIES, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2019 AND 2018

	2019	2018
ASSETS		
Current assets:		
Cash	$ 12,108,582	$ 4,450,160
Inventory	577,690	-
Vendor deposits	-	100,000
Prepaid expenses	141,221	78,442
Total current assets	12,827,493	4,628,602
Property and equipment, net	180,368	44,346
Right-to-use assets, net	714,342	-
Other assets:		
Patents, net	364,536	268,796
Trademarks	1,125	850
Prepaid expenses, long term	27,410	-
Deposits	101,839	54,238
Total assets	$ 14,217,113	$ 4,996,832
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued expenses, including $39,674 and $32,366 to related parties as of December 31, 2019 and 2018, respectively	$ 1,488,776	$ 954,655
Dividends payable	128,478	242,908
Lease liability, short term	412,288	-
Total current liabilities	2,029,542	1,197,563
Lease liability, long term	311,131	-
Total debt	2,340,673	1,197,563
Commitments and contingencies (Note 13)	-	-
Series C Preferred Stock, 215 and 475 shares issued and outstanding; liquidation preference of $215,000 and $475,000 as of December 31, 2019 and 2018, respectively	215,000	475,000
Equity:		
Preferred stock, $0.001 par value, authorized 1,000,000 shares, designated 200 shares of Series A, 600 shares of Series B, 4,200 shares of Series C, 1,400 shares of Series D, 1,000 shares of Series E Preferred Stock; 215 and 475 Series C shares outstanding as of December 31, 2019 and 2018, respectively	-	-
Common stock, $0.001 par value, authorized 200,000,000 shares, 23,323,087 and 16,868,783 issued and outstanding as of December 31, 2019 and 2018, respectively	23,323	16,869
Additional paid in capital	115,910,058	74,039,341
Accumulated deficit	(104,786,769)	(70,731,941)
Total stockholders' equity attributable to BioSig Technologies, Inc	11,146,612	3,324,269
Non-controlling interest	514,828	-
Total equity	11,661,440	3,324,269
Total liabilities and equity	$ 14,217,113	$ 4,996,832

See the accompanying notes to the consolidated financial statements.

BIOSIG TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31, 2019	2018
Operating expenses:		
Research and development	$ 9,738,819	$ 4,368,784
General and administrative	24,810,712	12,881,027
Depreciation and amortization	54,349	12,403
Total operating expenses	34,603,880	17,262,214
Loss from operations	(34,603,880)	(17,262,214)
Other income (expense):		
Interest income, net	132,751	10,897
Gain on disposal of assets	452	-
Loss before income taxes	(34,470,677)	(17,251,317)
Income taxes (benefit)	-	-
Net loss	(34,470,677)	(17,251,317)
Preferred stock dividend	(25,163)	(884,736)
Net loss attributable to common stockholders	(34,495,840)	(18,136,053)
Non-controlling interest	415,849	-
NET LOSS ATTRIBUTABLE TO BIOSIG TECHNOLOGIES, INC.	$ (34,079,991)	$ (18,136,053)
Net loss per common share, basic and diluted	$ (1.65)	$ (1.25)
Weighted average number of common shares outstanding, basic and diluted	20,694,662	14,504,360

See the accompanying notes to the consolidated financial statements.

BIOSIG TECHNOLOGIES, INC.
CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
TWO YEARS ENDED DECEMBER 31, 2019 AND 2018

	Series D Preferred stock		Series E Preferred stock		Common stock		Additional Paid in		Accumulated	Non-controlling	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Subscription	Deficit	Interest	Total
Balance, January 1, 2018	1,334	$ 1	-	$ -	11,728,482	$ 11,728	$ 53,233,228	$ 29,985	$ (56,524,786)	$ -	$ (3,249,844)
Reclassify fair value of derivative and warrant liabilities to equity upon adoption of ASU 2017-11	-	-	-	-	-	-	-	-	3,044,162	-	3,044,162
Common stock issued for services	-	-	-	-	897,050	898	4,242,447	-	-	-	4,243,345
Sale of common stock	-	-	-	-	2,123,078	2,123	9,167,583	(29,985)	-	-	9,139,721
Sale of Series E Preferred stock	-	-	1,000	1	-	-	1,492,968	-	-	-	1,492,969
Common stock issued upon exercise of warrants at $3.80 per share	-	-	-	-	583,328	584	2,216,813	-	-	-	2,217,397
Common stock issued upon exercise of options at $4.40 per share	-	-	-	-	140,001	140	615,460	-	-	-	615,600
Common stock issued upon cashless exercise of warrants	-	-	-	-	35,601	35	(35)	-	-	-	-
Common stock issued upon conversion of Series C Preferred Stock at $3.75 per share	-	-	-	-	136,002	136	509,864	-	-	-	510,000
Common stock issued settlement of Series C Preferred Stock accrued dividends at $4.19 per share	-	-	-	-	56,000	56	234,403	-	-	-	234,459
Common stock issued upon conversion of Series D Preferred Stock at $3.75 per share	(1,334)	(1)	-	-	533,600	534	(533)	-	-	-	-
Common stock issued settlement of Series D Preferred Stock accrued dividends at $3.41 per share	-	-	-	-	158,365	158	540,113	-	-	-	540,271
Common stock issued upon conversion of Series E Preferred Stock at $3.75 per share	-	-	(1,000)	(1)	400,000	400	(399)	-	-	-	-
Common stock issued settlement of Series E Preferred Stock accrued dividends at $4.08 per share	-	-	-	-	77,276	77	314,923	-	-	-	315,000
Stock based compensation	-	-	-	-	-	-	2,357,242	-	-	-	2,357,242
Preferred stock dividend	-	-	-	-	-	-	(884,736)	-	-	-	(884,736)
Net loss	-	-	-	-	-	-	-	-	(17,251,317)	-	(17,251,317)
Balance, December 31, 2018	-	$ -	-	$ -	16,868,783	$ 16,869	$ 74,039,341	$ -	$ (70,731,941)	$ -	$ 3,324,269

BIOSIG TECHNOLOGIES, INC.
CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
TWO YEARS ENDED DECEMBER 31, 2019 AND 2018

	Series D Preferred stock		Series E Preferred stock		Common stock		Additional Paid in		Accumulated	Non-controlling	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Subscription	Deficit	Interest	Total
Balance, December 31, 2018	-	$ -	-	$ -	16,868,783	$ 16,869	$ 74,039,341	$ -	$ (70,731,941)	$ -	$ 3,324,269
Common stock issued for services	-	-	-	-	1,558,317	1,558	9,673,770	-	-	-	9,675,328
Sale of common stock	-	-	-	-	2,386,462	2,386	10,004,802	-	-	-	10,007,188
Sale of subsidiary shares to non-controlling interest	-	-	-	-	-	-	4,080,632	-	-	930,677	5,011,309
Common stock issued upon exercise of warrants at an average of $4.02 per share	-	-	-	-	1,860,479	1,861	7,468,946	-	-	-	7,470,807
Common stock issued upon exercise of options at an average of $4.95 per share	-	-	-	-	189,620	190	937,844	-	-	-	938,034
Common stock issued upon cashless exercise of warrants	-	-	-	-	162,592	163	(163)	-	-	-	-
Common stock issued upon cashless exercise of options	-	-	-	-	92,788	93	(93)	-	-	-	-
Common stock issued upon conversion of Series C Preferred Stock at $3.75 per share	-	-	-	-	69,335	69	259,931	-	-	-	260,000
Common stock issued settlement of Series C Preferred Stock accrued dividends at $6.53 per share	-	-	-	-	21,379	21	139,571	-	-	-	139,592
Fair value of warrants issued to acquire research and development	-	-	-	-	-	-	3,162,342	-	-	-	3,162,342
Change in fair value of modified options	-	-	-	-	-	-	666,062	-	-	-	666,062
Stock based compensation	-	-	-	-	113,332	113	5,502,236	-	-	-	5,502,349
Preferred stock dividend	-	-	-	-	-	-	(25,163)	-	-	-	(25,163)
Net loss	-	-	-	-	-	-	-	-	(34,054,828)	(415,849)	(34,470,677)
Balance, December 31, 2019	-	$ -	-	$ -	23,323,087	$ 23,323	$ 115,910,058	$ -	$ (104,786,769)	$ 514,828	$ 11,661,440

See the accompanying notes to the consolidated financial statements.

BIOSIG TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31, 2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (34,470,677)	$ (17,251,317)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	54,349	12,403
Gain on disposal of equipment	(452)	-
Equity based compensation	15,177,677	6,600,587
Fair value of warrants to acquire research and development	3,162,342	-
Change in fair value of modified options	666,062	-
Changes in operating assets and liabilities:		
Inventory	(577,690)	-
Vendor deposits	100,000	-
Prepaid expenses	(90,189)	(61,504)
Security deposit	(47,601)	(37,154)
Accounts payable and accrued expenses	537,497	478,751
Lease liability, net	5,700	-
Deferred rent payable	-	2,807
Net cash used in operating activities	(15,482,982)	(10,255,427)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from disposal of equipment	2,749	-
Payments of patent costs	(111,316)	(268,796)
Payment of trademark costs	(275)	(850)
Purchase of property and equipment	(177,092)	(38,033)
Net cash used in investing activity	(285,934)	(307,679)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock	10,007,188	9,139,721
Proceeds from sale of subsidiary stock to non-controlling interest	5,011,309	-
Proceeds from sale of Series E preferred stock	-	1,492,969
Proceeds from exercise of warrants	7,470,807	2,217,397
Proceeds from exercise of options	938,034	615,600
Net cash provided by financing activities	23,427,338	13,465,687
Net increase in cash and cash equivalents	7,658,422	2,902,581
Cash and cash equivalents, beginning of the year	4,450,160	1,547,579
Cash and cash equivalents, end of the year	$ 12,108,582	$ 4,450,160
Supplemental disclosures of cash flow information:		
Cash paid during the period for interest	$ -	$ -
Cash paid during the period for income taxes	$ -	$ -
Non cash investing and financing activities:		
Common stock issued upon conversion of Series C Preferred Stock and accrued dividends	$ 399,592	$ 744,459
Common stock issued upon conversion of Series D Preferred Stock and accrued dividends	$ -	$ 540,271
Common stock issued upon conversion of Series E Preferred Stock and accrued dividends	$ -	$ 315,000
Reclassify fair value of derivative and warrant liabilities to equity upon adoption of ASU 2017-11	$ -	$ 3,044,162
Dividend payable on preferred stock charged to additional paid in capital	$ 25,163	$ 884,736
Right-to-use assets and lease liability recorded upon adoption of ASC 842	$ 422,215	$ -
Record right-to-use assets and related lease liability	$ 511,236	$ -

See the accompanying notes to the consolidated financial statements.

NOTE 1 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies applied in the preparation of the accompanying consolidated financial statements follows.

Business and organization

BioSig Technologies Inc. (the "Company") was initially incorporated on February 24, 2009 under the laws of the State of Nevada and subsequently re-incorporated in the state of Delaware in 2011. The Company and its efforts are principally devoted to improving the quality of cardiac recordings obtained during ablation of atrial fibrillation (AF) and ventricular tachycardia (VT). The Company has not generated any revenue to date and consequently its operations are subject to all risks inherent in the establishment of a new business enterprise.

On November 7, 2018, the Company formed NeuroClear Technologies, Inc. ("NeuroClear"), a Delaware Corporation, for the purpose to pursue additional applications of the PURE EP™ signal processing technology outside of electrophysiology. In 2019, NeuroClear sold 896,690 shares of its common stock for net proceeds of $5,011,309 to fund initial operations. As of December 31, 2019, the Company had a majority interest in NeuroClear of 87.8% (See Notes 9 and 11).

The consolidated financial statements include the accounts of BioSig Technologies, Inc. and its majority owned subsidiary, NeuroClear Technologies, Inc. to as the "Company" or "BioSig".

Effective September 10, 2018, the Company amended its Articles of Incorporation to implement a reverse stock split in the ratio of 1 share for every 2.5 shares of common stock. As a result, 40,333,758 shares of the Company's common stock were exchanged for 16,133,544 shares of the Company's common stock. These consolidated financial statements have been retroactively restated to reflect the reverse stock split (See Note 9).

Revenue Recognition

The Company recognizes revenue in accordance with Financial Accounting Standards Board "FASB" Accounting Standards Codification "ASC" 606. A five-step analysis a must be met as outlined in Topic 606: (i) identify the contract with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue when (or as) performance obligations are satisfied. Provisions for discounts and rebates to customers, estimated returns and allowances, and other adjustments are provided for in the same period the related sales are recorded. There were no changes to our revenue recognition policy from the adoption of ASC 606.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include the recoverability and useful lives of long-lived assets, the fair value of long term operating leases, patent capitalization, the fair value of the Company's stock, stock-based compensation, fair values relating to warrant and other derivative liabilities and the valuation allowance related to deferred tax assets. Actual results may differ from these estimates.

Concentrations of Credit Risk

Financial instruments and related items, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and cash equivalents. The Company places its cash and temporary cash investments with credit quality institutions. At times, such amounts may be in excess of the FDIC insurance limit. At December 31, 2019 and 2018, deposits in excess of FDIC limits were $11,608,582 and $4,200,160, respectively.

Inventory

The inventory is comprised of finished goods available for sale and are stated at the lower of cost or net realizable value using the first-in, first-out method of valuation. The inventory at December 31, 2019 and 2018 were $577,690 and $0, respectively.

Prepaid Expenses

Prepaid expenses are comprised of vendor deposits of $100,000 (2018), prepaid insurance and operating expense prepayments.

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over their estimated useful lives of 3 to 5 years. When retired or otherwise disposed, the related carrying value and accumulated depreciation are removed from the respective accounts and the net difference less any amount realized from disposition, is reflected in earnings.

Long-Lived Assets

The Company follows Accounting Standards Codification 360-10-15-3, "Impairment or Disposal of Long-lived Assets," which established a "primary asset" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long-lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

Fair Value of Financial Instruments

Accounting Standards Codification subtopic 825-10, Financial Instruments ("ASC 825-10") requires disclosure of the fair value of certain financial instruments. The carrying value of cash and cash equivalents, accounts payable and accrued liabilities as reflected in the balance sheets, approximate fair value because of the short-term maturity of these instruments. All other significant financial assets, financial liabilities and equity instruments of the Company are either recognized or disclosed in the consolidated financial statements together with other information relevant for making a reasonable assessment of future cash flows, interest rate risk and credit risk. Where practicable the fair values of financial assets and financial liabilities have been determined and disclosed; otherwise only available information pertinent to fair value has been disclosed.

