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

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**FORM 10-K**

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**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the Fiscal Year Ended December 31, 2018**

Commission File Number 000-55473

**BIOSIG TECHNOLOGIES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation  
or organization)

**26-433375**

(IRS Employer Identification No.)

**12424 Wilshire Blvd, Suite 745**

**Los Angeles, CA**

(Address of principal executive office)

**90025**

(Zip Code)

**(310) 620-9320**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, \$0.001 par value per share**

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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, 2018, based on the price at which the common stock was last sold on such date, is \$71,671,869. 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 14, 2019, there were 19,718,900 shares of the registrant's common stock outstanding.

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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](http://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 11, 2019. 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 wholly-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. As of December 31, 2018, NeuroClear did not have any significant assets, liabilities or operations.

### *Business Overview*

We are a development stage medical device company that is developing 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 of 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. Our PURE EP™ System received FDA 510(k) clearance in August 2018.

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The PURE EP™ System is a non-invasive computerized system intended to acquire, digitize, amplify, filter, measure and calculate, display, record and store electrocardiographic and intracardiac signals for patients undergoing EP procedures in an EP laboratory. The system is indicated for use under the supervision of licensed healthcare practitioners who are responsible for interpreting the data collected by the system. The PURE EP System aims to minimize noise and artifacts from cardiac recordings and acquire high-fidelity cardiac signals. Improving cardiac signals may potentially increase the diagnostic value of these signals, thereby possibly improving accuracy and efficiency of the EP studies and related procedures. The PURE EP System is intended to be used in addition to existing electrophysiology recorders. We believe that data provided by the PURE EP System will increase the workload capacity and enhance the capabilities of the typical electrophysiology laboratory.

Our initial focus is on improving intracardiac signal acquisition and enhance diagnostic information for catheter ablation procedures for the complex arrhythmias, atrial fibrillation, the most common cardiac arrhythmia, and ventricular tachycardia, an arrhythmia evidenced by a fast heart rhythm originating from the lower chambers of the heart, which can be life-threatening. Cardiac catheter ablation is a procedure that corrects conduction of electrical impulses in the heart that cause arrhythmias and is now a preferred treatment for certain arrhythmias. During this procedure, a catheter is usually inserted using a venous access into a specific area of the heart. Cryo or radiofrequency energy is delivered through the catheter to destroy small areas of the heart muscle that cause the abnormal heart rhythm. According to the *2017 HRS/EHRA/ECAS/APHRS/SOLAECE Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation*, the role of catheter ablation as first-line therapy, prior to a trial of a Class I or III antiarrhythmic agent, is an appropriate indication for catheter ablation of AF in patients with symptomatic paroxysmal or persistent AF.

Catheter ablation for many arrhythmias have high success rates; however, more complex or long-standing examples of the disease (like AF and VT) often require multiple procedures (each typically lasting from 3-6 hours), evidencing the need for additional research and technology to diagnose and treat these cases. Consequently, ablating AF and VT is regarded as being more difficult. Therefore, access to these procedures has traditionally been limited to being performed by only the most well-trained electrophysiologists.

Our overall goal is to establish the PURE EP System as a new platform in the EP market. We believe that the PURE EP System and its signal processing tools will contribute to an increase in the number of procedures performed in each EP lab and possibly improved patient outcomes because we believe that the PURE EP System may have the following advantages over the EP recording systems currently available on the market:

- Precise, uninterrupted, real-time evaluations of electrograms;
- Higher quality cardiac signal acquisition for accurate and more efficient electrophysiology studies and catheter ablation procedures to help reduce costs and length of procedures;
- Reliable display of information to better determine precise ablation targets, strategy and end point of procedures with the objective of reducing the need for multiple procedures;
- A device that can run in parallel with the existing EP lab equipment.

On February 18 and February 19, 2019, we conducted the first in-human use of our PURE EP™ System which was announced on February 20, 2019. The 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. Initial results showed improved signal detection and fidelity compared to the data acquired using the existing recording devices in the EP lab. We intend to conduct further clinical external evaluation at a select number of centers.

We also intend to continue additional research studies of our technology at Mayo Clinic. On November 13, 2018, we announced that we entered into a new advanced research agreement with Mayo Clinic. The program will be run under the leadership of Samuel J. Asirvatham, M.D., Mayo Clinic's Vice-Chair of Innovation and Medical Director, Electrophysiology Laboratory and will consist of a number of two- to three-year projects, which will focus on development of additional advanced features of PURE EP™ System within the field of EP and potential clinical applications of our technology in a new, previously unexplored, field.

As of March 14, 2019, we have conducted a total of fifteen pre-clinical studies to date with the PURE EP™ System prototype, fourteen 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 ventricular tachycardia (VT) model.

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Over the past year, our other significant achievements include:

- On January 3, 2018, we announced that Mr. Steve Chaussy had been elevated to our full time Chief Financial Officer.
- On January 9, 2018, we announced our partnership with Charles Austin and JK Advisors in preparation of the commercial launch of our PURE EP System.
- On January 10, 2018, Dr. Samuel J. Asirvatham performed our eleventh pre-clinical study at Mayo Clinic in Rochester, Minnesota.
- In March 2018, we formed an Advisory Board to advise the Company’s leadership on a range of subjects, including strategy, marketing, government affairs, partnerships, mergers and acquisitions, intellectual property, and capital markets.
- On March 28, 2018, we filed our 510(k) application with the U.S. Food and Drug Administration (FDA) for the PURE EP™ System.
- On May 9, 2018, we filed one “omnibus” hardware and software patent application with multiple claim sets, and a multiple feature-set graphical user interface (“GUI”) design patent, with detailed technical descriptions across multiple BioSig elements of novelty.
- On June 14, 2018, Dr. Asirvatham and his team performed our twelfth pre-clinical study at Mayo Clinic in Rochester, Minnesota.
- On July 18, the PURE EP System was featured in a poster presentation at the 40<sup>th</sup> International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC 2018) entitled, “Unipolar Intracardiac Signal Morphology as a Parameter for Catheter Contact Evaluation”.
- On August 6, 2018, we announced that our stock has been added to LD Micro index.
- On August 8, 2018, we received FDA 510(k) clearance for our PURE EP System.
- On August 20, 2018, we announced our relationship with Amy Ansfield Scott, former Biosense Webster (a Johnson & Johnson company) Director of Strategic Partnerships, to assist us in commercial adoption of our PURE EP System.
- On September 21, 2018, our common stock began trading on the Nasdaq Capital Market.
- On November 27, 2018, we announced that we signed an agreement with Texas Cardiac Arrhythmia Institute for first-in-human studies.
- On December 3, 2018, Dr. Asirvatham and his team performed our thirteenth pre-clinical study at Mayo Clinic in Rochester, Minnesota which was part of the new agreement announced November 13, 2018.
- On December 6, 2018, we announced that we signed an agreement with Mayo Clinic for first-in-human studies.
- On December 19, 2018, we announced that MaryAnn Edzards, former Biosense Webster (a Johnson & Johnson company) New Technology Education Manager, joined BioSig as Senior Director – Account Manager.
- On January 21, 2019, Dr. Asirvatham’s team at Mayo performed our fourteenth pre-clinical study at Mayo Clinic in Rochester, Minnesota which was part of the new agreement announced November 13, 2018.
- On February 5, 2019, we announced that John Kowalski, former Biosense Webster (a Johnson & Johnson company) Northeast Area Director, joined BioSig as Vice President of Sales.
- On February 12, 2019, we issued a 2019 Shareholder Letter which provided updates on our recent business development and highlighted our plans for future growth.
- On February 26, 2019, we announced expansion of our engineering team to drive R&D and manufacturing efforts.
- On March 6, 2019, we announced the appointment of Barry Keenan Ph.D, MBA, PMP as Vice President of Engineering to head up our advanced product development.

## Our Industry

Electrophysiology is the study of the propagation of electrical impulses throughout the heart. Electrophysiology studies are focused on the diagnosis and treatment of arrhythmias, a medical condition in which conduction of electrical impulses within the heart vary from the normal. Such conditions may be associated with significant health risks to patients. The invasive cardiac electrophysiology study for the evaluation of cardiac conduction disorders has evolved rapidly from a research tool to an established clinical treatment. This technique permits detailed analyses of the mechanism underlying cardiac arrhythmias and determines precise locations of the sites of origin of these arrhythmias, thereby aiding in treatment strategies.