The Company follows Accounting Standards Codification subtopic 820-10, Fair Value Measurements and Disclosures ("ASC 820-10") and Accounting Standards Codification subtopic 825-10, Financial Instruments ("ASC 825-10"), which permits entities to choose to measure many financial instruments and certain other items at fair value.

Derivative Instrument Liability

The Company accounts for derivative instruments in accordance with ASC 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of hedging relationship designation. Accounting for changes in fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged. At December 31, 2019 and 2018, the Company did not have any derivative instruments that were designated as hedges.

At December 31, 2019 and 2018, the Company had outstanding preferred stock and at December 31, 2018, warrants that contained embedded derivatives. These embedded derivatives include certain conversion features and reset provisions (See Note 7 and Note 8). On January 1, 2018, the Company adopted ASU 2017-11 and according reclassified the fair value of the reset provisions embedded in previously issued preferred stock and certain warrants with embedded anti-dilutive provisions from liability to equity.

Research and development costs

The Company accounts for research and development costs in accordance with the Accounting Standards Codification subtopic 730-10, Research and Development ("ASC 730-10"). Under ASC 730-10, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and developments costs are expensed when the contracted work has been performed or as milestone results have been achieved. Company-sponsored research and development costs related to both present and future products are expensed in the period incurred. The Company incurred research and development expenses of $9,738,819 and $4,368,784 for the year ended December 31, 2019 and 2018, respectively.

Net Income (loss) Per Common Share

The Company computes earnings (loss) per share under Accounting Standards Codification subtopic 260-10, Earnings Per Share ("ASC 260-10"). Net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the year. Diluted earnings per share, if presented, would include the dilution that would occur upon the exercise or conversion of all potentially dilutive securities into common stock using the "treasury stock" and/or "if converted" methods as applicable.

The computation of basic and diluted loss per share as of December 31, 2019 and 2018 excludes potentially dilutive securities when their inclusion would be anti-dilutive, or if their exercise prices were greater than the average market price of the common stock during the period.

Potentially dilutive securities excluded from the computation of basic and diluted net income (loss) per share are as follows:

	2019	2018
Series C convertible preferred stock	82,251	190,572
Options to purchase common stock	3,980,804	3,135,828
Warrants to purchase common stock	2,744,718	4,579,511
Vested restricted stock awards	25,000	-
Totals	6,832,773	7,905,911

Stock Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award as measured on the grant date. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period.

As of December 31, 2019, the Company had options to purchase 3,980,804 shares of common stock outstanding, of which options to purchase 2,874,017 shares of common stock were vested.

As of December 31, 2018, there were options to purchase 3,135,828 shares of common stock outstanding, of which options to purchase 3,007,946 shares of common stock were vested.

Income Taxes

The Company follows Accounting Standards Codification subtopic 740-10, Income Taxes ("ASC 740-10") for recording the provision for income taxes. Deferred tax assets and liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related asset or liability is expected to be realized or settled. Deferred income tax expenses or benefits are based on the changes in the asset or liability during each period. If available evidence suggests that it is more likely than not that some portion or all of the deferred tax assets will not be realized, a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized. Future changes in such valuation allowance are included in the provision for deferred income taxes in the period of change. Deferred income taxes may arise from temporary differences resulting from income and expense items reported for financial accounting and tax purposes in different periods.

On December 27, 2017, the Tax and Jobs Act (TCJA) was signed into law by the President of the United States, TCJA is a tax reform act that among other things, reduced corporate tax rates to 21 percent effective January 1, 2018. Accordingly, the Company adjusted its deferred tax assets and liabilities at December 31, 2018, using the new corporate rate of 21 percent. See Note 14.

Patents, net

The Company capitalizes certain initial asset costs in connection with patent applications including registration, documentation and other professional fees associated with the application. Patent costs incurred prior to the Company's U.S. Food and Drug Administration ("FDA") 510 (k) application on March 28, 2018 were charged to research and development expense as incurred. Commencing upon first in-man trials on February 18 and 19, 2019, capitalized costs are amortized to expense using the straight-line method over the lesser of the legal patent term or the estimated life of the product of 20 years. During the year ended December 31, 2019, the Company recorded amortization of $15,576 to current period operations.

Segment Information

Accounting Standards Codification subtopic Segment Reporting 280-10 ("ASC 280-10") establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. ASC 280-10 also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions how to allocate resources and assess performance. The information disclosed herein materially represents all the financial information related to the Company's only material principal operating segment.

Registration Rights

The Company accounts for registration rights agreements in accordance with the Accounting Standards Codification subtopic 825-20, Registration Payment Arrangements ("ASC 825-20"). Under ASC 825-20, the Company is required to disclose the nature and terms of the arrangement, the maximum potential amount and to assess each reporting period the probable liability under these arrangements and, if exists, to record or adjust the liability to current period operations.

Beginning on October 28, 2016, the Company entered into subscription agreements with certain accredited investors pursuant to which the Company sold to the investor units, which each unit consisting of one share of the Company's common stock and a warrant to purchase one half of one share of common stock (the "*Private Placement*"). In connection with the Private Placement, the Company also entered into a registration rights agreement with the investors, pursuant to which the Company agreed to provide certain registration rights with respect to the common stock and warrants issued under the Private Placement. The registration rights agreements require the Company to file a registration statement within 45 calendar days upon the final closing under the Private Placement and to be effective 120 calendar days thereafter. The final closing under the Private Placement occurred on March 31, 2017. On June 8, 2017, the Company filed the required registration statement and on September 19, 2017 was declared effective. The Company has estimated the liability under the registration rights agreement at $-0- as of December 31, 2019 and 2018.

Beginning on April 6, 2017, the Company entered into subscription agreements with certain accredited investors pursuant to which the Company sold to the investor units, which each unit consisting of one share of the Company's common stock and a warrant to purchase one half of one share of common stock. In connection with the Private Placement, the Company also entered into a registration rights agreement with the investors, pursuant to which the Company agreed to provide certain registration rights with respect to the common stock and warrants issued under the Private Placement. The registration rights agreements require the Company to file a registration statement within 45 calendar days upon the final closing under the Private Placement and to be effective 120 calendar days thereafter. The final closing under the Private Placement occurred on December 31, 2017.

On February 28, 2018, the Company filed the required registration statement and on March 26, 2018 was declared effective. The Company has estimated the liability under the registration rights agreement at $-0- as of December 31, 2019 and 2018.

On November 3, 2017, in connection with the Company's private placement of Series D Preferred Stock and warrants, the Company entered into a registration rights agreement with the purchasers pursuant to which the Company agreed to provide certain registration rights with respect to the common stock issuable upon conversion of Series D Preferred Stock and exercise of the warrants issued to holders of Series D Preferred Stock. Specifically, the Company agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the common stock issuable upon conversion of the Series D Preferred Stock and exercise of the warrants on or before December 18, 2017 and to cause such registration statement to be declared effective by the Securities and Exchange Commission, in the event that the registration statement is not reviewed by the Securities and Exchange Commission, within five trading days after the Company is notified that registration statement is not being reviewed by the Securities and Exchange Commission, and by March 18, 2018 in the event that the registration statement is reviewed by the Securities and Exchange Commission and the Securities and Exchange Commission issues comments. On December 18, 2017, the Company filed the required registration statement and on December 29, 2017 was declared effective. The Company has estimated the liability under the registration rights agreement at $-0- as of December 31, 2019 and 2018.

On February 16, 2018, in connection with the Company's private placement of Series E Preferred Stock and warrants, the Company also entered into a registration rights agreement (the "Registration Rights Agreement") whereby the Company agreed to file a registration statement with the Securities and Exchange Commission (the "SEC") within 90 days of the closing of the transactions contemplated by the Purchase Agreement (the "Filing Date") covering the resale of (a) all shares of Common Stock Issuable upon conversion of the Preferred Shares, (b) all shares of Common Stock issuable upon exercise of the Warrants, (c) all other shares of Common Stock issued pursuant to any transaction documents which have been, or which may, from time to time be issued or become issuable to the Investors under the Transaction Documents (without regard to any limitation or restriction on purchases), and (d) any securities issued or then issuable upon any stock split, dividend or other distribution, recapitalization or similar event ("Registrable Securities"), not then registered. The Company will use its reasonable best efforts to keep the registrations statement effective pursuant to Rule 415 under the Securities Act until the earlier of (i) the date on which the Investors shall have sold all the Registrable Securities covered thereby and (ii) that date that all Registrable Securities may be sold pursuant to Rule 144 without any public information requirement or volume or manner of sale limitations. On May 16, 2018, the Company filed the required registration statement. The Company has estimated the liability under the registration rights agreement at $-0- as of December 31, 2019 and 2018.

On March 12, 2019, in connection with the Company's private placement of common stock, the Company agreed that the Company would use commercially reasonable efforts to prepare and file a registration statement on Form S-3 or Form S-1 with the Securities and Exchange Commission covering the resale of the shares of common stock on or prior the date that is 45 calendar days after the closing date of the private placement, and to cause such registration statement to be declared effective by the Securities and Exchange Commission as soon as practicable thereafter.

On May 31, 2019, the Company filed the required registration statement, and on June 24, 2019, such registration statement was declared effective. The Company has estimated the liability under the registration rights agreement to be $0 as of December 31, 2019. All expenses related to the filing of such registration statement, including legal fees, was borne by the Company. The Company has estimated the liability under the registration rights agreement at $-0- as of December 31, 2019.

Adoption of Accounting Standards

ASC 842, Leases (Topic 842)

In February 2016, the Financial Accounting Standards Board established ASC Topic 842, Leases (Topic 842), by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. The Company adopted the new standard on January 1, 2019.

The new standard provides a number of optional practical expedients in transition. The Company has elected the 'package of practical expedients', which permit it not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter is not applicable to the Company.

The new standard had a material effect on the Company's financial statements. The most significant effects of adoption relate to (1) the recognition of new ROU assets and lease liabilities on its balance sheet for real estate operating leases; and (2) providing significant new disclosures about its leasing activities.

Upon adoption, the Company recognized additional operating lease liabilities, net of deferred rent, of approximately $422,000 based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. The Company also recognized corresponding ROU assets of approximately $419,000.

The new standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Beginning in 2019, the Company changed to its disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. See Note 5.

Accounting Standards Update ("ASU") No. 2017-11, Earnings Per Share (Topic 260)

In July 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features.

When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS.

Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt—Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update recharacterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception.

Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period.

On January 1, 2018, the Company adopted ASU 2017-11 and accordingly reclassified the fair value of the reset provisions embedded in previously issued Series C Preferred stock, Series D Preferred stock and certain warrants with embedded anti-dilutive provisions from liability to equity in aggregate of $3,044,162.

Recent Accounting Pronouncements

There were various updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to a have a material impact on the Company's financial position, results of operations or cash flows.

Subsequent Events

The Company evaluates events that have occurred after the balance sheet date but before the consolidated financial statements are issued. Based upon the evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the unaudited condensed consolidated financial statements, except as disclosed.

Reclassification

Certain amounts in the balance sheet at December 31, 2018 have been reclassified to conform to the presentation at December 31, 2019.

NOTE 2 – MANAGEMENT LIQUIDITY PLANS

The Company's primary efforts are principally devoted to improving the quality of cardiac recordings obtained during ablation of atrial fibrillation (AF) and ventricular tachycardia (VT). The Company has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future. Further, the Company has not generated revenues and there is no assurance that the Company will be able to generate cash flow to fund operations. In addition, there can be no assurance that the Company's ongoing research and development will be successfully completed or that any product will be approved or commercially viable.

At December 31, 2019, the Company had working capital of approximately $10.8 million. During the year ended December 31, 2019, the Company raised approximately $10 million, net of expenses, through the sale of common stock, net $5 million from sale of subsidiary stock and $8.4 million from the exercise of warrants and options.

On February 21, 2020, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Laidlaw & Company (UK) Ltd. (the "Underwriter"), relating to an underwritten public offering of 2,500,000 shares (the "Shares") of the Company's common stock, $0.001 par value per share. All of the Shares were sold by the Company. The public offering price of the Shares was $4.00 per share, and the Underwriter purchased the Shares from the Company pursuant to the Underwriting Agreement at a price of $3.68 per share. At closing on February 25, 2020, the Company received net proceeds of approximately $9,100,000, after deducting the underwriting discount and other offering expenses of approximately $100,000.

In addition, subsequent to December 31, 2019, the Company has received approximately $133,241 from the exercise of previously issued warrants.

At December 31, 2019, the Company had cash of approximately $12.1 million, which together with approximately $9.2 million of net proceeds from the sales of common stock and warrant exercises subsequent to December 31, 2019 (see above and Note 15), constitutes sufficient funds for the Company to meet its research and development and other funding requirements for at least the next 12 months.

NOTE 3 – RELATED PARTY TRANSACTIONS

The Company's President and shareholders have advanced funds to the Company for working capital purposes since the Company's inception in February 2009. No formal repayment terms or arrangements exist, and the Company is not accruing interest on these advances. The net amount of outstanding advances at December 31, 2019 and 2018 was $-0-.

Accrued expenses related primarily to travel reimbursements due related parties as of December 31, 2019 and 2018 was $12,051 and $32,366, respectively.

On November 1, 2017, in connection with Mr. Filler joining the Company's Board of Directors, the Company entered into a Master Services Agreement (the "Agreement") with 3LP Advisors LLC (d/b/a Sherpa Technology Group) ("Sherpa") and an initial statement of work (the "SOW"), pursuant to which Sherpa will develop, execute and expand the Company's intellectual property strategy over the course of the next approximately 18 months by evaluating the business and technology landscape in which the Company operates, and charting and executing a strategy of patent filing and licensing.

In connection with the SOW, the Company paid Sherpa fee of (i) $200,000 in cash, of which $25,000 will be paid on January 1, 2018, with the remainder to be paid upon completion of certain objectives, and (ii) a ten-year option to purchase up to 120,000 shares of the Company's common stock at an exercise of $3.75 per share of common stock, of which 60,000 options vest immediately and 60,000 options are performance conditioned (subsequently, condition met). Mr. Filler is the general counsel and partner of Sherpa.

During the years ended December 31, 2019 and 2018, the Company paid $279,030 and $427,219 as patent costs, consulting fees and expense reimbursements. As of December 31, 2019, and 2018, there was an unpaid balance of $27,623 and $0, respectively.