Pharmacological, or medicine-based, therapies have traditionally been used as initial treatments, 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 of most arrhythmias has a high success rate and multiple procedures per patient have been found to be more successful.

Catheter ablation is usually performed by an electrophysiologist (a specially trained cardiologist) in a specialized room in an electrophysiology lab. It is estimated that there are about 3,425 electrophysiology rooms in the U.S. and 3,915 electrophysiology rooms outside the U.S., each typically with an electrophysiology recording system costing an average of \$250,000. We believe that the current value of the electrophysiology recording device market in the U.S. is approximately \$856 million, based upon the number of electrophysiology labs in U.S. and the average cost of the recording system in each lab. With the potential of 12 million atrial fibrillation patients in the USA by the year 2050 and 17.9 million in Europe by 2060 (according to the most recent *Worldwide Epidemiology of Atrial Fibrillation: a Global Burden of Disease 2010 Study*) and improvements in technology for atrial fibrillation ablation therapy, significant growth is predicted for the number of hospitals building electrophysiology labs.

According to the 2018 HRI *Global Opportunities in Medical Devices & Diagnostics* report, analysts forecast the global market for electrophysiology devices will grow at a 10.4 percent compound annual growth rate, from \$4.537 billion in 2015 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 Atrial Fibrillation and Ventricular Tachycardia*

We believe that the clearer recordings and additional information provided by the PURE EP System may improve outcomes during electrophysiology studies and ablation procedures for a variety of arrhythmias. For patients who are candidates for ablation, an electrophysiology study is necessary to define the targeted sites for the ablation procedure. Two common, yet complex, conditions for which ablation procedures are performed are atrial fibrillation and ventricular tachycardia. We believe that in the near future, the PURE EP System may have a meaningful impact on assisting ablation strategies for these conditions.

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 atrial fibrillation and ventricular tachycardia, 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 atrial fibrillation and ventricular tachycardia 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; however, advancements in new technologies and techniques show a strong growth rate for these procedures.

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 atrial fibrillation 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. As a result, AF ablation is becoming the fastest growing procedure type in this market. The American College of Cardiology Foundation/American Heart Association Task Force reported that catheter-directed ablation of atrial fibrillation represents a substantial achievement that promises better therapy for a large number of patients presently resistant to pharmacological or electrical conversion to sinus rhythm (*2014 ACCF/AHA/HRS Focused Update on the Management of Patients With Atrial Fibrillation (Updating the 2011 Guideline)*). 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, ventricular tachycardia 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 accounting for more than 350,000 deaths in the U.S. each year. Ventricular tachycardia 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.

According to Dr. Srijoy Mahapatra, the status of ventricular tachycardia ablation is growing at a 14-17% compound annual growth rate due to the fact that ablation of ventricular tachycardia may help patients feel better and live longer, despite the risks, including the occurrence of stroke, and the modest success rates. The success of ventricular tachycardia ablation varies, depending on the patient's specific heart condition that caused ventricular tachycardia. The procedure is most effective in patients with otherwise normal hearts, in whom the success rate exceeds 90%. In patients with structural heart disease resulting from scar or cardiomyopathy, success rates range between 50% and 75% at six to 12 months. In cases in which a patient experiences a recurrence, two of three patients will still have less ventricular tachycardia than before the initial ablation (*Circulation* (2010) 122: e389-e391). Therefore, we believe that ablation will continue to become a preferred treatment for ventricular tachycardia, especially considering the challenges presented by ICD therapies; this increase in demand for ablation procedures will likely also increase the demand for technological advances in medical devices essential to ablation procedures, including electrophysiology recorders, in order to better support and ablation procedures.

#### *Electrophysiology Lab Environment and Electrophysiology Recording Systems*

The electrophysiology lab environment and recording systems create significant amounts of noise and artifacts during electrophysiology 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 electrophysiology lab equipment further hamper recordings of small electrophysiological potentials. Preserving spatiotemporal (space and time) characteristics of the signal in a very challenging electrophysiology 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 electrophysiology 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 electrophysiology 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 electrophysiology 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 electrophysiology 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 electrophysiology lab and the continual increase of ablation procedures, the electrophysiology 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 electrophysiology lab.

The requirement for optimal signal integrity is further amplified during ablation treatments of atrial fibrillation and ventricular tachycardia. Presently, one of the main objectives of the atrial fibrillation ablation procedure is to precisely identify, ablate and eliminate pulmonary vein potentials and one of the main objectives of the ventricular tachycardia 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 ventricular tachycardia. 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 electrophysiology recordings; otherwise, the signals that are needed to guide the ablation procedures will be difficult to distinguish due to noise interference.

## **Our Products**

We intend to bring to the EP market our PURE EP™ System, which received FDA 510(k) clearance in August 2018. The non-invasive 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. The system is indicated for use under the supervision of licensed healthcare practitioners who are responsible for interpreting the data collected by the system. The PURE EP System aims to minimize noise and artifacts in cardiac recordings and acquire high-fidelity cardiac signals. Improving cardiac signals may potentially increase the diagnostic value of these signals, thereby possibly improving accuracy and efficiency of the EP studies and related procedures

The PURE EP System uses a combination of analog and digital signal processing to acquire and display cardiac data. We believe because our technology consists of proprietary hardware, software and algorithms, the original cardiac data is less distorted. In addition, we are developing a library of software tools that are designed to be configured to fit the needs of electrophysiologists in different settings and/or for different arrhythmia treatments. With the software, the PURE EP System can be positioned to provide information that can be used by electrophysiologists to help guide the ablation catheter; shorten procedure times and can reduce the complexity of maneuvers necessary for identifying ablation targets for various arrhythmias, including atrial fibrillation and ventricular tachycardia. The PURE EP System is intended to be used in addition to existing electrophysiology recorders. We believe that the less distorted cardiac data provided by the PURE EP System will increase the workload ability and enhance the capabilities of the typical electrophysiology laboratory.



### *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 spatiotemporal characteristics of electrocardiograms and intracardiac electrograms. We used a custom-built electrocardiogram/intracardiac simulator with a database of various electrocardiogram signals combined with electrophysiology signals, along with waveforms from publicly available databases. The ability to faithfully reproduce database waveforms generated by an electrocardiogram/intracardiac simulator was tested using the PURE EP System and conventional electrophysiology recorders, the GE CardioLab and St. Jude EP-WorkMate.

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, spatiotemporal 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 spatiotemporal characteristics by the PURE EP System. A notch filter is used to remove a specific frequency from the signal, especially either 60Hz in the U.S. and 50Hz in Europe, and can be implemented in hardware or software.

During our initial analysis, we did not subject the evaluation of the data produced by our technology to any third-party review, as would be required for the publication of a formal study.

### *Proof of Concept Testing*

We developed the PURE EP System’s proof of concept unit, which is the version of the product prior to prototype. The proof of concept unit was designed using separate analog and digital boards to allow for easier debugging and to demonstrate single channel electrocardiogram and intracardiac acquisition capabilities. The proof of concept unit was built to (i) verify that the PURE EP System performs in line with our intended design of the product, (ii) validate a portion of the hardware design that we intend to use in the prototype, and (iii) verify the software used by the PURE EP System. The main objectives of the proof of concept unit were to demonstrate that the system’s hardware and software have the ability to faithfully record small cardiac signals in an EP laboratory environment and to obtain initial performance results.

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. As part of the testing, we simultaneously recorded electrocardiogram and intracardiac signals on our proof of concept unit and GE’s CardioLab recording system. An identical signal was applied to the input of both systems and the monitor of our proof of concept unit was positioned next to the monitor of GE’s CardioLab recording system to allow for visual comparison. 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. However, because this was a proof of concept test, without any clearly established protocols, we cannot present this data for publication and we do not have any independent verification or peer review of these findings.

Subsequently, in the third quarter of 2013, we analyzed the results of our proof of concept unit (which verified the capabilities of the main components of the PURE EP System) and 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 that are in development. Since March 2016, we have published nine manuscripts in collaboration with the physicians from Mayo Clinic evidencing our pre-clinical findings.

*Post FDA Clearance Testing*

On February 18 and February 19, 2019, we conducted the first in-human use of our PURE EP™ System which was announced on February 20, 2019. The 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. Initial results showed improved signal detection and fidelity compared to the data acquired using the existing recording devices in the EP lab.