On February 15, 2018 Mr. Filler was granted options to purchase 20,000 shares of common stock at an exercise price of $3.55 per share for their 2017 board service. The granted options vested as of February 15, 2018 and are exercisable for a ten-year term.

On May 4, 2018, Mr. Londoner, Mr. Chaussy and Dr. Drakulic were granted 240,000, 100,000 and 60,000 shares of common stock at a cost basis of $4.425 per share for their 2017 performance, respectively. The granted shares vested immediately.

On August 16, 2018, Mr. Filler acquired 4,800 shares of the Company's common stock, 1,200 warrants to acquire the Company's common stock at an exercise price of $6.85 and exercisable for three years and 1,200 warrants to acquire the Company's common stock at an exercise price of $3.75 expiring on May 16, 2019 in participation in the Company's private placement of its common stock. The issued warrants vested as of August 16, 2018.

On October 16, 2018, Mr. Tanaka and Mr. Weild were granted options to purchase 34,566 and 69,132 shares of common stock at an exercise price of $5.09 per share for their 2018 board service. Mr. Tanaka's options vest with 17,283 vesting on October 16, 2018 and 17,283 vesting January 1, 2019 and are exercisable for a ten-year term. Mr. Weild's options vest with 17,283 on October 16, 2018; 17,283 on January 1, 2019, 2020 and 2021 each and are exercisable for a ten-year term.

On October 26, 2018, Mr. Gallagher was issued 94 shares of the Company's common stock in a cashless exercise 490 warrants to purchase the Company common stock.

On November 6, 2018, Mr. Londoner, as Chairman of the board of directors, was granted 60,000 shares of common stock at a cost basis of $5.33 per share for his 2018 board service. The granted shares vested immediately.

On November 6, 2018, Mr. O'Donnell, Mr. Filler, Mr. Fischer each were granted 50,000 shares of common stock for their 2018 board of directors of committee chairmanships services at a cost basis of $5.33 per share. The granted shares vested immediately.

On November 6, 2018, Mr. Fischer and Mr. Foley each were granted 25,000 shares of common stock for their 2018 board of directors' services at a cost basis of $5.33 per share. The granted shares vested immediately.

On January 2, 2019, Mr. O'Donnell was granted 30,000 shares of common stock at a cost basis of $4.33 per share for his appointment as Lead Director. The granted shares vested immediately.

On January 7, 2019, Mr. Londoner, Mr. Chaussy and Dr. Drakulic were granted 240,000, 100,000 and 70,000 shares of common stock at a cost basis of $4.48 per share, respectively. The granted shares vested immediately.

On April 24, 2019, Mr. Gallagher was issued 4,000 shares of the Company's common stock in an exercise of warrants to purchase the Company common stock at $4.875 per share.

On May 1, 2019, Dr. Zeldis was issued 1,097 shares of the Company's common stock in an exercise of warrants to purchase the Company common stock at $3.75 per share.

On May 17, 2019, Mr. Filler was issued 1,200 shares of the Company's common stock in an exercise of warrants to purchase the Company common stock at $3.75 per share.

On May 17, 2019, in connection with the resignation of Mr. Fischer and Mr. Tanaka, the Company extended for up to two years 236,768 and 392,137 previously granted options that would normally expire 90 days after leaving service.

On May 22, 2019, Dr. Zeldis was issued an aggregate of 17,138 shares of the Company's common stock upon conversion of 50 shares of the Company's Series C preferred stock and accrued dividends.

On May 22, 2019, Dr. Zeldis was issued 1,097 shares of the Company's common stock in an exercise of warrants to purchase the Company common stock at $6.85 per share.

On May 22, 2019, Dr. Zeldis was issued 20,000 shares of the Company's common stock in an exercise of options to purchase the Company common stock at $3.40 per share.

On May 24, 2019, Mr. Tanaka (former board of director member) was issued 28,077 shares of the Company's common stock in a cashless exercise 95,857 options to purchase the Company common stock.

On June 20, 2019, Mr. Tanaka (former board of director member) was issued 10,610 shares of the Company's common stock in a cashless exercise 34,566 options to purchase the Company common stock.

On June 21, 2019, Mr. Navarro was granted restricted stock units representing 50,000 shares of common stock at a cost basis of $9.25 for joining the Company's board of directors. The granted restricted stock units vest 50% on June 21, 2020 and 50% on June 21, 2021.

On July 8, 2019, Mr. Londoner, Mr. Chaussy and Mr. Drakulic were granted 60,000, 25,000 and 10,000 shares of common stock at a cost basis of $8.71 per share for their first half 2019 performance, respectively. The granted shares vested immediately.

On September 24, 2019, Ms. Pease was granted restricted stock units representing 40,000 shares of common stock at a cost basis of $8.07 for joining the Company's board of directors. The granted restricted stock units vest 50% on September 24, 2020 and 50% on September 24, 2021.

On October 2, 2019, Mr. Tanaka (former board of director member) was issued 46,847 shares of the Company's common stock in a cashless exercise 191,714 options to purchase the Company common stock.

On October 16, 2019, Mr. Londoner, Mr. O'Donnell and Mr. Chaussy were granted options to purchase 250,000, 25,000 and 150,000 shares of common stock in NeuroClear Technologies, Inc. at an exercise price of $5.00 per share for their service in establishing NeuroClear. The granted options vested as of October 16, 2019 and are exercisable for a ten-year term.

On October 16, 2019, Mr. Londoner and Mr. Filler were granted 30,000 and 25,000 shares of common stock at a cost basis of $7.06 per share for 2018 performance, respectively. The granted shares vested immediately. The granted shares vested immediately

On October 30, 2019, Mr. Navarro, Mr. Foley and Dr. Zeldis were each granted options to purchase 29,000 shares of common stock at an exercise price of $7.15 per share for their 2019 board service. The granted options vested as of October 30, 2019 and are exercisable for a ten-year term.

On October 30, 2019, Mr. Gallagher, Mr. O'Donnell and Mr. Weild were each granted options to purchase 36,240 shares of common stock at an exercise price of $7.15 per share for their 2019 board service. The granted options vested as of October 30, 2019 and are exercisable for a ten-year term.

On December 12, 2019, Mr. Londoner, Mr. Chaussy, Dr. Drakulic were granted 225,000, 75,000 and 30,000 shares of common stock at a cost basis of $6.57 per share for their second half 2018 performance, respectively. The granted shares vested immediately.

On December 20, 2019, Mr. O'Donnell was issued 7,254 shares of the Company's common stock in a cashless exercise 38,320 options to purchase the Company common stock.

During the years ended December 31, 2019 and 2018, Mr. Chaussy guaranteed issued corporate credit cards.

NOTE 4 – PROPERTY AND EQUIPMENT

Property and equipment as of December 31, 2019 and 2018 is summarized as follows:

	2019	2018
Computer equipment	$ 155,126	$ 105,447
Furniture and fixtures	71,463	32,619
Manufacturing equipment	29,098	-
Less accumulated depreciation	(75,319)	(93,720)
Property and equipment, net	$ 180,368	$ 44,346

Property and equipment are stated at cost and depreciated using the straight-line method over their estimated useful lives of 3 to 5 years. When retired or otherwise disposed, the related carrying value and accumulated depreciation are removed from the respective accounts and the net difference less any amount realized from disposition, is reflected in earnings.

During the year ended December 31, 2019, the Company recognized a gain of $452 on disposal of equipment.

Depreciation expense was $38,773 and $12,403 for year ended December 31, 2019 and 2018, respectively.

NOTE 5 – RIGHT TO USE ASSETS AND LEASE LIABILITY

On October 1, 2019, the Company entered into a lease agreement whereby the Company leased approximately 1,400 square feet of office space in Rochester Minnesota commencing November 1, 2019 and expiring on October 31, 2021 at an initial rate of $3,411 per month with escalating payments. The lease agreement includes an option to extend the lease for two additional periods of two years each past its initial term.

In determining the length of the lease term to its Rochester, Minnesota lease primarily due to i) the renewal rate is at future market rate to be determined and ii) Company does not have significant leasehold improvements that would restrict its ability to consider relocation. At the lease commencement date, the Company estimated the lease liability and the right of use assets at present value using the Company's estimated incremental borrowing rate of 8% and determined their initial present values, at inception, of $77,012.

On August 14, 2019, the Company entered into a lease agreement whereby the Company leased storage space in the same building as our Los Angeles, California facilities, commencing September 1, 2019, and expiring on June 30, 2021, at an initial rate of $235 per month with escalating payments. In connection with the lease, the Company paid a security deposit of $250. There is no option to extend the lease past its initial term. At the lease commencement date, the Company estimated the lease liability and the right of use assets at present value using the Company's estimated incremental borrowing rate of 8% and determined their initial present values, at inception, of $4,960.

On April 12, 2019, the Company entered into a sublease agreement whereby the Company leased approximately 4,343 square feet of office space in Westport, Connecticut commencing May 1, 2019 and expiring on October 31, 2021 at an initial rate of $18,277 per month, inclusive of a fixed utility charge, with escalating payments. In connection with the lease the Company paid a security deposit of $68,764, of which $34,382 represents the last two months of the term. There is no option to extend the lease past its initial term. At the lease commencement date, the Company estimated the lease liability and the right of use assets at present value using the Company's estimated incremental borrowing rate of 8% and determined their initial present values, at inception, of $506,276.

On October 1, 2018, the Company entered into a lease agreement whereby the Company leased office space in Norwalk, Connecticut commencing on October 1, 2018, for $2,000 per month, which expired on September 30, 2019.

On May 22, 2018, the Company entered into a fifth lease amendment agreement, whereby the Company agreed to extend the lease for the original office space and expand with additional space in Los Angeles, California, commencing June 14, 2018 and expiring on June 30, 2021 at an initial rate of $14,731 per month with escalating payments. In connection with the lease, the Company is obligated to lease parking spaces at an aggregate approximate cost of $1,070 per month. The Company has an option to extend the lease for an additional 3-year (option) term.

On April 11, 2018, the Company extended a short-term lease agreement whereby the Company leased office space in Austin, Texas commencing on August 1, 2018, for $979 per month, which expired on July 31, 2019.

In adopting ASC Topic 842, Leases (Topic 842), the Company has elected the 'package of practical expedients', which permit it not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter is not applicable to the Company. In addition, the Company elected not to apply ASC Topic 842 to arrangements with lease terms of 12 month or less. In determining the length of the lease term to its long-term lease, the Company determined not to consider an embedded 3-year option in the Los Angeles lease primarily due to i) the renewal rate is at future market rate to be determined and ii) Company does not have significant leasehold improvements that would restrict its ability to consider relocation.

At lease commencement dates, the Company estimated the lease liability and the right of use assets at present value using the Company's estimated incremental borrowing rate of 8% and determined their initial present values, at inception, of $1,007,703.

On January 1, 2019, upon adoption of ASC Topic 842, the Company recorded right to use assets of $418,838, lease liability of $422,215 and eliminated deferred rent of $3,377.

Right to use assets is summarized below:

	December 31, 2019
Los Angeles, CA, Suite 740	$ 218,875
Los Angeles, CA, Suite 745	277,592
Los Angeles, CA, Storage	4,960
Westport, CT, 54 Wilton Rd	506,276
Rochester, MN, 14 4th Street	77,012
Subtotal	1,084,715
Less accumulated depreciation	(370,373)
Right to use assets, net	$ 714,342

During the year ended December 31, 2019, the Company recorded $413,763 as lease expense to current period operations.

Lease liability is summarized below:

	December 31, 2019
Los Angeles, CA, Suite 740	$ 118,009
Los Angeles, CA, Suite 745	149,910
Los Angeles, CA, Storage	4,111
Westport, CT, 54 Wilton Rd	380,708
Rochester, MN, 14 4th Street	70,681
Total lease liability	723,419
Less: short term portion	(412,288)
Long term portion	$ 311,131

Maturity analysis under these lease agreements are as follows:

Year ended December 31, 2020	$ 455,124
Year ended December 31, 2021	321,386
Total	776,510
Less: Present value discount	(53,091)
Lease liability	$ 723,419

Lease expense for the year ended December 31, 2019 was comprised of the following:

Operating lease expense	$ 345,667
Short-term lease expense	66,422
Variable lease expense	1,674
	$ 413,763

NOTE 6 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses at December 31, 2019 and 2018 consist of the following:

	2019	2018
Accrued accounting and legal	$ 118,783	$ 59,439
Accrued reimbursements and travel	58,566	27,853
Accrued consulting	170,284	89,718
Accrued research and development expenses	230,035	351,631
Accrued product purchases	346,206	-
Accrued marketing	11,181	-
Accrued office and other	17,885	14,304
Accrued payroll	522,503	395,000
Deferred rent	-	3,377
Accrued settlement related to arbitration	13,333	13,333
	$ 1,488,776	$ 954,655

NOTE 7 – SERIES C 9% CONVERTIBLE PREFERRED STOCK

Series C 9% Convertible Preferred Stock

On January 9, 2013, the Board of Directors authorized the issuance of up to 4,200 shares of 9% Series C Convertible Preferred Stock (the "Series C Preferred Stock").

The Series C Preferred Stock is entitled to preference over holders of junior stock upon liquidation in the amount of $1,000 plus any accrued and unpaid dividends; entitled to dividends as a preference to holders of junior stock at a rate of 9% per annum of the stated value of $1,000 per share, payable quarterly beginning on September 30, 2013 and are cumulative. The holders of the Series C Preferred Stock vote together with the holders of our common stock on an as-converted basis but may not vote the Series C Preferred Stock in excess of the beneficial ownership limitation of the Series C Preferred Stock. The beneficial ownership limitation is 4.99% of our then outstanding shares of common stock following such conversion or exercise, which may be increased to up to 9.99% of our then outstanding shares of common stock following such conversion or exercise upon the request of an individual holder. The beneficial ownership limitation is determined on an individual holder basis, such that the as-converted number of shares of one holder is not included in the shares outstanding when calculating the limitation for a different holder.

In connection with the sale of the Series C preferred stock, the Company issued an aggregate of 532,251 warrants to purchase the Company's common stock at $6.53 per share expiring five years from the initial exercise date. The warrants contained full ratchet anti-dilution price protection upon the issuance of equity or equity-linked securities at an effective common stock purchase price of less than $6.53 per share as well as other customary anti-dilution protection. The warrants were exercisable for cash; or if at any time after six months from the issuance date, there was no effective registration statement registering the resale, or no current prospectus available for the resale, of the shares of common stock underlying the warrants, the warrants could be exercised by means of a "cashless exercise".