*The current PURE EP System*



*Technology and Development Plan*

Our technology team consists of seven 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, Mount Sinai Hospital in New York, NY and the Texas Cardiac Arrhythmia Institute in Austin, TX. Prior to commercialization of the PURE EP System, we envision outsourcing manufacturing of the complete PURE EP System to Minnetronix (or, if Minnetronix is unavailable, another similarly situated manufacturer), as Minnetronix built the beta units for use in our recent in-human studies. In addition, we expect to identify a second medical device manufacturer in California.

On February 18 and February 19, 2019, we conducted the first in-human use of our PURE EP™ System which was announced on February 20, 2019. The 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. Initial results showed improved signal detection and fidelity compared to the data acquired using the existing recording devices in the EP lab. We intend to conduct further clinical external evaluation at a select number of centers.

We also intend to continue additional research studies of our technology at Mayo Clinic. On November 13, 2018, we announced that we entered into a new advanced research agreement with Mayo Clinic. The program will be run under the leadership of Samuel J. Asirvatham, M.D., Mayo Clinic's Vice-Chair of Innovation and Medical Director, Electrophysiology Laboratory and will consist of a number of two- to three-year projects, which will focus on development of additional advanced features of PURE EP™ System within the field of EP and potential clinical applications of our technology in a new, previously unexplored, field.

As of March 14, 2019, we have conducted a total of fifteen pre-clinical studies to date with the PURE EP™ System prototype, fourteen 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 ventricular tachycardia (VT) model.

We plan to obtain CE Mark for the PURE EP System. CE marking is a mandatory approval for medical devices sold in Europe. We expect to submit our initial application for CE Mark approval in the second half of 2019.

We anticipate that our initial customers will be hospitals and other health care facilities that operate EP labs. Currently, we do not have any customers.

## **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, each with a per unit price of approximately \$250,000:

- 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, we believe that the above recording systems are built on relatively old technologies and all use the identical approach in applying digital filters to remove noise and artifacts. We are of the opinion 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 atrial fibrillation and ventricular tachycardia. 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. We envision outsourcing manufacturing of the complete PURE EP System to Minnetronix and to identify a second medical device manufacturer in California.

## **Research and Development Expenses**

Research and development expenses for the fiscal years ended December 31, 2018, 2017 were \$4,368,784 and \$4,756,468, respectively.

## **Sales, Marketing and Customer Service**

We plan to implement a market development program prior to launch of our PURE EP System. As the product progresses through development and testing, we intend to gather the data produced by the PURE EP System's processing and presenting electrocardiogram and intracardiac signals and use such data for posters, presentations at cardiology conferences, and, if appropriate, submissions to scientific journals. We believe that as we gather additional data from our planned pre-clinical and clinical studies and user preference studies, we will be able to better determine the focus of our marketing efforts. We also plan to leverage our relationships with cardiac research and treatment centers to gain early product evaluation and validation. We believe that through these efforts, we may be able to gain preliminary acceptance of our PURE EP product by experienced professionals and academics in the electrophysiology field.

We also intend to simultaneously develop a branding strategy to introduce and support the PURE EP System. The strategy may include our presence at major relevant cardiology meetings on a national and regional basis to engage and educate physicians concerning the PURE EP System and any of our other products, as well as engaging in a variety of other direct marketing methods. We also intend to develop a small direct sales force together with a distribution network that has existing relationships with hospitals and electrophysiologists.

## **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 directed at systems and methods for the evaluation of electrophysiology systems. In March 2014, the inventors listed on the patent application filed in December 2013 assigned all of their rights to the patent application to us. In December 2014, we filed this patent application under the Patent Cooperation Treaty (PCT) with the U.S. Receiving Office. Our patent application filed in December 2013 represents a significant portion of our core proprietary intellectual property. Our patent application filed in December 2013 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.

This patent application describes signal processing evaluators that assess how well a cardiac signal system reading a cardiac signal (such as the PURE EP System or another system) filters out noise, such as non-cardiac signals or other body-generated artifacts. Such noise is filtered by such systems with varying success, thus, an evaluator such as described in the patent application may be used to provide comparison data for a particular system versus another given the same or similar input. The patent application also describes a simulator that can send a simulated signal to a cardiac signal system (the PURE EP System or another system) in order to challenge such cardiac signal system to filter out typical noise.

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 a multiple feature-set graphical user interface (“GUI”) design patent. 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

On February 8, 2019, we filed a Track One request with our US non-provisional utility patent application, “Systems and Methods to Visually Align Signals Using Delay”.

On February 8, 2019, we filed a Track One request with our US non-provisional utility patent application, “Systems and Methods for Signal Acquisition and Visualization”.

On November 19, 2018, we filed a Track One request with our US non-provisional utility patent application, “Systems, Apparatus, and Methods for Conveying Biomedical Signals Between a Patient and Monitoring and Treatment Devices”.

On November 19, 2018, we filed a Track One request with our US non-provisional utility patent application, “Apparatus and Methods for Removing a Large-Signal Voltage Offset from a Biomedical Signal”.

These Track One patent applications are pending at the USPTO and we would expect to receive a first response from the USPTO in at least one or more of them during Q2 2019. All of the patent applications described herein are still pending.

### *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.

## **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.

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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;



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- 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 14, 2019, we had 20 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 our condition as a going concern is in doubt, we will be forced to cease our business operations unless we can raise sufficient funds to satisfy our working capital needs.***

As shown in the accompanying financial statements during years ended December 31, 2018 and 2017, we incurred net losses attributable to common stockholders of \$18,136,053 and \$12,815,620, respectively and used \$10,255,427 in cash for operating activities for the year ended December 31, 2018. As of March 14, 2019, we had cash on hand of approximately \$11 million. These factors, among others, raise substantial doubt that we will be able to continue as a going concern for a reasonable period of time.

Our existence is dependent upon management's ability to develop profitable operations. We are devoting substantially all of our efforts to developing product candidates and there can be no assurance that our efforts will be successful. There is no assurance that can be given that our actions will result in profitable operations or the resolution of our liquidity problems.

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***Because we are a development stage company with one product near commercialization, we expect to incur substantial additional operating losses.***

We are a development 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. 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 we are uncertain when we expect to generate revenues from the commercial sale of our PURE EP System, which received FDA 510(k) clearance in August 2018, if ever. 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 U.S. Food and Drug Administration 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 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, the PURE EP System may not be commercially available for a number of months as it will require substantial further capital expenditures to manufacture. In order to further develop 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 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.***

It is unlikely that we will generate revenues from our products until we have conducted clinical trials and receive necessary clearances from regulatory authorities for our products. Therefore, until we have a commercially viable product, 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 the next nine months. 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.

***The results of clinical studies may not support the usefulness of our technology.***

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:

- 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 protocol 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.

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;

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- 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.

***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.

***The electrophysiology market is highly competitive.***

There are a number of groups and organizations, such as healthcare, medical device and software companies in the electrophysiology market that may develop a competitive offering to our products. The largest companies in the electrophysiology 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. 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.

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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 no sales, marketing or distribution operations and will need to expand our expertise in these areas.***

While we currently have no sales, marketing or distribution operations, we are in the process of building such operations in connection with the commercialization of our planned products, and we will need to expand our expertise in these areas. To increase internal sales, distribution and marketing expertise and be able to conduct these operations, we would 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 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. 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.

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. We intend to obtain appropriate insurance coverage once we reach a manufacturing stage. 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, product liability insurance is expensive. In the future we may not be able to obtain coverage on acceptable terms, if at all. Moreover, our insurance coverage may not adequately protect us from liability that we incur in connection with clinical trials or sales of our products. 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. In addition, any products liability litigation, regardless of outcome or strength of claims, may divert time and resources away from the day-to-day operation of our business and product development efforts. Any of these outcomes could adversely impact our business 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);

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- 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.

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- 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.

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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 have identified a material weakness in our internal control over financial reporting which, if not remediated, could adversely affect our reputation, business or stock price.***

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.

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, but mitigating controls to completely mitigate internal control weaknesses have been deemed to be impractical and prohibitively costly, due to the size of our organization. While management expects to continue to use reasonable care in following and seeking improvements to effective internal control processes that have been and continue to be in use by us, we cannot assure you that our remedial measures will be sufficient to address the material weakness. Moreover, we cannot assure you that we will not identify additional material weaknesses in our internal control over financial reporting in the future. If we are unable to remediate the material weakness, our ability to record, process and report financial information accurately, and to prepare financial statements within the time periods specified by the rules and forms of the Securities and Exchange Commission, could be adversely affected. The occurrence of or failure to remediate the material weakness may adversely affect our reputation and business and the market price of our common stock and any other securities we may issue.

## **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;

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- 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.

### **Risks Related to our Common Stock**

***Although our shares of common stock are now listed on the NASDAQ Capital Market, 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 are now listed on the NASDAQ Capital Market under the symbol “BSGM,” 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.

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

The market price of our common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- the outcomes of potential future patent litigation;
- our ability to monetize our future patents;
- changes in our industry;
- announcements of technological innovations, new products or product enhancements by us or others;
- announcements by us of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments;
- changes in earnings estimates or recommendations by security analysts, if our common stock is covered by analysts;
- investors’ general perception of us;
- future issuances of common stock;

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- the addition or departure of key personnel;
- general market conditions, including the volatility of market prices for shares of technology companies, generally, and other factors, including factors unrelated to our operating performance; and
- the other factors described in this “Risk Factors” section.

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.

***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 or the exercise of options and warrants to purchase shares of our common stock.***

As of March 14, 2019, we have outstanding options to purchase 3,940,848 shares of common stock and have reserved 1,013,322 shares of our common stock for further issuances pursuant to our 2012 Equity Incentive Plan. In addition, as of March 14, 2019, we may be required to issue 190,572 shares of our common stock for issuance upon conversion of outstanding convertible Series C preferred stock which includes accrued dividends as of December 31, 2018 and 4,427,210 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.

***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 14, 2019, three of our stockholders beneficially owned over 25.25% 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 are an “emerging growth company” and we cannot be certain that the reduced disclosure requirements applicable to emerging growth companies will not make our common stock less attractive to investors.***

The JOBS Act permits “emerging growth companies” like us to rely on some of the reduced disclosure requirements that are already available to smaller reporting companies. As long as we qualify as an emerging growth company or a smaller reporting company, we would be permitted to omit the auditor’s attestation on internal control over financial reporting that would otherwise be required by the Sarbanes-Oxley Act, as described above, and are also exempt from the requirement to submit “say-on-pay”, “say-on-pay frequency” and “say-on-parachute” votes to our stockholders and may avail ourselves of reduced executive compensation disclosure that is already available to smaller reporting companies.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, as long as we are an emerging growth company. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We intend to take advantage of the benefits of this until we are no longer an emerging growth company or until we affirmatively and irrevocably opt out of this exemption. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

We will cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year during which we had total annual gross revenues of \$1 billion (as indexed for inflation); (ii) the last day of the fiscal year following the fifth anniversary of the date of the first sale of common stock under our registration statement on Form S-1 that became effective on June 23, 2014; (iii) the date on which we have, during the previous 3-year period, issued more than \$1 billion in non-convertible debt; or (iv) the date on which we are deemed to be a “large accelerated filer,” as defined by the Securities and Exchange Commission, which would generally occur upon our attaining a public float of at least \$700 million. Once we lose emerging growth company status, we expect the costs and demands placed upon our management to increase, as we would have to comply with additional disclosure and accounting requirements, particularly if we would also not qualify as a smaller reporting company. In addition, until such time, we cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and could cause our stock price to decline.



***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.

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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.

***Our Series C Preferred Stock and certain of our warrants contain anti-dilution provisions that may result in the reduction of their conversion prices or exercise prices in the future.***

Our Series C Preferred Stock and certain of our warrants contain anti-dilution provisions, which provisions require the lowering of the conversion price or exercise price, as applicable, to the purchase price of future offerings. Furthermore, with respect to such warrants, if we complete an offering below the exercise price of such warrants, the number of shares issuable under such warrants will be proportionately increased such that the aggregate exercise price payable after taking into account the decrease in the exercise price, shall be equal to the aggregate exercise price prior to such adjustment. If in the future we issue securities for less than the conversion or exercise price of our Series C Preferred Stock and such warrants, respectively, we will be required to further reduce the relevant conversion or exercise prices, and the number of shares underlying such warrants will be increased. We may find it more difficult to raise additional equity capital while our Series C Preferred Stock and such warrants are outstanding.

**ITEM 1B – UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2 – PROPERTIES**

We maintain our principal executive and engineering office 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 through June 30, 2020 and monthly payments of \$16,033 from July 1, 2020 until June 30, 2021. In connection with the lease of our office space, we are obligated to lease parking spaces at an aggregate approximate cost of \$1,071 per month. In addition, we entered into a lease for storage space within the building that commenced on December 1, 2017 and expires on August 31, 2019. Our monthly lease payments with respect to such storage space is approximately \$223 per month.

On April 11, 2018, we extended a short-term lease agreement whereby we agreed to lease office space in Austin, Texas commencing on August 1, 2018 and expiring July 31, 2019 for \$979 per month.

On October 1, 2018, we entered into a lease agreement whereby we leased office space in Norwalk, Connecticut commencing on October 1, 2018 and expiring on September 30, 2019 for \$2,000 per month.

We believe our current facilities are sufficient to meet our needs.

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

<b>Year Ending December 31,</b>	
2019	222,919
2020	204,657
2021	111,713
	<u>\$ 539,289</u>

**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 following table sets forth, for the periods indicated, the high and low bid prices per share of our common stock as reported by the OTCQB and the Nasdaq Capital Market, as applicable. The OTCQB quotations reflect inter-dealer prices, without retail markup, markdown or commissions, and may not represent actual transactions.

	<b>Fiscal Year 2018</b>	
	<b>High</b>	<b>Low</b>
First Quarter	\$ 4.25	\$ 3.21
Second Quarter	\$ 6.52	\$ 3.90
Third Quarter	\$ 7.87	\$ 3.87
Fourth Quarter	\$ 5.74	\$ 3.50

  

	<b>Fiscal Year 2017</b>	
	<b>High</b>	<b>Low</b>
First Quarter	\$ 5.00	\$ 3.00
Second Quarter	\$ 4.40	\$ 3.07
Third Quarter	\$ 4.00	\$ 3.12
Fourth Quarter	\$ 4.38	\$ 3.22

**Holders of Record**

As of March 14, 2019, there were approximately 383 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. In addition, the terms of our Series C Preferred Stock prohibit us from paying dividends in the future on our common stock. We may not pay dividends on our common stock absent consent from the holders representing a super-majority of the outstanding shares of our Series C Preferred Stock.

## 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.”*

We are a development stage medical device company that is developing 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 EP studies and cardiac catheter ablation of AF and 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. Our PURE EP System received FDA 510(k) clearance in August 2018. The PURE EP™ System is a non-invasive 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. The system is indicated for use under the supervision of licensed healthcare practitioners who are responsible for interpreting the data collected by the system. The PURE EP System aims to minimize noise and artifacts from cardiac recordings and acquire high-fidelity cardiac signals. Improving cardiac signals may potentially increase the diagnostic value of these signals, thereby possibly improving accuracy and efficiency of the EP studies and related procedures. The PURE EP System is intended to be used in addition to existing electrophysiology recorders. We believe that data provided by the PURE EP System will increase the workload ability and enhance the capabilities of the typical electrophysiology laboratory.

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 development 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, 2018 and 2017, the Company did not have any derivative instruments that were designated as hedges.

On December 31, 2018 and 2017, we had outstanding preferred stock and 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, 2018 Compared to Twelve Months Ended December 31, 2017*

*Revenues and Cost of Goods Sold.* We had no revenues or cost of goods sold during the twelve months ended December 31, 2018 and 2017.

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*Research and Development Expenses.* Research and development expenses for the twelve months ended December 31, 2018 were \$4,368,784, a decrease of \$387,684 or 8%, from \$4,756,468 for the twelve months ended December 31, 2017. This decrease is primarily due reduction in design costs as we develop our proprietary technology platform, and that in 2017, we issued warrants to acquire research and development with a fair value of \$543,927 (see discussion below) as compared to \$0 in 2018, net with increases in personnel and consulting costs.

Research and development expenses were comprised of the following:

	<u>2018</u>	<u>2017</u>
Salaries and equity compensation	\$ 1,972,721	\$ 1,481,421
Consulting expenses	987,972	500,628
Clinical studies and design work	1,249,370	2,066,028
Acquired research and development	-	543,927
Travel, supplies, other	158,721	164,464
Total	<u>\$ 4,368,784</u>	<u>\$ 4,756,468</u>

Stock based compensation for research and development personnel was \$1,056,571 and \$432,929 for the year ended December 31, 2018 and 2017, respectively.