As a result of an amendment to the conversion price of our Series C Preferred Stock, pursuant to the full-ratchet anti-dilution protection provision of the warrants, the exercise price of the warrants was decreased from $6.53 per share to $3.75 per share and the aggregate number of shares issuable under the warrants was increased to 926,121. As of December 31, 2019, all issued warrants in connection with the Series C preferred stock have expired or have been exercised.

Issuances:

During the month of February 2013, the holders of previously issued convertible bridge notes converted into 600 shares of the Company's Series C Preferred Stock.

During the months of February, March, May, and July 2013, the Company sold an aggregate of 2,181 shares of the Company's Series C Preferred Stock for net proceeds of $1,814,910.

On May 11, 2015, the Company sold an aggregate of 450 shares of its Series C Preferred Stock for net proceeds of $450,000.

2019 and 2018 conversions:

In February 2018, the Company issued 3,968 shares of its common stock in exchange for 10 shares of the Company's Series C Preferred Stock and accrued dividends.

In March 2018, the Company issued 4,004 shares of its common stock in exchange for 10 shares of the Company's Series C Preferred Stock and accrued dividends.

In April 2018, the Company issued 140,408 shares of its common stock in exchange for 370 shares of the Company's Series C Preferred Stock and accrued dividends.

In May 2018, the Company issued 7,587 shares of its common stock in exchange for 20 shares of the Company's Series C Preferred Stock and accrued dividends.

In July 2018, the Company issued 36,035 shares of its common stock in exchange for 100 shares of the Company's Series C Preferred Stock and accrued dividends.

In April 2019, the Company issued 3,507 shares of its common stock in exchange for 10 shares of the Company's Series C Preferred Stock and accrued dividends.

In May 2019, the Company issued 17,138 shares of its common stock in exchange for 50 shares of the Company's Series C Preferred Stock and accrued dividends.

In June 2019, the Company issued 70,069 shares of its common stock in exchange for 200 shares of the Company's Series C Preferred Stock and accrued dividends.

In summary, the Company issued an aggregate of 90,714 shares of its common stock in exchange for 260 shares of the Company's Series C Preferred stock (stated value of $260,000) and $139,592 accrued dividends for the year ended December 31, 2019 and an aggregate of 192,002 shares of its common stock in exchange for 510 shares of the Company's Series C Preferred stock (stated value of $510,000) and $234,459 accrued dividends for the year ended December 31, 2018.

Series C Preferred Stock issued and outstanding totaled 215 and 475 as of December 31, 2019 and 2018, respectively. As of December 31, 2019, and 2018, the Company has accrued $128,478 and $242,908 dividends payable on the Series C Preferred Stock.

Registration Rights Agreement

In connection with the Company's private placement of Series C Preferred Stock and warrants, the Company entered into a registration rights agreement with the purchasers pursuant to which the Company agreed to provide certain registration rights with respect to the common stock issuable upon conversion of Series C Preferred Stock and exercise of the warrants issued to holders of Series C Preferred Stock. Specifically, the Company agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the common stock issuable upon conversion of the Series C Preferred Stock and exercise of the warrants on or before July 22, 2013 and to cause such registration statement to be declared effective by the Securities and Exchange Commission, in the event that the registration statement is not reviewed by the Securities and Exchange Commission, within five trading days after the Company is notified that registration statement is not being reviewed by the Securities and Exchange Commission, and by November 22, 2013 in the event that the registration statement is reviewed by the Securities and Exchange Commission and the Securities and Exchange Commission issues comments.

If (i) the registration statement is not filed by July 22, 2013, (ii) the registration statement is not declared effective by the Securities and Exchange Commission within five trading days after the Company is notified that the registration statement is not being reviewed by the Securities and Exchange Commission, in the case of a no review, (iii) the registration statement is not declared effective by the Securities and Exchange Commission by November 22, 2013 in the case of a review by the Securities and Exchange Commission pursuant to which the Securities and Exchange Commission issues comments or (iv) the registration statement ceases to remain continuously effective for more than 20 consecutive calendar days or more than an aggregate of 45 calendar days during any 12-month period after its first effective date, then the Company is subject to liquidated damage payments to the holders of the shares sold in the private placement in an amount equal to 0.25% of the aggregate purchase price paid by such purchasers per month of delinquency.

Notwithstanding the foregoing, (i) the maximum aggregate liquidated damages due under the registration rights agreement shall be 3% of the aggregate purchase price paid by the purchasers, and (ii) if any partial amount of liquidated damages remains unpaid for more than seven days, the Company shall pay interest of 18% per annum, accruing daily, on such unpaid amount.

Pursuant to the registration rights agreement, the Company must maintain the effectiveness of the registration statement from the effective date until the date on which all securities registered under the registration statement have been sold, or are otherwise able to be sold pursuant to Rule 144 without volume or manner-of-sale restrictions, subject to the right to suspend or defer the use of the registration statement in certain events.

The Company filed a registration statement on July 22, 2013, which was originally declared effective on June 23, 2014. At December 31, 2019 and 2018, the Company estimated the liability at $-0-.

NOTE 8 – WARRANT AND DERIVATIVE LIABILITIES

Series C 9% Convertible Preferred Stock and related warrants

At the time of issuance and until March 31, 2015, the Company determined that the anti-dilutive provisions embedded in the Series C Preferred Stock and related warrants (see Note 6) did not meet the defined criteria of a derivative in such that the net settlement requirement of delivery of common shares does not meet the "readily convertible to cash" as described in Accounting Standards Codification 815 and therefore bifurcation was not required. There was no established market for the Company's common stock. As of March 31, 2015, the Company determined a market had been established for the Company's common stock and accordingly, reclassified from equity to liability treatment the fair value of the embedded reset provisions of the Series C Preferred Stock and warrants of $1,242,590 and $4,097,444, respectively.

The Company valued the reset provisions of the Series C Preferred Stock and warrants in accordance with ASC 470-20 using the Multinomial Lattice pricing model and the following assumptions: estimated contractual terms, a risk free interest rate of 0.56% to 0.89%, a dividend yield of 0%, and volatility of 141%.

Series D Convertible Preferred Stock and related warrants

At issuance, the Company determined that certain anti-dilutive provisions embedded in the Series D Preferred Stock and related warrants (see Note 9) met the defined criteria of a derivative and accordingly, reclassified from equity to liability the determined fair value of the embedded reset provisions of the Series D Preferred Stock and warrants of $397,162 and $652,054, respectively.

The Company valued the reset provisions of the Series D Preferred Stock and warrants in accordance with ASC 470-20 using the Multinomial Lattice pricing model and the following assumptions: estimated contractual terms, a risk free interest rate of 1.74%, a dividend yield of 0%, and volatility of 130%.

At December 31, 2017, the Company marked to market the fair value of the reset provisions of the Preferred Stock and warrants and determined fair values of $685,922 and $2,358,240, respectively. The fair values of the embedded derivatives were determined using the Multinomial Lattice pricing model and the following assumptions: estimated contractual term of 1.43 to 3.36 years, a risk-free interest rate of 1.39% to 1.89%, a dividend yield of 0%, and volatility of 131%.

On January 1, 2018, the Company adopted ASU 2017-11 and accordingly reclassified the fair value of the reset provisions embedded in previously issued Series C Preferred stock, Series D Preferred stock and certain warrants with embedded anti-dilutive provisions from liability to equity in aggregate of $3,044,162.

NOTE 9 – STOCKHOLDER EQUITY

Preferred stock

The Company is authorized to issue 1,000,000 shares of $0.001 par value preferred stock. As of December 31, 2019, and 2018, the Company has authorized 200 shares of Series A preferred stock, 600 shares of Series B preferred stock, 4,200 shares of Series C Preferred Stock, 1,400 shares of Series D Preferred Stock and 1,000 shares of Series E Preferred Stock. As of December 31, 2019, and December 31, 2018, there were no outstanding shares of Series A, Series B, Series D and Series E preferred stock.

Series C Preferred Stock

In February 2018, the Company issued 3,968 shares of its common stock in exchange for 10 shares of the Company's Series C Preferred Stock and accrued dividends.

In March 2018, the Company issued 4,004 shares of its common stock in exchange for 10 shares of the Company's Series C Preferred Stock and accrued dividends.

In April 2018, the Company issued 140,408 shares of its common stock in exchange for 370 shares of the Company's Series C Preferred Stock and accrued dividends.

In May 2018, the Company issued 7,587 shares of its common stock in exchange for 20 shares of the Company's Series C Preferred Stock and accrued dividends.

In July 2018, the Company issued 36,035 shares of its common stock in exchange for 100 shares of the Company's Series C Preferred Stock and accrued dividends.

In April 2019, the Company issued 3,507 shares of its common stock in exchange for 10 shares of the Company's Series C Preferred Stock and accrued dividends.

In May 2019, the Company issued 17,138 shares of its common stock in exchange for 50 shares of the Company's Series C Preferred Stock and accrued dividends.

In June 2019, the Company issued 70,069 shares of its common stock in exchange for 200 shares of the Company's Series C Preferred Stock and accrued dividends.

Cumulatively from January 1, 2019 to December 31, 2019, the Company exchanged 260 shares of the Company's Series C Preferred Stock and dividends with a recorded value of $399,592 for 90,714 shares of common stock.

Series D Preferred Stock

On November 3, 2017, the Board of Directors authorized the issuance of up to 1,400 shares of Series D Convertible Preferred Stock (the "Series D Preferred Stock") and accordingly, the Company filed the Certificate of Designations for the Series D Preferred Stock with the Secretary of State of the State of Delaware. Pursuant to such Certificate of Designations, in the event of the Company's liquidation or winding up of its affairs, the holders of Preferred Shares will be entitled to a liquidation preference of the stated value per Preferred Share of $1,500 (the "Stated Value") plus any accrued but unpaid dividends or any other fees due the holder.

A holder of Preferred Shares was entitled at any time to convert any whole or partial number of shares of Preferred Shares into shares of Common Stock determined by dividing the Stated Value of the Preferred Shares being converted by the conversion price of $3.75 per share (the "Conversion Price"). The Conversion Price was subject to "full ratchet" anti-dilution price protection upon the issuance of equity or equity-linked securities at a price lower than the Conversion Price as well as other customary anti-dilution protection.

A holder of the Preferred Shares was entitled to receive cumulative dividends at the rate per Preferred Share (as a percentage of the Stated Value per Preferred Share) of 9% per annum, with respect to the Series D Preferred Stock on each date that such Holder converts Preferred Shares into Common Stock (with respect only to Preferred Shares being converted). The Company coud have paid such dividends, at its option, in cash, Common Stock or a combination thereof. Payment of dividends in shares of Common Stock was subject to the satisfaction of certain equity conditions set forth in the Certificate of Designations. Upon the conversion of Preferred Shares prior to November 3, 2020, the Company was to also pay to the Holders of the Preferred Shares so converted cash, or at the Company's option, Common Stock or a combination thereof, with respect to the Preferred Shares so converted in an amount equal to $270 per $1,000 of Stated Value of the Preferred Shares being converted, less the amount of all prior dividends paid on such converted Preferred Shares before the relevant date of conversion.

On November 3, 2017, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional accredited investors (the "Investors"), pursuant to which the Company sold an aggregate of 1,334 shares (the "Preferred Shares") of its Series D Preferred Stock, par value $0.001 per share, and Class A Warrants to purchase an aggregate of 266,800 shares of the Company's common stock, par value $0.001 per share at an exercise price of $4.375 per share (the "Class A Warrants"), in exchange for aggregate net cash proceeds of $1,929,960, net of expenses of $70,040. Contemporaneously with the entry into the Purchase Agreement, the Company and the Purchasers agreed to exchange outstanding warrants to purchase 312,203 shares of the Common Stock at an exercise price of $3.75 per share for new Class B Warrants to purchase an equal number of shares of common stock at the same exercise price (the "Class B Warrants"). Class A Warrants are exercisable immediately and expire on May 3, 2021, and have an exercise price of $4.375 per share. The Class B Warrants are exercisable immediately and expire on November 3, 2020, and have an exercise price of $3.75. The Class A Warrants and Class B Warrants otherwise have similar terms, including, a "full ratchet" anti-dilution adjustment in the event that the Company issues any common stock at a per share price lower than the applicable exercise price then in effect.

On November 6, 2017, the terms of the Class A Warrants automatically adjusted due to the full-ratchet anti-dilution protection provision contained in such warrants. As a result of the adjustment, the exercise price applicable to the Class A Warrants decreased to $3.75 per share from $4.375 per share, and the number of shares issuable under each warrant was increased such that the aggregate exercise price payable under such warrant, after taking into account the decrease in the exercise price, is equal to the aggregate exercise price prior to such adjustment. An additional 44,467 shares of common stock may be issued upon exercise of the Class A Warrants due to the adjustment.

In connection with the Company's private placement of Series D Preferred Stock and warrants, the Company entered into a registration rights agreement with the purchasers pursuant to which the Company agreed to provide certain registration rights with respect to the common stock issuable upon conversion of Series D Preferred Stock and exercise of the warrants issued to holders of Series D Preferred Stock. Specifically, the Company agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the common stock issuable upon conversion of the Series D Preferred Stock and exercise of the warrants on or before December 18, 2017 and to cause such registration statement to be declared effective by the Securities and Exchange Commission, in the event that the registration statement is not reviewed by the Securities and Exchange Commission, within five trading days after the Company is notified that registration statement is not being reviewed by the Securities and Exchange Commission, and by March 18, 2018 in the event that the registration statement is reviewed by the Securities and Exchange Commission and the Securities and Exchange Commission issues comments. On December 18, 2017, the Company filed the required registration statement and on December 29, 2017 was declared effective. The Company has estimated the liability under the registration rights agreement at $-0- as of December 31, 2018.

2018 Conversions:

In January 2018, the Company issued an aggregate of 94,364 shares of its common stock in exchange for 180 shares of the Company's Series D Preferred Stock and accrued dividends.

In February 2018, the Company issued an aggregate of 52,573 shares of its common stock in exchange for 100 shares of the Company's Series D Preferred Stock and accrued dividends.

In March 2018, the Company issued an aggregate of 195,692 shares of its common stock in exchange for 367 shares of the Company's Series D Preferred Stock and accrued dividends.