On March 15, 2017, we entered into a know-how license agreement with Mayo Foundation for Medical Education and Research whereby we were 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. As such, we are obligated to pay to Mayo Foundation a 1% or 2% royalty payment on net sales of licensed products, as defined.

In consideration, we issued 630,000 warrants to acquire the Company's common stock at an exercise price of \$3.75, expiring on March 15, 2020. The estimated fair value of \$543,927 was charged to operations as acquired research and development.

*General and Administrative Expenses.* General and administrative expenses for the twelve months ended December 31, 2018 were \$12,881,027, an increase of \$4,742,910, or 58%, from \$8,138,117 incurred in the twelve months ended December 31, 2017. 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 \$8,199,609 in the twelve months ended December 31, 2018 from \$5,579,117 for the twelve months ended December 31, 2017, an increase of \$2,620,492, or 47%. This increase is due to the value of the stock-based compensation increasing to \$5,544,018 in 2018, as a result of the vesting of stock and stock options issued to board members, officers and employees, as compared to \$4,316,542 of stock-based compensation in 2017, along with added additional personnel in 2018.

Professional services for the twelve months ended December 31, 2018 totaled \$644,438, an increase of \$281,775, or 78%, over the \$362,663 recognized for the twelve months ended December 31, 2017. Of professional services, legal fees totaled \$542,788 for the twelve months ended December 31, 2018, an increase of \$269,125, or 98%, from \$273,663 incurred for the twelve months ended December 31, 2017. The significant increase in legal fees in 2018 is due to extensive legal work in developing and registering patents. Accounting fees incurred in the twelve months ended December 31, 2018 amounted to \$101,650, an increase of \$12,650, or 14%, from \$89,000 incurred for the same period in 2017. The increase in accounting fees was primarily related to an increase in audit and other requirements in 2018 as compared to 2017 as we continue to develop our operations including fees associated with our capital raising transactions and the filing of our registration statements.

Consulting fees totaled \$2,398,639 for the twelve months ended December 31, 2018, an increase of \$945,634 or 65%, from \$1,453,005 for the twelve months ended December 31, 2017. 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.

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Travel, meals and entertainment costs for the twelve months ended December 31, 2018 were \$489,522, an increase of \$109,552, or 29%, from \$379,970 incurred during the twelve months ended December 31, 2017. During 2018, additional travel was required than in 2017 due to our marketing and fund-raising efforts.

Rent for the twelve months ended December 31, 2018 totaled \$205,675, an increase of \$62,700, or 44%, from \$142,975 incurred during the same period in 2017. In 2018, our significant increase was the result of our lease renewal and expansion in California along with the lease of additional offices in Texas and Connecticut in 2018.

*Depreciation Expense.* Depreciation expense for the twelve months ended 2018 totaled \$12,403 as compared to \$11,698 incurred during the same period in 2017. The increase is due primarily to additional equipment purchased in 2018

*Gain (loss) on change in fair values of derivatives.* Beginning in March 2015, we are required to estimate the fair value of the embedded beneficial conversion features of our issued Series C Preferred stock and certain warrants with reset (anti-dilution) provisions. In addition, in November 2017; we issued a Series D Preferred stock and warrants with also contained reset (anti-dilutive) provisions. During the year ended December 31, 2017, we incurred a gain on change in fair values of these derivatives of \$210,465. On January 1, 2018, we adopted ASU 2017-11 and according 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 and are no longer required to treat certain embedded beneficial conversion features or reset (anti-dilution) provisions as liabilities.

*Interest Income (expense).* Interest income for the twelve months ended December 31, 2018 totaled \$10,897 as compared to \$75 earned during the twelve months ended December 31, 2017. The increase in 2018 was due larger cash balances in our interest-bearing accounts.

*Preferred Stock Dividend.* Preferred stock dividend for the year ended December 31, 2018 totaled \$884,736, an increase of \$764,859, or 638% from \$119,877 incurred during the year ended December 31, 2017. Preferred stock dividends are primarily related to the issuance of our Series C, D and E Preferred Stock from 2013 through 2018. The significant increase in 2018 as compared to 2017 is the result of 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.

*Net Loss Available to Common Stockholders.* Net loss available to common stockholders for the twelve months ended December 31, 2018 was \$18,136,053, compared to a net loss of \$12,815,620 for the twelve months ended December 31, 2017, an increase of \$5,320,433 or 42%. The primary reasons for the increase, as described above, are the increases in general and administrative and preferred stock dividends, net with a reduction in research and development expenses from 2017 to 2018.

## **Liquidity and Capital Resources**

### *Twelve Months Ended December 31, 2018 Compared to Twelve Months Ended December 31, 2017*

As of December 31, 2018, we had a working capital of \$3,431,039, comprised of cash of \$4,450,160 and prepaid expenses of \$178,442, which was offset by \$954,655 of accounts payable and accrued expenses and accrued dividends on preferred stock issuances of \$242,908. For the twelve months ended December 31, 2018, cash provided by financing activities totaled \$13,465,687, comprised of proceeds from the sale of our common stock and convertible securities of \$9,139,721, sale of our Series E Preferred stock of \$1,492,969 and proceeds from the exercise of options and warrants of \$2,832,997. In the comparable period in 2017, \$6,041,214 was raised through the sale of our common stock and convertible securities and \$1,929,960 from the sale of our Series D Preferred stock. At December 31, 2018, we had cash of \$4,450,160 compared to \$1,547,579 at December 31, 2017. Our cash is held in bank deposit accounts. At December 31, 2018 and 2017, we had no convertible debentures outstanding.

Cash used in operations for the twelve months ended December 31, 2018 and 2017 was \$10,255,427 and \$7,470,054, 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.



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Cash used in investing activities for the twelve months ended December 31, 2018 was \$307,679, compared to \$9,436 for the twelve months ended December 31, 2017. During the twelve months ended December 31, 2018, we incurred \$268,796 in patent costs, \$850 in trademark registration and \$38,033 purchases of office furniture and computer equipment. For the twelve months ended December 31, 2017, we purchased office furniture and computer equipment of \$9,436.

On January 5, 2018, we consummated one closing under the Unit Purchase Agreement, dated April 6, 2017, by and among certain accredited investors (as defined by Rule 501 under the Securities Act of 1933, as amended), pursuant to which we issued 80,000 shares of our common stock and 40,000 warrants to purchase one share of our common stock, exercisable at a price of \$3.75 per share and expiring January 5, 2021, in exchange for aggregate consideration of \$299,985, net of \$15 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.

On February 16, 2018, we entered into a Securities Purchase Agreement with certain institutional accredited investors, pursuant to which we sold to the Investors an aggregate of 1,000 shares of our its Series E Preferred Stock, par value \$0.001 per share, and warrants to purchase an aggregate of 200,000 shares of our common stock, par value \$0.001 per share, at an exercise price of \$3.75 per share, in exchange for aggregate consideration of \$1,492,969, net of transaction expenses of \$7,031. 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 April 30, 2018 through May 11, 2018, we entered into a Unit Purchase Agreement (the "Purchase Agreement") with certain accredited investors (the "Investors"), pursuant to which the Company sold to the Investors an aggregate of 1,333,202 shares of the Company's common stock and warrants to purchase an aggregate of 666,603 shares of the Company's common stock, at an exercise price of \$4.375 per share, in exchange for aggregate consideration of \$4,998,445, net of transaction expenses of \$1,061 (the "April 2018 private placement"). 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 July 31, 2018 through August 17, 2018, we entered into a Unit Purchase Agreement (the "Purchase Agreement") with certain accredited investors (the "Investors"), pursuant to which the Company sold to the Investors an aggregate of 709,866 shares of the Company's common stock, warrants to purchase an aggregate of 177,476 shares of the Company's common stock, at an exercise price of \$3.75 per share and warrants to purchase an aggregate of 177,476 shares of the Company's common stock, at an exercise price of \$6.85, in exchange for aggregate consideration of \$3,871,276, net of transaction expenses of \$197,745 (the "July 2018 private placement"). 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.

As consideration for serving as our placement agent in connection with July 2018 the private placement, we issued to Laidlaw & Company (UK) Ltd. warrants to purchase an aggregate of 40,482 shares of common stock at an exercise price of \$6.85 per share and paid cash fees equal to \$173,831.

In their report dated March 15, 2019, our independent registered public accounting firm stated at December 31, 2018, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is an issue raised due to our net losses and negative cash flows from operations since inception and our expectation that these conditions will continue for the foreseeable future. In addition, we will require additional financing to fund future operations. Further, we do not have any commercial products available for sale and have not generated revenues to date, and there is no assurance that, if approval of our products is received, we will be able to generate cash flow to fund operations. In addition, there can be no assurance that our research and development will be successfully completed or that any product will be approved or commercially viable. Our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities, obtaining loans from various financial institutions or being awarded grants from government agencies, where possible. Our continued net operating losses increase the difficulty in meeting such goals and there can be no assurances that such methods will prove successful.

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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, 2018, the aggregate stated value of our Series C Preferred Stock was \$475,000. 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 research and development expenses, 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 being 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 not be sufficient to fund our operating expenses and capital equipment requirements. We anticipate we will need approximately \$10 million in addition to our current cash on hand to fund our operating expenses and capital equipment requirements for the next 12 months. We will have to raise additional funds to continue our operations and, while we have been successful in doing so in the past, there can be no assurance that we will be able to do so in the future. Our continuation as a going concern is dependent upon our ability to obtain necessary additional funds to continue operations and the attainment of profitable operations.

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**

In February 2016, the FASB 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 does not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter is not applicable to the Company.

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The new standard will have 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 will recognize additional operating lease liabilities, net of deferred rent, of approximately \$419,000 based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. The Company expects to recognize corresponding ROU assets of approximately \$419,000.

The new standard also provides practical expedients for an entity's ongoing accounting. The Company will elect 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 expects changes to its disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. These revised disclosures will be made in the Company's first quarterly report in 2019.

There were various other updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to 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. ("Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the results of its consolidated operations and its cash flows for each of the years in the two-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

### The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred losses from operations since inception and has used net cash in operating activities. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

### Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("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 consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated 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, New York  
March 15, 2019

**BIOSIG TECHNOLOGIES, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**DECEMBER 31, 2018 AND 2017**

ASSETS	<u>2018</u>	<u>2017</u>
Current assets:		
Cash	\$ 4,450,160	\$ 1,547,579
Prepaid expenses	178,442	116,938
Total current assets	<u>4,628,602</u>	<u>1,664,517</u>
Property and equipment, net	44,346	18,716
Other assets:		
Patents, net	268,796	-
Trademarks	850	-
Deposits	<u>54,238</u>	<u>17,084</u>
Total assets	<u>\$ 4,996,832</u>	<u>\$ 1,700,317</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses, including \$32,366 and \$27,375 to related parties as of December 31, 2018 and 2017, respectively	\$ 954,655	\$ 473,098
Dividends payable	242,908	447,901
Warrant liability	-	2,358,240
Derivative liability	<u>-</u>	<u>685,922</u>
Total current liabilities	1,197,563	3,965,161
Series C Preferred Stock, 475 and 985 shares issued and outstanding; liquidation preference of \$475,000 and \$985,000 as of December 31, 2018 and 2017, respectively	<u>475,000</u>	<u>985,000</u>
Commitments and Contingencies (Note 11)	-	-
Stockholders' equity (deficit)		
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		
Series D Preferred Stock, \$0.001 par value, 0 and 1,334 shares issued and outstanding; liquidation preference of \$0 and \$2,001,000 as of December 31, 2018 and 2017, respectively	-	1
Common stock, \$0.001 par value, authorized 200,000,000 shares, 16,868,783 and 11,728,482 issued and outstanding as of December 31, 2018 and 2017, respectively	16,869	11,728
Additional paid in capital	74,039,341	53,233,228
Common stock subscription	-	29,985
Accumulated deficit	<u>(70,731,941)</u>	<u>(56,524,786)</u>
Total stockholders' equity (deficit)	<u>3,324,269</u>	<u>(3,249,844)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 4,996,832</u>	<u>\$ 1,700,317</u>

See the accompanying notes to the consolidated financial statements.

**BIOSIG TECHNOLOGIES, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Operating expenses:		
Research and development	\$ 4,368,784	\$ 4,756,468
General and administrative	12,881,027	8,138,117
Depreciation	12,403	11,698
Total operating expenses	<u>17,262,214</u>	<u>12,906,283</u>
Loss from operations	(17,262,214)	(12,906,283)
Other income (expense):		
Gain on change in fair value of derivatives	-	210,465
Interest income	<u>10,897</u>	<u>75</u>
Loss before income taxes	(17,251,317)	(12,695,743)
Income taxes (benefit)	<u>-</u>	<u>-</u>
Net loss	(17,251,317)	(12,695,743)
Preferred stock dividend	<u>(884,736)</u>	<u>(119,877)</u>
<b>NET LOSS AVAILABLE TO COMMON STOCKHOLDERS</b>	<b><u>\$ (18,136,053)</u></b>	<b><u>\$ (12,815,620)</u></b>
Net loss per common share, basic and diluted	<u>\$ (1.25)</u>	<u>\$ (1.25)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>14,504,360</u>	<u>10,220,275</u>

See the accompanying notes to the consolidated financial statements.

**BIOSIG TECHNOLOGIES, INC.**  
**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)**  
**TWO YEARS ENDED DECEMBER 31, 2018**

	Series D Preferred stock		Series E Preferred stock		Common stock		Additional Paid in Capital	Common stock Subscription	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, January 1, 2017	-	\$ -	-	\$ -	9,035,274	\$ 9,035	\$41,032,804	\$ -	\$ (43,829,043)	\$ (2,787,204)
Sale of common stock	-	-	-	-	1,652,615	1,653	6,009,576	-	-	6,011,229
Sale of Series D preferred stock	1,334	1	-	-	-	-	1,929,959	-	-	1,929,960
Common stock issued for services	-	-	-	-	908,715	908	3,385,709	-	-	3,386,617
Common stock issued upon conversion of Series C Preferred Stock at \$3.75 per share	-	-	-	-	22,668	23	84,977	-	-	85,000
Common stock issued settlement of Series C Preferred Stock accrued dividends at \$3.32 per share	-	-	-	-	9,608	9	31,859	-	-	31,868
Common stock received and canceled in connection with short term swing profit reimbursement	-	-	-	-	(4,298)	(4)	4	-	-	-
Common stock subscription received	-	-	-	-	-	-	-	29,985	-	29,985
Reclassify initial fair value of derivative and warrant liability of Series D preferred stock and warrants at issuance	-	-	-	-	-	-	(1,049,216)	-	-	(1,049,216)
Reclassify fair value of derivative liability to equity upon conversion of Series C Preferred Stock to common shares	-	-	-	-	-	-	20,757	-	-	20,757
Fair value of warrant issued to acquire research and development	-	-	-	-	-	-	543,927	-	-	543,927
Stock based compensation	-	-	-	-	103,900	104	1,362,749	-	-	1,362,853
Preferred stock dividend	-	-	-	-	-	-	(119,877)	-	-	(119,877)
Net loss	-	-	-	-	-	-	-	-	(12,695,743)	(12,695,743)
Balance, December 31, 2017	1,334	\$ 1	-	\$ -	11,728,482	\$ 11,728	\$53,233,228	\$ 29,985	\$ (56,524,786)	\$ (3,249,844)





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

See the accompanying notes to the consolidated financial statements.