In April 2018, the Company issued an aggregate of 230,936 shares of its common stock in exchange for 454 shares of the Company's Series D Preferred Stock and accrued dividends.

In May 2018, the Company issued an aggregate of 104,684 shares of its common stock in exchange for 206 shares of the Company's Series D Preferred Stock and accrued dividends.

In June 2018, the Company issued an aggregate of 13,716 shares of its common stock in exchange for 27 shares of the Company's Series D Preferred Stock and accrued dividends.

In summary, the Company issued an aggregate of 691,965 shares of its common stock in exchange for 1,334 shares of the Company's Series D Preferred stock (stated value of $2,001,000) and $540,271 accrued dividends for the year ended December 31, 2018.

As of December 31, 2019, and 2018, the Company had 0 Series D Preferred Stock issued and outstanding and has accrued $0 dividends payable on the Series D Preferred stock.

Series E Preferred Stock

On February 1, 2018, the Board of Directors authorized the issuance of up to 1,000 shares of Series E Convertible Preferred Stock (the "Series E Preferred Stock") and accordingly, the Company filed the Certificate of Designations for the Series E Preferred Stock with the Secretary of State of the State of Delaware. Pursuant to such Certificate of Designations, in the event of the Company's liquidation or winding up of its affairs, the holders of Preferred Shares were entitled to a liquidation preference of the stated value per Preferred Share of $1,500 (the "Stated Value") plus any accrued but unpaid dividends or any other fees due the holder.

A holder of Preferred Shares was entitled at any time to convert any whole or partial number of shares of Preferred Shares into shares of Common Stock determined by dividing the Stated Value of the Preferred Shares being converted by the conversion price of $3.75 per share (the "Conversion Price"). The Conversion Price was subject to "full ratchet" anti-dilution price protection upon the issuance of equity or equity-linked securities at a price lower than the Conversion Price as well as other customary anti-dilution protection.

A holder of the Preferred Shares was entitled to receive cumulative dividends at the rate per Preferred Share (as a percentage of the Stated Value per Preferred Share) of 7% per annum, with respect to the Series E Preferred Stock on each date that such Holder converts Preferred Shares into Common stock (with respect only to Preferred Shares being converted). The Company could have paid such dividends, at its option, in cash, Common Stock or a combination thereof. Payment of dividends in shares of Common Stock is subject to the satisfaction of certain equity conditions set forth in the Certificate of Designations. Upon the conversion of Preferred Shares prior to issuance, the Company was to also pay to the Holders of the Preferred Shares so converted cash, or at the Company's option, Common Stock or a combination thereof, with respect to the Preferred Shares so converted in an amount equal to $210 per $1,000 of Stated Value of the Preferred Shares being converted, less the amount of all prior dividends paid on such converted Preferred Shares before the relevant date of conversion.

On February 16, 2018, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional accredited investors (the "Investors"), pursuant to which the Company sold to the Investors an aggregate of 1,000 shares (the "Preferred Shares") of its Series E Preferred Stock, par value $0.001 per share, and warrants to purchase an aggregate of 200,000 shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an exercise price of $3.75 per share (the "Warrants"), in exchange for aggregate consideration of $1,492,969, net of transaction expenses of $7,031 (the "Transaction").

The Purchase Agreement contains representations and warranties of the Company and the Investors that are typical for transactions of this type. The Purchase Agreement also contains covenants on the part of the Company that are typical for transactions of this type. For a period of twelve months after the closing date of Transaction, the Investors are entitled to a right of first refusal (the "ROFR") with respect to subsequent sales of securities by the Company (other than with respect to issuances of Excluded Securities (as defined in the Purchase Agreement)) Pursuant to the ROFR, each Investor will have the opportunity to elect to purchase its pro rata portion of thirty percent (30%) of any securities being offered by the Company in the subsequent offering.

In connection with the entry into the Purchase Agreement, the Investors and the Company also entered into a registration rights agreement (the "Registration Rights Agreement") whereby the Company agreed to file a registration statement with the Securities and Exchange Commission (the "SEC") within 90 days of the closing of the transactions contemplated by the Purchase Agreement (the "Filing Date") covering the resale of (a) all shares of Common Stock Issuable upon conversion of the Preferred Shares, (b) all shares of Common Stock issuable upon exercise of the Warrants, (c) all other shares of Common Stock issued pursuant to any transaction documents which have been, or which may, from time to time be issued or become issuable to the Investors under the Transaction Documents (without regard to any limitation or restriction on purchases), and (d) any securities issued or then issuable upon any stock split, dividend or other distribution, recapitalization or similar event ("Registrable Securities"), not then registered.

The Company will use its reasonable best efforts to keep the registrations statement effective pursuant to Rule 415 under the Securities Act until the earlier of (i) the date on which the Investors shall have sold all the Registrable Securities covered thereby and (ii) that date that all Registrable Securities may be sold pursuant to Rule 144 without any public information requirement or volume or manner of sale limitations.

The Warrants are exercisable immediately and expire on August 16, 2021 and have an exercise price of $4.38 per share. The Warrants include a "full ratchet" anti-dilution adjustment in the event that the Company issues any common stock or common stock equivalent at a per share price lower than the applicable exercise price then in effect.

As a result of sale of the Company's common stock in April 2018, the full-ratchet anti-dilution protection provision of the warrants decreased the exercise price of the warrants from $4.38 per share to $3.75 per share and increased the aggregate number of shares issuable under the warrants from 200,000 to 233,334.

In connection with its entry into the Purchase Agreement, on February 14, 2018, the Company entered into a consent agreement (the "Consent") with the holders of the Company's Series D Convertible Preferred Stock (the "Series D Holders"). Pursuant to the Consent, the Series D Holders consented to the Transaction and are entitled at any time on or before April 17, 2018, to elect to receive the more favorable terms of the Transaction. In consideration for their entry into the Consent, the Company issued to the Series D Holders warrants to purchase up to an aggregate of 40,000 shares of Common Stock (the "Consent Warrants"). The Consent Warrants are exercisable immediately and expire on February 14, 2021 and have an exercise price of $3.75 per share. The Consent Warrants include a "full ratchet" anti-dilution adjustment in the event that the Company issues any common stock or common stock equivalent at a per share price lower than the applicable exercise price then in effect.

2018 Conversions:

In August 2018, the Company issued an aggregate of 141,852 shares of its common stock in exchange for 307 shares of the Company's Series E Preferred Stock and accrued dividends.

In September 2018, the Company issued an aggregate of 150,504 shares of its common stock in exchange for 318 shares of the Company's Series E Preferred Stock and accrued dividends.

In November 2018, the Company issued an aggregate of 184,920 shares of its common stock in exchange for 375 shares of the Company's Series E Preferred Stock and accrued dividends.

In summary, the Company issued an aggregate of 477,276 shares of its common stock in exchange for 1,000 shares of the Company's Series E Preferred stock (stated value of $1,500,000) and $315,000 accrued dividends for the year ended December 31, 2018.

As of December 31, 2019, and 2018, the Company had 0 Series E Preferred Stock issued and outstanding and has accrued $0 dividends payable on the Series E Preferred stock.

Common stock

On September 10, 2018, the Company amended its Articles of Incorporation to implement a reverse stock split in the ratio of 1 share for every 2.5 shares of common stock. No fractional shares were issued from such aggregation of common stock, upon the reverse split; any fractional share was rounded up and converted to the nearest whole share of common stock. As a result, 40,333,758 of the Company's common stock were exchanged for 16,133,544 of the Company's common stock resulting in the transfer of $24,200 from common stock to additional paid in capital. These consolidated financial statements have been retroactively restated to reflect the reverse stock split.

The Company is authorized to issue 200,000,000 shares of $0.001 par value common stock. As of December 31, 2019 and 2018, the Company had 23,323,087 and 16,868,783 shares issued and outstanding, respectively.

During the year ended December 31, 2018, the Company issued 897,050 shares of its common stock for services totaling $4,243,345 ($4.730 per share).

During the year ended December 31, 2018, the Company entered into securities purchase agreements with investors pursuant to which the Company issued 2,115,078 shares of common stock and 1,090,040 warrants for aggregate proceeds of $9,139,721.

During the year ended December 31, 2018, the Company issued 8,000 shares of common stock and 4,000 warrants for a previously received common stock subscription of $29,985.

During the year ended December 31, 2018, the Company issued 583,328 shares of common stock in exchange for proceeds of $2,217,397 from the exercise of warrants.

During the year ended December 31, 2018, the Company issued 35,601 shares of common stock in exchange for the exercise of 187,389 cashless exercises of warrants.

During the year ended December 31, 2018, the Company issued 140,001 shares of common stock in exchange for proceeds of $615,600 from the exercise of options.

During the year ended December 31, 2019, the Company issued an aggregate of 1,558,317 shares of its common stock for services totaling $9,675,328 ($6.21 per share).

During the year ended December 31, 2019, the Company issued an aggregate of 113,332 shares of its common stock for vested restricted stock units as stock-based compensation.

On March 14, 2019, the Company entered into securities purchase agreements with investors pursuant to which the Company issued 2,155,127 shares of common stock for aggregate proceeds of $8,619,278, net of $1,230 in expenses.

On December 31, 2019, the Company entered into securities purchase agreements with investors pursuant to which the Company issued 231,335 shares of common stock for aggregate proceeds of $1,387,910, net of $100 in expenses.

During the year ended December 31, 2019, the Company issued 1,860,479 shares of common stock in exchange for proceeds of $7,470,807 from the exercise of warrants.

During the year ended December 31, 2019, the Company issued 162,592 shares of common stock in exchange for the exercise of 309,926 cashless exercises of warrants.

During the year ended December 31, 2019, the Company issued 189,620 shares of common stock in exchange for proceeds of $938,034 from the exercise of options.

During the year ended December 31, 2019, the Company issued 92,788 shares of common stock in exchange for the exercise of 360,457 cashless exercises of options.

During the year ended December 31, 2019, NeuroClear, a previous wholly-owned subsidiary, sold 739,000 shares of its common stock ("Subsidiary Stock") for net proceeds of $3,694,645 ($5.00 per share). In connection with the sale, the Company provided that in the event that (i) the Subsidiary Stock is not listed on a national securities exchange by October 31, 2020, or (ii) a change of control, as defined in the stock purchase agreement, of NeuroClear occurs, whichever is earlier, at the option of the holder of Subsidiary Stock, each share of Subsidiary Stock may be exchanged into 0.9 of a share of common stock of the Company.

During the year ended December 31, 2019, NeuroClear, a previous wholly-owned subsidiary, sold 157,690 shares of Subsidiary Stock for net proceeds of $1,316,664 ($8.35 per share). In connection with the sale, the Company provided that in the event that (i) the Subsidiary Stock is not listed on a national securities exchange by October 31, 2020, or (ii) a change of control, as defined in the stock purchase agreement, of NeuroClear occurs, whichever is earlier, at the option of the holder of Subsidiary Stock, each share of Subsidiary Stock may be exchanged into 1.1 of a share of common stock of the Company.

In connection with certain Company securities purchase agreements described above, the Company entered into registration rights agreements with the purchasers in such private placements pursuant to which the Company agreed to provide certain registration rights with respect to the common stock issued to the investors participating in such private placements and the common stock issuable upon exercise of the related warrants issued such investors.

Specifically, the Company agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the shares of common stock issued pursuant to the private placement and issuable upon the exercise of the warrants within 45 days of the termination date of such private placement and to cause such registration statement to be declared effective by the Securities and Exchange Commission, in the event that the registration statement is not reviewed by the Securities and Exchange Commission, within 30 calendar days after the Company is notified that registration statement is not being reviewed by the Securities and Exchange Commission, and within 180 calendar days of the initial filing date of the registration statement in the event that the registration statement is reviewed by the Securities and Exchange Commission and the Securities and Exchange Commission issues comments.

If (i) the registration statement is not filed within 45 days of the applicable termination date, (ii) the registration statement is not declared effective by the Securities and Exchange Commission within 30 calendar days after the Company is notified that registration statement is not being reviewed by the Securities and Exchange Commission, in the case of a no review, (iii) the registration statement is not declared effective by the Securities and Exchange Commission within 180 calendar days of the initial filing date of the registration statement in the case of a review by the Securities and Exchange Commission pursuant to which the Securities and Exchange Commission issues comments or (iv) the registration statement ceases to remain continuously effective for more than 10 consecutive calendar days or more than an aggregate of 15 calendar days during any 12-month period after its first effective date, then the Company is subject to liquidated damage payments to the holders of the shares sold in the private placement in an amount equal to 1.0% of the aggregate purchase price paid by such purchasers per month of delinquency, provided, however, that the Company will not be required to make any payments any of the foregoing events occurred at such time that all securities registered or to be registered in the registration statement are eligible for resale pursuant to Rule 144 (without volume restrictions or current public information requirements) promulgated by the Securities and Exchange Commission pursuant to the Securities Act of 1933, as amended and provided, further, that the Company will not be required to make any liquidated damage payments with respect to any securities registered or to be registered in the registration statement that the Company is unable to register due to limits imposed by the Securities and Exchange Commission's interpretation of Rule 415 under the Securities Act of 1933, as amended.

Notwithstanding the foregoing, (i) the maximum aggregate liquidated damages due under the registration rights agreements shall be 3% to 6% of the aggregate purchase price paid by the purchasers and (iii) if any partial amount of liquidated damages remains unpaid for more than seven days, the Company shall pay interest of 18% per annum, accruing daily, on such unpaid amount.

Pursuant to the registration rights agreements, the Company must maintain the effectiveness of the registration statement from the effective date until the date on which all securities registered under the registration statement have been sold, or are otherwise able to be sold pursuant to Rule 144 without volume or manner-of-sale restrictions, subject to the right to suspend or defer the use of the registration statement in certain events.

The Company filed registration statements, which was declared effective to satisfy the requirements under the registration rights agreements with the purchasers of its common stock and warrants prior to April 6, 2017. The final closing under the April 6, 2017 Private Placement occurred on December 31, 2017. On February 28, 2018, the Company filed the required registration statement and on March 26, 2018 was declared effective. The Company has estimated the liability under the registration rights agreement at $-0- as of December 31, 2019 and 2018.

On November 3, 2017, in connection with the Company's private placement of Series D Preferred Stock and warrants, the Company entered into a registration rights agreement with the purchasers pursuant to which the Company agreed to provide certain registration rights with respect to the common stock issuable upon conversion of Series D Preferred Stock and exercise of the warrants issued to holders of Series D Preferred Stock. On December 18, 2017, the Company filed the required registration statement and on December 29, 2017 was declared effective. The Company has estimated the liability under the registration rights agreement at $-0- as of December 31, 2019 and 2018.

On February 16, 2018, in connection with the Company's private placement of Series E Preferred Stock and warrants, the Company also entered into a registration rights agreement (the "Registration Rights Agreement") whereby the Company agreed to file a registration statement with the Securities and Exchange Commission (the "SEC") within 90 days of the closing of the transactions contemplated by the Purchase Agreement (the "Filing Date") covering the resale of (a) all shares of Common Stock Issuable upon conversion of the Preferred Shares, (b) all shares of Common Stock issuable upon exercise of the Warrants, (c) all other shares of Common Stock issued pursuant to any transaction documents which have been, or which may, from time to time be issued or become issuable to the Investors under the Transaction Documents (without regard to any limitation or restriction on purchases), and (d) any securities issued or then issuable upon any stock split, dividend or other distribution, recapitalization or similar event ("Registrable Securities"), not then registered.

On May 16, 2018, the Company filed the required registration statement. The Company has estimated the liability under the registration rights agreement at $-0- as of December 31, 2019.

NOTE 10 – OPTIONS, RESTRICTED STOCK UNITS AND WARRANTS

BioSig Technologies, Inc.

2012 Equity Incentive Plan

On October 19, 2012, the Company's Board of Directors approved the 2012 Equity Incentive Plan ("the "Plan") and terminated the Long-Term Incentive Plan (the "2011 Plan"). The Plan provides for the issuance of options, stock appreciation rights, restricted stock and restricted stock units to purchase up to 9,474,450 (as amended) shares of the Company's common stock to officers, directors, employees and consultants of the Company (as amended). Under the terms of the Plan the Company may issue Incentive Stock Options as defined by the Internal Revenue Code to employees of the Company only and nonstatutory options. The Board of Directors of the Company or a committee thereof administers the Plan and determines the exercise price, vesting and expiration period of the grants under the Plan.

However, the exercise price of an Incentive Stock Option should not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more stockholder and 100% of fair value for a grantee who is not 10% stockholder. The fair value of the common stock is determined based on the quoted market price or in absence of such quoted market price, by the administrator in good faith.

Additionally, the vesting period of the grants under the Plan will be determined by the administrator, in its sole discretion, with an expiration period of not more than ten years. The Company reserved 1,303,951 shares of its common stock for future issuance under the terms of the Plan.

During the year ended December 31, 2018, the Company granted an aggregate of 559,698 options to officers, directors and key consultants.

During the year ended December 31, 2018, the Company granted an aggregate of 897,050 stock grants to officers, employees and key consultants under the plan. See Note 9.

During the year ended December 31, 2019, the Company granted an aggregate of 1,599,053 options to officers, directors and key consultants.

During the year ended December 31, 2019, the Company granted an aggregate of 1,558,317 stock grants to officers, employees and key consultants under the plan. See Note 9.

Options

The following table presents information related to stock options at December 31, 2019:

Options Outstanding			Options Exercisable
Exercise Price	Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$ 2.51-5.00	1,533,361	7.7	$ 1,168,361
5.01-7.50	2,124,110	5.1	1,552,044
7.51-10.00	323,333	8.0	153,612
	3,980,804	6.3	2,874,017

A summary of the stock option activity and related information for the 2012 Plan for the years ended December 31, 2019 and 2018 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2018	3,404,131	$ 5.28	5.7	$ -
Grants	559,698	$ 4.65	10.0	$ -
Exercised	(140,001)	$ 4.40	-	-
Canceled	(688,000)	$ 4.64		-
Outstanding at December 31, 2018	3,135,828	$ 5.34	5.2	$ -
Grants	1,599,053	5.99	10.0	$ -
Exercised	(550,077)	$ 5.44		
Canceled	(204,000)	$ 5.51		
Outstanding at December 31, 2019	3,980,804	$ 5.58	6.3	$ 3,130,791
Exercisable at December 31, 2019	2,874,017	$ 5.47	5.1	$ 2,469,138

The aggregate intrinsic value in the preceding tables represents the total pretax intrinsic value, based on options with an exercise price less than the Company's stock price of $5.92 as of December 31, 2019, which would have been received by the option holders had those option holders exercised their options as of that date.

Option valuation models require the input of highly subjective assumptions. The fair value of stock-based payment awards was estimated using the Black-Scholes option model with a volatility figure derived using the Company's own historical stock prices. The Company accounts for the expected life of options based on the contractual life of options for non-employees.

For employees, the Company accounts for the expected life of options in accordance with the "simplified" method, which is used for "plain-vanilla" options, as defined in the accounting standards codification. The risk-free interest rate was determined from the implied yields of U.S. Treasury zero-coupon bonds with a remaining life consistent with the expected term of the options. The fair value of stock-based payment awards during the years ended December 31, 2019 and 2018 was estimated using the Black-Scholes pricing model.

On February 15, 2018, the Company granted 20,000 options to purchase the Company stock in connection with the services rendered at the exercise price of $3.55 per share for a term of ten years with vesting immediately.

On May 4, 2018, the Company granted 226,000 options to purchase the Company stock in connection with the services rendered at the exercise price of $4.43 per share for a term of ten years with vesting immediately.

On May 14, 2018, the Company granted 100,000 options to purchase the Company stock in connection with the services rendered at the exercise price of $4.43 per share for a term of ten years with vesting immediately.

On October 16, 2018, the Company granted 34,566 options to purchase the Company stock in connection with the services rendered at the exercise price of $5.09 per share for a term of ten years with 17,283 vesting immediately and 17,283 vesting January 1, 2019.

On October 16, 2018, the Company granted 69,132 options to purchase the Company stock in connection with the services rendered at the exercise price of $5.09 per share for a term of ten years with 17,283 vesting immediately and 17,283 vesting January 1, 2019, 17,283 vesting January 1, 2020 and 17,283 vesting January 1, 2021.

On October 16, 2018, the Company granted 110,000 options to purchase the Company stock in connection with the services rendered at the exercise price of $5.09 per share for a term of ten years vesting immediately.

The following assumptions were used in determining the fair value of employee options for the year ended December 31, 2018:

Risk-free interest rate		2.65% to 3.16%
Dividend yield		0%
Stock price volatility		92.08% to 94.10%
Expected life		5 to 10 years
Weighted average grant date fair value	$	3.37

On January 22, 2019, the Company granted 460,000 options to purchase the Company stock in connection with the services rendered at the exercise price of $4.33 per share for a term of ten years with quarterly vesting beginning April 1, 2019 for three years.

On March 14, 2019, the Company granted 345,000 options to purchase the Company stock in connection with the services rendered at the exercise price of $6.66 per share for a term of ten years with 20,000 options vesting on March 14, 2020, 175,000 options vesting quarterly beginning April 1, 2019 for three years and 150,000 options vesting one third on anniversary for three years.

On July 2, 2019, the Company granted 158,333 options to purchase the Company stock in connection with the services rendered at the exercise price of $9.056 per share for a term of ten years with 133,333 options vesting quarterly beginning September 30, 2019 for three years, and 25,000 vesting as follows: 1/6th on vesting date, then remaining options quarterly vesting beginning September 30, 2019 for three years.

On October 8, 2019, the Company granted 45,000 options to purchase the Company stock in connection with the services rendered at the exercise price of $8.00 per share for a term of ten years with quarterly vesting beginning December 31, 2019 for three years.

On October 30, 2019, the Company granted 195,720 options to purchase the Company stock in connection with the services rendered at the exercise price of $7.15 per share for a term of ten years vesting immediately.

On December 27, 2019, the Company granted 395,000 options to purchase the Company stock in connection with the services rendered at the exercise price of $6.16 per share for a term of ten years with 15,000 vesting immediately and 380,000 vesting quarterly beginning March 31, 2020 for three years.

The following assumptions were used in determining the fair value of employee options for the year ended December 31, 2019:

Risk-free interest rate		1.45% to 2.74%
Dividend yield		0%
Stock price volatility		86.74% to 91.55%
Expected life		5 to 10 years
Weighted average grant date fair value	$	5.75

On May 17, 2019, in connection with the retirement of two members of the Company's board of directors, the Company extended the life of 628,905 previously issued director options from the contractual 90 days from termination of service to the earlier of the initial life up or May 17, 2021. The change in estimated fair value of the modified options of $666,062 was charged to current period operations.

The following assumptions were used in determining the change in fair value of the modified options at May 17, 2019:

Risk-free interest rate	2.33% - 2.40%
Dividend yield	0%
Stock price volatility	89.97%
Expected life	0.12– 2 years

The fair value of all options vesting during the year ended December 31, 2019 and 2018 of $2,165,810 and $2,357,242, respectively, was charged to current period operations. Unrecognized compensation expense of $4,513,290 and $173,446 at December 31, 2019 and 2018, respectively, will be expensed in future periods.

Restricted Stock

The following table summarizes the restricted stock activity for the two years ended December 31, 2019:

Restricted shares issued as of January 1, 2018	-
Granted	-
Vested	-
Total restricted shares issued as of December 31, 2018	-
Granted	376,000
Vested	(113,332)
Vested restricted shares as of December 31, 2019	25,000
Unvested restricted shares as of December 31, 2019	262,668

On February 28, 2019, the Company granted an aggregate of 70,000 restricted stock grants for services with 23,332 vested immediately; 23,334 vesting at one-year anniversary and 23,334 vesting at two-year anniversary.

On March 20, 2019, the Company granted an aggregate of 120,000 restricted stock grants for services vesting quarterly beginning on April 1, 2019 over one year.

On June 21, 2019, the Company granted 50,000 restricted stock units for services with 25,000 vesting at one-year anniversary and 25,000 at two-year anniversary.

On August 7, 2019, the Company granted 40,000 restricted stock grants for services vesting at one-year anniversary.

On September 24, 2019, the Company granted 40,000 restricted stock grants for services with 20,000 vesting at one-year anniversary and 20,000 at two-year anniversary.

On December 12, 2019, the Company granted 6,000 restricted stock grants for services with 3,000 vesting on February 2, 2020 and 3,000 on May 2, 2020.

On December 26, 2019, the Company granted 50,000 restricted stock grants for services with 25,000 vesting immediately and 25,000 on June 30, 2020.

Stock based compensation expense related to restricted stock grants was $1,586,736 and $0 for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, the stock-based compensation relating to restricted stock of $1,017,983 remains unamortized.

NeuroClear Technologies, Inc.

2019 Long-Term Incentive Plan

On September 24, 2019, NeuroClear Technologies, Inc.'s Board of Directors approved the 2019 Long-Term Incentive Plan (the "NeuroClear Plan"), subject to NeuroClear's stockholders. The Plan provides for the issuance of options, stock appreciation rights, restricted stock and restricted stock units to purchase up to 1,750,000 shares of NeuroClear's common stock to officers, directors, employees and consultants of the NeuroClear. Under the terms of the Plan, NeuroClear may issue Incentive Stock Options as defined by the Internal Revenue Code to employees of NeuroClear only and nonstatutory options. The Board of Directors of NeuroClear or a committee thereof administers the Plan and determines the exercise price, vesting and expiration period of the grants under the Plan.

However, the exercise price of an Incentive Stock Option should not be less than 110% of fair market value of the common stock at the date of the grant for a 10% or more stockholder and 100% of fair market value for a grantee who is not 10% stockholder. The fair market value of the common stock is determined based on the quoted market price or in absence of such quoted market price, by the administrator in good faith.

Additionally, the vesting period of the grants under the NeuroClear Plan will be determined by the administrator, in its sole discretion, with an expiration period of not more than ten years.

NeuroClear Options

On October 11, 2019, the Company granted 575,000 options to purchase NeuroClear common stock in connection with services rendered at an exercise price of $5.00 per share, for a term of 10 years, vesting immediately.

The fair value of the stock-based payment awards was estimated using the Black-Scholes option model with a volatility figure derived from an index of historical stock prices of comparable entities with the market value of stock price based on recent sales. The Company accounts for the expected life of options in accordance with the "simplified" method, which is used for "plain-vanilla" options, as defined in the accounting standards codification. The risk-free interest rate was determined from the implied yields of U.S. Treasury zero-coupon bonds with a remaining life consistent with the expected term of the options.

The following assumptions were used in determining the change in fair value of the NeuroClear options at October 11, 2019:

Risk-free interest rate	1.56%
Dividend yield	0%
Stock price volatility	71.0%
Expected life	5 years

The fair value of the granted NeuroClear options of $1,696,250 was charged to current period operations.

Restricted stock units (NeuroClear)

On September 24, 2019, the Company granted 40,000 restricted stock units for services vesting monthly over one year.

Stock based compensation expense related to restricted stock unit grants of NeuroClear was $53,552 and $0 for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, the stock-based compensation relating to restricted stock of $146,448 remains unamortized.

Warrants

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at December 31, 2019:

Exercise Price	Number Outstanding	Expiration Date
$ 0.0025	153,328	January 2020
$ 3.75	715,844	February 2020 to January 2021
$ 4.375	602,272	April 2021 to May 2021
$ 4.60	9,167	January 2020
$ 5.05	8,566	January 2020
$ 6.16	568,910	November 2027
$ 6.85	205,523	July 2021 to August 2021
$ 9.375	481,108	March 2020
	2,744,718	

On January 5, 2018, the Company issued 40,000 warrants to purchase the Company's common stock at $3.75 per share, expiring on January 5, 2021, in connection with the sale of the Company's common stock.

On February 14, 2018, the Company entered into a consent agreement with the holders of the Company's Series D Convertible Preferred Stock. Pursuant to the consent, the Series D Holders consented to the Series E Preferred Stock transaction and are entitled at any time on or before April 17, 2018, to elect to receive the more favorable terms of the transaction. In consideration for their entry into the consent, the Company issued to the Series D Holders warrants to purchase up to an aggregate of 40,000 shares of common stock. The consent warrants are exercisable immediately and expire on February 14, 2021 and have an exercise price of $3.75 per share. The warrants contain certain anti-dilutive provisions (see Note 8).

On February 16, 2018, the Company issued an aggregate of 200,000 warrants to purchase the Company's common stock at $4.375 per share, expiring on August 16, 2021, in connection with the sale of the Company's Series E preferred stock. The warrants contain certain anti-dilutive provisions. On April 30, 2018, the exercise prices of the previously issued 200,000 warrants were reset to $3.75 and an additional 33,334 warrants were issued at $3.75 per share due to reset provisions (see Note 8).