**BIOSIG TECHNOLOGIES, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (17,251,317)	\$ (12,695,743)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	12,403	11,698
Equipment distribution as officer compensation		3,210
Change in derivative liabilities	-	(210,465)
Equity based compensation	6,600,587	4,749,470
Fair value of issued warrant to acquire research and development	-	543,927
Changes in operating assets and liabilities:		
Prepaid expenses	(61,504)	17,325
Security deposit	(37,154)	10,528
Accounts payable and accrued expenses	478,751	102,338
Deferred rent payable	2,807	(2,342)
Net cash used in operating activities	<u>(10,255,427)</u>	<u>(7,470,054)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Payments of patent costs	(268,796)	-
Payment of trademark costs	(850)	-
Purchase of property and equipment	(38,033)	(9,436)
Net cash used in investing activity	<u>(307,679)</u>	<u>(9,436)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from sale of common stock	9,139,721	6,011,229
Proceeds from sale of Series D preferred stock	-	1,929,960
Proceeds from sale of Series E preferred stock	1,492,969	-
Proceeds from exercise of warrants	2,217,397	-
Proceeds from exercise of options	615,600	-
Proceeds from common stock subscription	-	29,985
Net cash provided by financing activities	<u>13,465,687</u>	<u>7,971,174</u>
Net increase in cash and cash equivalents	2,902,581	491,684
Cash and cash equivalents, beginning of the period	1,547,579	1,055,895
Cash and cash equivalents, end of the period	<u>\$ 4,450,160</u>	<u>\$ 1,547,579</u>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid during the period for interest	\$ -	\$ -
Cash paid during the period for income taxes	\$ -	\$ -
<b>Non cash investing and financing activities:</b>		
Common stock issued upon conversion of Series C Preferred Stock and accrued dividends	\$ 744,459	\$ 116,868
Reclassify initial fair value of derivative and warrant liabilities from equity upon issuance of Series D preferred stock	\$ -	\$ 1,049,216
Reclassify fair value of derivative liability to equity	\$ -	\$ 20,757
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	<u>\$ 3,044,162</u>	<u>\$ -</u>

See the accompanying notes to the consolidated financial statements.

**BIOSIG TECHNOLOGIES INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**

**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., a Delaware Corporation, for the purpose to pursue additional applications of the PURE EP™ signal processing technology outside of electrophysiology. As of December 31, 2018, there were no significant assets or liabilities in NeuroClear Technologies, Inc, or operations since its formation.

The consolidated financial statements include the accounts of BioSig Technologies, Inc. and its wholly 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 8).

*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 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, 2018 and 2017, deposits in excess of FDIC limits were \$4,200,160 and \$1,297,579, respectively.

**BIOSIG TECHNOLOGIES INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**

*Prepaid Expenses*

Prepaid expenses are comprised of vendor deposits of \$100,000, 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, 2018 and 2017, the Company did not have any derivative instruments that were designated as hedges.

At December 31, 2018 and 2017, the Company had outstanding preferred stock and warrants that contained embedded derivatives. These embedded derivatives include certain conversion features and reset provisions (See Note 6 and Note 7).

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*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 \$4,368,784 and \$4,756,468 for the year ended December 31, 2018 and 2017, respectively.

*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 12.

*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, 2018 and 2017 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:

	<b>2018</b>	<b>2017</b>
Series C convertible preferred stock	126,667	262,667
Series D convertible preferred stock	-	533,600
Options to purchase common stock	3,135,828	3,404,131
Warrants to purchase common stock	4,579,511	5,115,805
<b>Totals</b>	<b>7,842,006</b>	<b>9,316,203</b>

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*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. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. 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, 2018, the Company had 3,135,828 options outstanding to purchase shares of common stock, of which 3,007,946 were vested.

As of December 31, 2017, there were outstanding stock options to purchase 3,404,131 shares of common stock, 2,938,995 shares of which were vested.

*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 patent approval, capitalized costs will be amortized to expense using the straight-line method over the lesser of the legal patent term or the estimated life of the product.

*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 investors 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 agreements 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, 2018 and 2017.

Beginning on April 6, 2017, the Company entered into subscription agreements with certain accredited investors pursuant to which the Company sold to the investors 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 agreements 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, 2018.

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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, 2018 and 2017.

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, 2018.

*Adoption of Accounting Standards*

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.



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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.

In February 2016, the FASB 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 does not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter is not applicable to the Company.

The new standard will have 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 will recognize additional operating lease liabilities, net of deferred rent, of approximately \$419,000 based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. The Company expects to recognize corresponding ROU assets of approximately \$419,000.

The new standard also provides practical expedients for an entity’s ongoing accounting. The Company will elect 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 expects changes to its disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. These revised disclosures will be made in the Company’s first quarterly report in 2019.

*Recent Accounting Pronouncements*

In January 2017, the FASB issued ASU 2017-04, Intangibles – Goodwill and Other (Topic 350). The amendments in this update simplify the test for goodwill impairment by eliminating Step 2 from the impairment test, which required the entity to perform procedures to determine the fair value at the impairment testing date of its assets and liabilities following the procedure that would be required in determining fair value of assets acquired and liabilities assumed in a business combination. The amendments in this update are effective for public companies for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. We are evaluating the impact of adopting this guidance on the Company’s consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805); Clarifying the Definition of a Business. The amendments in this update clarify the definition of a business to help companies evaluate whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The amendments in this update are effective for public companies for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company adopted ASU 2017-01 in the first quarter of 2018 and such adoption did not have a material impact on the consolidated unaudited financial statements.

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There were various other updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to 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 consolidated financial statements, except as disclosed.

**NOTE 2 – GOING CONCERN AND MANAGEMENT'S LIQUIDITY PLANS**

As of December 31, 2018, the Company had cash of \$4,450,160 and working capital of \$3,431,039. The Company raised \$9,139,721 through the sale of common stock and warrants, \$1,492,969 through the sale of Series E preferred stock and warrants and \$2,832,997 through the exercise of warrants and options in 2018 (Note 9). Subsequent to December 31, 2018, the Company raised \$8,619,278 from sale of common stock and \$418,718 from the exercise of previous issued warrants (Note 13). During the year ended December 31, 2018, the Company used net cash in operating activities of \$10,255,427. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management believes that the Company has sufficient funds to meet its research and development and other funding requirements for at least the next 9 months.

The Company's primary source of operating funds since inception has been cash proceeds from private placements of common and preferred stock. The Company has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future. The Company has stockholders' deficiencies at December 31, 2018 and requires additional financing to fund future operations. Further, the Company does not have any commercial products available for sale and there is no assurance that if approval of their products is received that the Company will be able to generate cash flow to fund operations. In addition, there can be no assurance that the Company's research and development will be successfully completed or that any product will be commercially viable.

Accordingly, the accompanying consolidated financial statements have been prepared in conformity with U.S. GAAP, which contemplates continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the consolidated financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty.

**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, 2018 and 2017 was \$-0-.

Accrued expenses related primarily to travel reimbursements due related parties as of December 31, 2018 and 2017 was \$32,366 and \$27,375, respectively.

On April 1, 2017, the Company received and canceled 4,298 shares of its common stock as payment for short-swing profit pursuant to Section 16(b) of the U.S. Securities Exchange Act of 1934, as amended from Mr. Londoner.

On June 16, 2017 Mr. Cash was granted 40,000 shares of common stock at a cost basis of \$3.425 per share in connection with his severance settlement. The granted shares vested immediately.

On November 8, 2017, Mr. Londoner, Mr. Chaussy and Mr. O'Donnell were granted 180,000, 100,000 and 80,000 shares of common stock at a cost basis of \$3.80 per share for their 2017 performance, respectively. The granted shares vested immediately.

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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 \$3.625 per share of common stock, of which 60,000 options vest immediately and 60,000 options are performance conditioned. Mr. Filler is the general counsel and partner of Sherpa.

During the year ended December 31, 2018, the Company paid \$427,219 as patent costs, consulting fees and expense reimbursements. As of December 31, 2018 and 2017, there was an unpaid balance of \$0.

On November 9, 2017, Mr. Londoner, Mr. O'Donnell and Mr. Weild, as members of the board of directors, were granted each 20,000 shares of common stock at a cost basis of \$3.725 per share for their 2017 board and committee service. The granted shares vested immediately.

On November 9, 2017, Mr. Tanaka, Mr. Filler and Mr. Foley, as members of the board of directors, were granted each 12,000 shares of common stock at a cost basis of \$3.725 per share for their 2017 board service. The granted shares vested immediately.

On December 22, 2017 Mr. Gallagher and Mr. Fischer were granted options to purchase 15,971 and 26,390 shares of common stock at an exercise price of \$3.425 per share for their 2017 board service. The granted options vested as of December 22, 2017 and are exercisable for a ten year term.

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 and Mr. Chaussy were granted 240,000 and 100,000 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. Gallaher 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, O'Donnell Partners LLC (a company controlled by 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.

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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.

**NOTE 4 – PROPERTY AND EQUIPMENT**

Property and equipment as of December 31, 2018 and 2017 is summarized as follows:

	<b>2018</b>	<b>2017</b>
Computer equipment	\$ 105,447	\$ 87,059
Furniture and fixtures	32,619	12,975
Subtotal	138,066	100,034
Less accumulated depreciation	(93,720)	(81,318)
Property and equipment, net	\$ 44,346	\$ 18,716

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.