On April 30, 2018, the Company issued 638,606 warrants to purchase the Company's common stock at $4.375 per share, expiring on April 30, 2021, in connection with the sale of the Company's common stock.

On May 11, 2018, the Company issued 28,000 warrants to purchase the Company's common stock at $4.375 per share, expiring on May 11, 2021, in connection with the sale of the Company's common stock.

On July 31, 2018, the Company issued 41,174 and 41,174 warrants to purchase the Company's common stock at $3.75 and $6.85 per share, expiring on April 30, 2019 and July 30, 2021, respectively, in connection with the sale of the Company's common stock.

On August 7, 2018, the Company issued 40,482 warrants to purchase the Company's common stock at $6.85 per share, expiring on August 7, 2021 in connection with placement services provided for the sale of our common stock.

On August 16, 2018, the Company issued 82,266 and 82,266 warrants to purchase the Company's common stock at $3.75 and $6.85 per share, expiring on May 16, 2019 and August 16, 2021, respectively, in connection with the sale of the Company's common stock.

On August 17, 2018, the Company issued 54,036 and 54,036 warrants to purchase the Company's common stock at $3.75 and $6.85 per share, expiring on May 17, 2019 and August 17, 2021, respectively, in connection with the sale of the Company's common stock. In addition, in connection with the sale, the Company issued on August 7, 2018, 40,482 warrants to purchase the Company's common stock at $6.85 per share, expiring on August 7, 2021 for placement agent services.

On November 20, 2019, the Company issued an aggregate of 568,910 warrants to purchase the Company's common stock at $6.16 per share, expiring on November 20, 2027, to Mayo Foundation in connection with two know-how licensing agreements (See Note 13). The fair value of the of the issued warrants of $1,886,894, determined using the Black-Scholes option model with an estimated volatility of 71%, risk free rate of 1.69%, dividend yield of -0- and fair value of the Company's common stock of $6.16, was charged to current period operations as acquired research and development.

A summary of the warrant activity for the years ended December 31, 2019 and 2018 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2018	5,115,805	$ 4.55	1.7	$ 551,636
Grants	1,375,374	$ 4.54	3.0	-
Exercised	(770,717)	$ 3.99	-	-
Canceled/Expired	(1,140,951)	$ 4.23	-	-
Outstanding at December 31, 2018	4,579,511	$ 4.73	1.5	$ 1,924,388
Grants	568,910	6.16	7.0	-
Exercised	(2,170,406)	$ 3.99		
Canceled/Expired	(233,297)	$ 7.24		
Outstanding at December 31, 2019	2,744,718	$ 5.40	2.2	$ 3,410,763
Vested and expected to vest at December 31, 2019	2,744,718	$ 5.40	2.2	$ 3,410,763
Exercisable at December 31, 2019	2,744,718	$ 5.40	2.2	$ 3,410,763

The aggregate intrinsic value in the preceding tables represents the total pretax intrinsic value, based on warrants with an exercise price less than the Company's stock price of $5.92 as of December 31, 2019, which would have been received by the warrant holders had those warrant holders exercised their warrants as of that date.

Warrants (NeuroClear)

On November 20, 2019, NeuroClear issued 473,772 warrants to purchase the Company's common stock at $5.00 per share, expiring on November 20, 2027, to Mayo Foundation in connection with a know-how licensing agreement (See Note 13). The fair value of the of the issued warrants of $1,275,448, determined using the Black-Scholes option model with an estimated volatility of 71%, risk free rate of 1.69%, dividend yield of -0- and the estimate fair value of NeuroClear' s common stock of $5.00, based on recent sales activity, was charged to current period operations as acquired research and development.

NOTE 11 – NON-CONTROLLING INTEREST

On November 7, 2018, the Company formed NeuroClear, a Delaware Corporation, for the purpose to pursue additional applications of the PURE EP™ signal processing technology outside of electrophysiology. In 2019, NeuroClear sold an aggregate of 896,690 shares of its common stock for net proceeds of $5,011,309 to fund initial operations. As of December 31, 2019, the Company had a majority interest in NeuroClear of 87.8%.

A reconciliation of the NeuroClear Technologies, Inc. non-controlling loss attributable to the Company:

Net loss attributable to the non-controlling interest for the year ended December 31, 2019:

Net loss	$	(3,807,763)
Average Non-controlling interest percentage of profit/losses		10.92%
Net loss attributable to the non-controlling interest	$	(415,849)

The following table summarizes the changes in non-controlling interest for the nine months ended September 30, 2019:

Balance, December 31, 2018	$	-
Allocation of equity to non-controlling interest due to sale of subsidiary stock		930,677
Net loss attributable to non-controlling interest		(415,849)
Balance, December 31, 2019	$	514,828

NOTE 12 – FAIR VALUE MEASUREMENT

The Company adopted the provisions of Accounting Standards Codification subtopic 825-10, Financial Instruments ("ASC 825-10"). ASC 825-10 defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required or permitted to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance. ASC 825-10 establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 825-10 establishes three levels of inputs that may be used to measure fair value:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs to the valuation methodology that are significant to the measurement of fair value of assets or liabilities.

All items required to be recorded or measured on a recurring basis are based upon level 3 inputs.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is disclosed and is determined based on the lowest level input that is significant to the fair value measurement.

The carrying value of the Company's cash and cash equivalents, accounts payable and other current assets and liabilities approximate fair value because of their short-term maturity.

As of December 31,2019, and 2018, the Company did not have any items that would be classified as level 1, 2 or 3 disclosures.

As of December 31, 2019, and 2018, the Company did not have any derivative instruments that were designated as hedges.

There were no derivative and warrant liability as of December 31, 2019 and 2018.

The following table provides a summary of changes in fair value of the Company's level 3 financial liabilities as of December 31, 2019:

	Warrant Liability	Derivative
Balance, January 1, 2018	$ 2,358,240	$ 685,922
Total (gains) losses		
Transfers out due to the adoption of ASU 2017-11 effective January 1, 2018	(2,358,240)	(685,922)
Balance, December 31, 2018 and 2019	$ -	$ -

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Operating leases

See Note 5 for operating lease discussion

Licensing agreements

2017 Know-how License Agreement

On March 15, 2017, the Company entered into a know-how license agreement with Mayo Foundation for Medical Education and Research whereby the Company was granted an exclusive license, with the right to sublicense, certain know how and patent applications in the field of signal processing, physiologic recording, electrophysiology recording, electrophysiology software and autonomics to develop, make and offer for sale. The agreement expires in ten years from the effective date.

The Company is obligated to pay to Mayo Foundation a 1% or 2% royalty payment on net sales of licensed products, as defined.

In consideration, the Company issued 252,000 warrants to acquire the Company's common stock at an exercise price of $3.75, expiring on March 15, 2020. The warrant fully exercised in 2019.

Patent and Know-How License Agreement

On November 20, 2019, the Company entered into a patent and know-how license agreement (the "EP Software Agreement") with Mayo Foundation for Medical Education and Research ("Mayo"). The EP Software Agreement grants to the Company an exclusive worldwide license, with the right to sublicense, within the field of electrophysiology software and under certain patent rights as described in the EP Software Agreement (the "Patent Rights"), to make, have made, use, offer for sale, sell and import licensed products and a non-exclusive license to the Company to use the research and development information, materials, technical data, unpatented inventions, trade secrets, know-how and supportive information of Mayo to develop, make, have made, use, offer for sale, sell, and import licensed products. The EP Software Agreement will expire upon the later of either (a) the expiration of the Patent Rights or (b) the 10th anniversary of the date of the first commercial sale of a licensed product, unless earlier terminated by Mayo for the Company's failure to cure a material breach of the EP Software Agreement, the Company's or a sublicensee's commencement of any action or proceedings against Mayo or its affiliates other than for an uncured material breach of the EP Software Agreement by Mayo, or insolvency of the Company.

In connection with the EP Software Agreement, the Company issued to Mayo an 8-year warrant (the "EP Software Warrant") to purchase 284,455 shares of the Company's common stock at an exercise price of $6.16. The EP Software Warrant is immediately exercisable and may be exercised on a cashless basis if there is no effective registration statement registering or a current prospectus available for the resale of the shares underlying the EP Software Warrant. The Company agreed to pay Mayo an upfront consideration of $25,000. The Company also agreed to make earned royalty payments to Mayo in connection with the Company's sales of the licensed products to third parties and sublicense income received by the Company and to make milestone payments of up to $625,000 in aggregate.

Amended and Restated Patent and Know-How License Agreement

On November 20, 2019, the Company entered into an amended and restated patent and know-how license agreement (the "Tools Agreement") with Mayo. The Tools Agreement contains terms of license grant substantially identical to the EP Software Agreement, although it is for different patent rights and covers the field of electrophysiology systems.

In connection with the Tools Agreement, the Company issued to Mayo an 8-year warrant (the "Tools Warrant") to purchase 284,455 shares of the Company's common stock at an exercise price of $6.16. The Tools Warrant is immediately exercisable and may be exercised on a cashless basis if there is no effective registration statement registering or a current prospectus available for the resale of the shares underlying the Tools Warrant. The Company agreed to pay Mayo an upfront consideration of $100,000. The Company also agreed to make earned royalty payments to Mayo in connection with the Company's sales of the licensed products to third parties and sublicense income received by the Company and to make milestone payments of up to $550,000 in aggregate.

NeuroClear Patent and Know-How License Agreement

On November 20, 2019, the Company's majority-owned subsidiary, NeuroClear, entered into a patent and know-how license agreement (the "NeuroClear Agreement") with Mayo. The NeuroClear Agreement contains terms of license grant substantially identical to the EP Software Agreement and the Tools Agreement, although it is for different patent rights and covers the field of stimulation and electroporation for hypotension/syncope management, renal and non-renal denervation for hypertension treatment, and for use in treatment of arrhythmias in the autonomic nervous system.

In connection with the NeuroClear Agreement, NeuroClear issued to Mayo an 8-year warrant (the "NeuroClear Warrant") to purchase 473,772 shares of NeuroClear's common stock at an exercise price of $5.00 per share. The NeuroClear Warrant is immediately exercisable and may be exercised on a cashless basis if there is no effective registration statement registering or a current prospectus available for the resale of the shares underlying the NeuroClear Warrant. NeuroClear agreed to pay Mayo an upfront consideration of $50,000. NeuroClear also agreed to make earned royalty payments to Mayo in connection with NeuroClear's sales of the licensed products to third parties and sublicense income received by the Company and to make milestone payments of up to $700,000 in aggregate.

Employment agreements

As of December 31, 2019, and 2018, there are no outstanding employment agreements.

Defined Contribution Plan

Effective January 1, 2019, the Company established a qualified defined contribution plan (the "401(k) Plan") pursuant to Section 401(k) of the Code, whereby all eligible employees may participate. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) plan, subject to defined limitations. The Company is required to make contributions to the 401(k) Plan equal to 3 percent of each participant's eligible compensation, subject to limitations under the Code. For the year ended December 31, 2019, the Company charged operations $110,443 for contributions under the 401(k) Plan.

Litigation

The Company is subject at times to other legal proceedings and claims, which arise in the ordinary course of its business. Although occasional adverse decisions or settlements may occur, the Company believes that the final disposition of such matters should not have a material adverse effect on its financial position, results of operations or liquidity. There was no outstanding litigation as of December 31, 2019.

NOTE 14 – INCOME TAXES

At December 31, 2019, the Company has available for federal income tax purposes a net operating loss carry forward of approximately $64,000,000, expiring in the year 2037, that may be used to offset future taxable income. The Company has provided a valuation reserve against the full amount of the net operating loss benefit, since in the opinion of management based upon the earnings history of the Company; it is more likely than not that the benefits will not be realized. Due to possible significant changes in the Company's ownership, the future use of its existing net operating losses may be limited. All or portion of the remaining valuation allowance may be reduced in future years based on an assessment of earnings sufficient to fully utilize these potential tax benefits. During the year ended December 31, 2019, the Company has increased the valuation allowance by $6,300,000 from $7,200,000 to $13,500,000.We have adopted the provisions of ASC 740-10-25, which provides recognition criteria and a related measurement model for uncertain tax positions taken or expected to be taken in income tax returns. ASC 740-10-25 requires that a position taken or expected to be taken in a tax return be recognized in the financial statements when it is more likely than not that the position would be sustained upon examination by tax authorities.

Tax position that meet the more likely than not threshold is then measured using a probability weighted approach recognizing the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. The Company had no tax positions relating to open income tax returns that were considered to be uncertain.

The Company is required to file income tax returns in the U.S. Federal various State jurisdictions. The Company is no longer subject to income tax examinations by tax authorities for tax years ending before December 31, 2013.

The effective rate differs from the statutory rate of 21% as of December 31, 2019 and 2018 due to the following:

	2019	2018
Statutory rate on pre-tax book loss	(21.00)%	(21.00)%
(Gain) loss on change in fair value of derivatives	-%	-%
Stock based compensation	3.35%	8.25%
Fair value of warrant to acquire research and development	1.93%	-%
Other	0.04%	0.04%
Valuation allowance	15.68%	12.71%
	0.00%	0.00%

The Company's deferred taxes as of December 31, 2019 and 2018 consist of the following:

	2019	2018
Non-Current deferred tax asset:		
Net operating loss carry-forwards	$ 13,500,000	$ 7,200,000
Valuation allowance	(13,500,000)	(7,200,000)
Net non-current deferred tax asset	$ -	$ -

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cut and Jobs Act (the "Tax Act"). The Tax Act establishes new tax laws that affect 2018 and future years, including a reduction in the U.S. federal corporate income tax rate to 21% effective January 1, 2018. For certain deferred tax assets and deferred tax liabilities, we have recorded a provisional decrease of $3,200,000 with a corresponding net adjustment to valuation allowance of $3,200,000 as of January 1, 2018.

NOTE 15 – SUBSEQUENT EVENTS

Equity Financing

On February 21, 2020, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Laidlaw & Company (UK) Ltd. (the "Underwriter"), relating to an underwritten public offering of 2,500,000 shares (the "Shares") of the Company's common stock, $0.001 par value per share (the "Common Stock") with final closing on February 25, 2020. All of the Shares were sold by the Company. The public offering price of the Shares is $4.00 per share, and the Underwriter has agreed to purchase the Shares from the Company pursuant to the Underwriting Agreement at a price of $3.68 per share. After the underwriting discount, but before offering expenses payable by it, the Company received net proceeds from the offering of $9,200,000.

Pursuant to the Underwriting Agreement, the Company issued to the Underwriter or its designees warrants to purchase up to an aggregate 125,000 shares of Common Stock, or 5% of the number of Shares sold in the offering (the "Underwriter Warrants" and together with the Common Stock issuable upon exercise of the Underwriter Warrants, the "Underwriter Securities"). The Underwriter Warrants will be exercisable following the date of issuance and ending five years from the date of the execution of the Underwriting Agreement, at a price per share equal to $4.80 (120% of the public offering price per Share) and are exercisable on a "cashless" basis. The Company also agreed to reimburse the Underwriter for certain of their out-of-pocket expenses incurred in connection with the offering, including, among other things, the reasonable fees and expenses of counsel, which fees and expenses may not exceed $100,000.

Common stock issuances

In January 2020, the Company issued an aggregate of 55,000 shares of the Company's common stock for vested restricted stock units.

In January 2020, the Company issued 3,750 shares of the Company's common stock in exchange for 10 shares of Series C preferred stock and accrued dividends.

In January 2020, the Company issued an aggregate of 11,141 shares of the Company's common stock in exchange for the cashless exercise of 309,630 options.

In January 2020, the Company issued an aggregate of 10,574 shares of the Company's common stock in exchange for the cashless exercise of 32,360 warrants.

In January 2020, the Company issued 3,800 shares of the Company's common stock in exchange for proceeds of $14,246 from the exercise of warrants

In February 2020, the Company issued an aggregate of 26,334 shares of the Company's common stock for vested restricted stock units.

In February 2020, the Company issued an aggregate of 31,732 shares of the Company's common stock in exchange for proceeds of $118,995 from the exercise of warrants.

Option issuances

On January 10, 2020, the Company granted an aggregate of 60,000 options to purchase shares of the Company's common stock to consultants. The options are exercisable at $6.00 for ten years and vested quarterly over three years.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusions of Management Regarding Effectiveness of Disclosure Controls and Procedures

At the end of the period covered by this Annual Report on Form 10-K, an evaluation was carried out under the supervision of and with the participation of our management, including our principal executive and our principal financial officer of the effectiveness of the design and operations of our disclosure controls and procedures (as defined in Rule 13a – 15(e) and Rule 15d – 15(e) under the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were not effective in ensuring that: (i) information required to be disclosed by the Company in reports that it files or submits to the SEC under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms and (ii) material information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for accurate and timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, for the Company (including its consolidated subsidiaries) and all related information appearing in our Annual Report on Form 10-K. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes those policies and procedures that:

1. pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

2. provide reasonable assurance that the transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with the authorization of management and/or of our Board of Directors; and

3. provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness in future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019, based on the criteria in a framework developed by the Company's management pursuant to and in compliance with the criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations ("COSO") of the Treadway Commission. This evaluation included review of the documentation of controls, evaluation of the design effectiveness of controls, walkthroughs of the operating effectiveness of controls and a conclusion on this evaluation. Based on this evaluation, management has concluded that our internal control over financial reporting was not effective as of December 31, 2019, because management identified that inadequate segregation of duties resulted in deficiencies, which, in aggregate, amounted to a material weakness in the Company's internal control over financial reporting.

Management's Remediation Plan

In 2020, we have added additional measures including incorporating personnel and third-party service providers, who are not involved in initialing and recording transactions, that we believe will remediate the underlying deficiencies in segregation of duties as identified by us.

Changes in Internal Control over Financial Reporting

Other than the changes discussed above in the Remediation Plan, there has been no change in our internal control over financial reporting during the fourth quarter ended December 31, 2019 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Liggett & Webb, P.A., an independent registered public accounting firm, as stated in its report below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
of BioSig Technologies, Inc.

Adverse Opinion on Internal Control over Financial Reporting

We have audited BioSig Technologies, Inc.'s (the Company's) internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, because of the effect of the material weakness described in the following paragraph on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standard of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2019, of the Company and our report dated March 13, 2020 expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Conclusions on Management's Annual Report on Internal Control over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Material Weakness

A material weakness is a control deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Material weaknesses have been identified and included in management's assessment as set forth below:

- The Company did not maintain effective policies, procedures or controls in aggregate to ensure adequate segregation of duties within its business processes, financial applications and IT systems. Specifically, the Company did not have appropriate controls in place to ensure adequate segregation of job responsibilities including maintaining a sufficient complement of personnel within its accounting department and establishing sufficient system user access controls for the initiating, authorizing and recording transactions within the Company's financial applications and information systems, including eliminating super user administrator rights from certain accounting personnel.

These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2019 financial statements, and this report does not affect our report dated March 13, 2020, on those financial statements.

/s/ Liggett & Webb, P.A.

New York, NY
March 13, 2020

ITEM 9B – OTHER INFORMATION

None.

PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to the 2020 Proxy Statement to be filed within 120 days after the end of the year ended December 31, 2019.

ITEM 11 - EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the 2020 Proxy Statement to be filed within 120 days after the end of the year ended December 31, 2019.

ITEM 12 – SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to the 2020 Proxy Statement to be filed within 120 days after the end of the year ended December 31, 2019.

ITEM 13 – CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to the 2020 Proxy Statement to be filed within 120 days after the end of the year ended December 31, 2019.

ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to the 2020 Proxy Statement to be filed within 120 days after the end of the year ended December 31, 2019.

PART IV

ITEM 15 – EXHIBITS, FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

(1) Financial Statements

The following financial statements are included herein:

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of December 31, 2019 and 2018
Consolidated Statements of Operations for the years ended December 31, 2019 and 2018
Consolidated Statement of Stockholders' Equity (Deficit) for the two years ended December 31, 2019
Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018
Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

None.

(3) Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form S-1 filed on July 22, 2013)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.2 to the Form S-1 filed on July 22, 2013)
3.3	Certificate of Second Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.3 to the Form S-1 filed on July 22, 2013)
3.4	Certificate of Third Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.5 to the Form S-1/A filed on January 21, 2014)
3.5	Certificate of Fourth Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.6 to the Form S-1/A filed on March 28, 2014)
3.6	Certificate of Fifth Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on August 21, 2014)
3.7	Certificate of Sixth Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on November 25, 2016)
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on November 9, 2017)
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on February 16, 2018)
3.10	Certificate of Seventh Amendment to the Amended and Restated Certificate of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on September 10, 2018)
3.11	Bylaws of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.4 to the Form S-1 filed on July 22, 2013)
3.12	Amended and Restated Bylaws of BioSig Technologies, Inc. (incorporated by reference to the Exhibit 3.1 to the Form 8-K filed on September 27, 2019)
3.13	Amendment No. 1 to Amended and Restated Bylaws of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on October 22, 2019)
4.1*	Description of Securities.
4.2	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on February 24, 2020)
10.1+	BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form S-1 filed on July 22, 2013)
10.2+	Form of Stock Option Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Form S-1 filed on July 22, 2013)
10.3+	Amendment No. 1 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.27 to the Form S-1/A filed on March 28, 2014)

10.4	Patent Assignment, dated March 17, 2014, by and among Budimir Drakulic, Thomas Foxall, Sina Fakhar and Branislav Vlajinic and BioSig Technologies, Inc. (incorporated by reference to Exhibit 10.29 to the Form S-1/A filed on May 1, 2014)
10.5+	Form of Restricted Stock Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on September 5, 2014)
10.6	Form of "B" Warrant used in connection with December 19, 2014 private placement (incorporated by reference to Exhibit 10.40 to the Form 10-K filed on February 20, 2015)
10.7+	Amendment No. 2 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 99.3 to the Form S-8 filed on April 17, 2015)
10.8+	Amendment No. 3 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.41 to the Form S-1 filed on May 20, 2015)
10.9+	Amendment No. 4 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to the Form 8-K filed on May 29, 2015)
10.10	Form of Warrant used in connection with October 28, 2016 private placement (incorporated by reference to the Item 1.01 – Entry Into a Material Definitive Agreement to the Form 8-K filed on November 3, 2016)
10.11+	Amendment No. 5 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on November 25, 2016)
10.12	Form of Warrant used in connection with April 6, 2017 private placement (incorporated by reference to Exhibit 10.62 to the Form S-1/A filed on August 3, 2017)
10.13	Form of Warrant used in connection with the April 30, 2018 private placement (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on May 1, 2018).
10.14+	Amendment No. 6 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on July 30, 2018)
10.15	Form of Series B Common Stock Purchase Warrant in connection with the July 30, 2018 private placement (incorporated by reference to Exhibit 10.3 to the Form 8-K filed on August 16, 2018)
10.16	Securities Purchase Agreement dated as of March 12, 2019, by and between BioSig Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on March 14, 2019)
10.17+	First Amendment to Stock Option Agreement by and between BioSig Technologies, Inc. and Roy T. Tanaka (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on May 22, 2019)
10.18+	First Amendment to Stock Option Agreement by and between BioSig Technologies, Inc. and Seth H. Z. Fischer (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on May 22, 2019)
10.19	Form of Securities Purchase Agreement dated as of August 5, 2019, by and between NeuroClear Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 5, 2019)
10.20	Form of Securities Purchase Agreement dated as of September 5, 2019, by and between NeuroClear Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on September 5, 2019)
10.21	Patent License Agreement, dated September 12, 2019, by and between Mayo Foundation for Medical Education and Research and BioSig Technologies, Inc. (incorporated by reference to Exhibit 10.3 to the Form 10-Q filed on October 23, 2019)
10.22	Form of Securities Purchase Agreement dated as of October 21, 2019, by and between NeuroClear Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on October 24, 2019)
10.23+	Amendment No. 7 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on November 20, 2019)
10.24	Form of Securities Purchase Agreement dated as of December 31, 2019, by and between BioSig Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on December 31, 2019)
10.25	Lease Agreement, dated October 1, 2019, by and between CMD Holdings LLC and BioSig Technologies, Inc. (incorporated by reference to Exhibit 10.4 to the Form 10-Q filed on October 23, 2019)
10.26*	Common Stock Purchase Warrant of BioSig Technologies, Inc., dated November 20, 2019, issued to Mayo Foundation for Medical Education and Research (EP Software Warrant)
10.27*	Common Stock Purchase Warrant of BioSig Technologies, Inc., dated November 20, 2019, issued to Mayo Foundation for Medical Education and Research (Tools Warrant)
10.28*	Common Stock Purchase Warrant of NeuroClear Technologies, Inc., dated November 20, 2019, issued to Mayo Clinic Ventures

21.1*	Subsidiary List of BioSig Technologies, Inc.
23.1*	Consent of Liggett & Webb, P.A.
31.01*	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.02*	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.01**	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101 INS*	XBRL Instance Document
101 SCH*	XBRL Taxonomy Extension Schema Document
101 CAL*	XBRL Taxonomy Calculation Linkbase Document
101 LAB*	XBRL Taxonomy Labels Linkbase Document
101 PRE*	XBRL Taxonomy Presentation Linkbase Document
101 DEF*	XBRL Taxonomy Extension Definition Linkbase Document

* Filed herewith.

** Furnished herewith.

+ Indicates a management contract or compensatory plan.

ITEM 16 – FORM 10-K SUMMARY

None.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIOSIG TECHNOLOGIES, INC.

Date: March 13, 2020

By: /s/ KENNETH L. LONDONER
Kenneth L. Londoner
Chief Executive Officer and Executive Chairman
(Principal Executive Officer)

Date: March 13, 2020

By: /s/ STEVEN CHAUSSY
Steven Chaussy
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ DONALD E. FOLEY Donald E. Foley	Director	March 13, 2020
/s/ ANDREW L. FILLER Andrew L. Filler	Director	March 13, 2020
/s/ PATRICK J. GALLAGHER Patrick J. Gallagher	Director	March 13, 2020
/s/ MARTHA PEASE Martha Pease	Director	March 13, 2020
/s/ Dr. JEROME ZELDIS Dr. Jerome Zeldis	Director	March 13, 2020
/s/ JEFFREY F. O'DONNELL, SR. Jeffrey F. O'Donnell, Sr.	Director	March 13, 2020
/s/ DAVID WEILD IV David Weild IV	Director	March 13, 2020
/s/ SAMUEL E. NAVARRO Samuel E. Navarro	Director	March 13, 2020

CORPORATE INFORMATION

DIRECTORS AND EXECUTIVE OFFICERS

Kenneth L. Londoner
Chief Executive Officer, Executive Chairman and Director

Steve Chaussy
Chief Financial Officer

Jeffrey F. O'Donnell, Sr.
Lead Independent Director
Director of ViralClear Pharmaceuticals, Inc.

Andrew L. Filler
Director
Partner and General Counsel of Sherpa Technology Group

David Weild IV
Director
Founder, Chairman and Chief Executive Officer of Weild & Co., Inc.

Donald E. Foley
Director
Director of AXA Equitable EQAT and Wilmington Trust Mutual Fund Complexes

Dr. Jerome B. Zeldis, M.D., Ph.D.
Director
Executive Chairman of ViralClear Pharmaceuticals, Inc.
Director of Soligenix, Inc. and PTC Therapeutics, Inc.

Martha Pease
Director
Partner and Director of Boston Consulting Group

Patrick J. Gallagher
Director
Senior Managing Director and Head of Healthcare Sales of Laidlaw & Co. (UK) Ltd.

Samuel E. Navarro
Director
Managing Partner of Gravitas Healthcare, LLC

Budimir S. Drakulic, Ph.D.
Chief Scientist

CORPORATE HEADQUARTERS

54 Wilton Road, 2nd Floor
Westport, Connecticut 06880
Telephone: (203) 409-5444

STOCK LISTING

NASDAQ Capital Market: BSGM

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Liggett & Webb, P.A.
432 Park Ave S
New York, NY 10016

TRANSFER AGENT AND REGISTRAR

Action Stock Transfer
2469 E. Fort Union Blvd, Suite 214
Salt Lake City, UT 84121
Telephone: (801) 274-1088

ANNUAL GENERAL MEETING OF SHAREHOLDERS

The 2020 Annual General Meeting of Stockholders will be held at 10:00 a.m. Eastern Time on June 26, 2020, at 54 Wilton Road, 2nd Floor, Westport, Connecticut 06880. Stockholders of record on April 28, 2020, are entitled to notice of and to vote at the Annual General Meeting.

COMPANY WEBSITE

www.biosig.com