Depreciation expense was \$12,403 and \$11,698 for year ended December 31, 2018 and 2017, respectively.

**NOTE 5 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses at December 31, 2018 and 2017 consist of the following:

	<b>2018</b>	<b>2017</b>
Accrued accounting and legal	\$ 59,439	\$ 93,595
Accrued reimbursements and travel	27,853	2,600
Accrued consulting	89,718	109,059
Accrued research and development expenses	351,631	246,030
Accrued office and other	14,304	7,912
Accrued payroll	395,000	-
Deferred rent	3,377	569
Accrued settlement related to arbitration	13,333	13,333
	\$ 954,655	\$ 473,098

**NOTE 6 – 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.

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In addition, absent the approval of holders representing at least 67% of the outstanding shares of the Series C Preferred Stock, we may not (i) increase the number of authorized shares of preferred stock, (ii) amend our charter documents, including the terms of the Series C Preferred Stock, in any manner adverse to the holders of the Series C Preferred Stock, including authorizing or creating any class of stock ranking senior to, or otherwise pari passu with, the shares of Series C Preferred Stock as to dividends, redemption or distribution of assets upon a liquidation, or (iii) perform certain covenants, including:

- 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.

Any holder of Series C Preferred Stock is entitled at any time to convert any whole or partial number of shares of Series C Preferred Stock into shares of our common stock at a price of \$3.75 per share. The Series C Preferred Stock is subject to 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 \$3.75 per share as well as other customary anti-dilution protection.

In the event that:

- (i) we fail to, or announce our intention not to, deliver common stock share certificates upon conversion of our Series C Preferred Stock prior to the seventh trading day after such shares are required to be delivered,
- (ii) we fail for any reason to pay in full the amount of cash due pursuant to our failure to deliver common stock share certificates upon conversion of our Series C Preferred Stock within five calendar days after notice therefor is delivered,
- (iii) we fail to have available a sufficient number of authorized and unreserved shares of common stock to issue upon a conversion of our Series C Preferred Stock,
- (iv) we fail to observe or perform any other covenant, agreement or warranty contained in, or otherwise commit any breach of our obligations under, the securities purchase agreement, the registration rights agreement, the certificate of designation or the warrants entered into pursuant to the private placement transaction for our Series C Preferred Stock, which failure or breach could have a material adverse effect, and such failure or breach is not cured within 30 calendar days after written notice was delivered,
- (v) we are party to a change of control transaction,
- (vi) we file for bankruptcy or a similar arrangement or are adjudicated insolvent,
- (vii) we are subject to a judgment, including an arbitration award against us, of greater than \$100,000, and such judgment remains unvacated, unbonded or unstayed for a period of 45 calendar days,

The holders of the Series C Preferred Stock are entitled, among other rights, to redeem their shares of Series C Preferred Stock at any time for greater than their stated value or increase the dividend rate on their shares of Series C Preferred Stock to 18%. The Company determined that certain of the defined triggering events were outside the Company's control and therefore classified the Series C Preferred Stock outside of equity.

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 contain 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 are exercisable for cash; or if at any time after six months from the issuance date, there is 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 may be exercised by means of a "cashless exercise".

As a result of an amendment to the conversion price of our Series C Preferred Stock, the full-ratchet anti-dilution protection provision of the warrants decreased the exercise price of the warrants from \$6.53 per share to \$3.75 per share and increased the aggregate number of shares issuable under the warrants to 926,121.

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In accordance with ASC 470-20, at issuance, the Company recognized an embedded beneficial conversion feature present in the Series C Preferred Stock when it was issued. The Company allocated the net proceeds between the intrinsic value of the conversion option (\$1,303,671) and the warrants (\$1,064,739) to additional paid-in capital. The aggregate debt discount, comprised of the relative intrinsic value of the conversion option (\$1,303,671), the relative fair value of the warrants (\$1,064,739), and the issuance costs (\$412,590), for a total of \$2,781,000, is amortized over an estimated one year as interest expense.

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 issued warrants 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 is not required. There was no established market for the Company’s common stock. As described in Note 7, as of March 31, 2015, the Company determined a market had been established for the Company’s common stock and accordingly, reclassified 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, from equity to liabilities.

*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.

*2018 and 2017 conversions:*

In June 2017, the Company issued an aggregate of 24,338 shares of its common stock in exchange for 65 shares of the Company’s Series C Preferred Stock and accrued dividends.

In July 2017, the Company issued an aggregate of 7,938 shares of its common stock in exchange for 20 shares of the Company’s Series C Preferred Stock and accrued dividends.

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 summary, the Company issued 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 and an aggregate of 32,276 shares of its common stock in exchange for 85 shares of the Company’s Series C Preferred stock (stated value of \$85,000) and \$31,868 accrued dividends for the year ended December 31, 2017.

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Series C Preferred Stock issued and outstanding totaled 475 and 985 as of December 31, 2018 and 2017, respectively. As of December 31, 2018 and 2017, the Company has accrued \$242,908 and \$419,283 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, 2018 and 2017, the Company estimated the liability at \$-0-.

**NOTE 7 – 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.

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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 8) 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 8 – 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, 2018 and 2017, 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 (2018) 1,000 shares of Series E Preferred Stock. As of December 31, 2018 and December 31, 2017, there were no outstanding shares of Series A and Series B preferred stock and as of December 31, 2018, there were no outstanding Series D and Series E preferred stock.

*Series C Preferred Stock*

In June 2017, the Company issued an aggregate of 24,338 shares of its common stock in exchange for 65 shares of the Company's Series C Preferred Stock and accrued dividends.

In July 2017, the Company issued an aggregate of 7,938 shares of its common stock in exchange for 20 shares of the Company's Series C Preferred Stock and accrued dividends.

Cumulatively from January 1, 2017 to December 31, 2017, the Company exchanged 85 shares of the Company's Series C Preferred Stock and dividends with a recorded value of \$116,868 for 32,276 shares of common 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.



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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.

Cumulatively from January 1, 2018 to December 31, 2018, the Company exchanged 510 shares of the Company's Series C Preferred Stock and dividends with a recorded value of \$744,459 for 192,002 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 is 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 is 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 shall be 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 may pay 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 November 3, 2020, the Company shall 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.

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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 and 2017.

*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, 2018 and 2017, the Company has 0 and 1,334 Series D Preferred Stock issued and outstanding and has accrued \$0 and \$28,618 dividends payable on the Series D Preferred stock, respectively.

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*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 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 is 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 is 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 shall be 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 may pay 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 shall 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.

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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, 2018 and 2017, the Company has 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, 2018 and 2017, the Company had 16,868,783 and 11,728,482 shares issued and outstanding, respectively.

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During the year ended December 31, 2017, the Company issued an aggregate of 730,000 shares of common stock under the terms of its 2012 Equity Plan for services rendered totaling \$2,705,250 (\$3.71 average per share).

During the year ended December 31, 2017, the Company issued an aggregate of 178,715 shares of its common stock for services totaling \$681,367 (\$3.81 per share).

During the year ended December 31, 2017, the Company issued an aggregate of 54,000 and 49,900 shares of its common stock for vested restricted stock units and stock based compensation previously accrued in 2016.

During the year ended December 31, 2017, the Company entered into securities purchase agreements with investors pursuant to which the Company issued 1,652,615 shares of common stock and 898,520 warrants for aggregate proceeds of \$6,011,229, net of \$186,075 in expenses.

In April 2017, the Company received and canceled 4,298 shares of its common stock as payment for short-swing profit pursuant to Section 16(b) of the U.S. Securities Exchange Act of 1934, as amended from an officer and member of the Company's Board of Directors.

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.

In connection with certain 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.

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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, 2018 and 2017.

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, 2018 and 2017.

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, 2018.

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**NOTE 9 – OPTIONS, RESTRICTED STOCK UNITS AND WARRANTS***Options*

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 to purchase up to 15,186,123 (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 910,346 shares of its common stock for future issuance under the terms of the Plan.

During the year ended December 31, 2017, the Company granted an aggregate of 1,400,696 options to officers, directors and key consultants.

During the year ended December 31, 2017, the Company granted an aggregate of 803,900 stock grants to officers, employees and key consultants under the plan. See Note 8.

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 8.

The following table presents information related to stock options at December 31, 2018:

<b>Options Outstanding</b>			<b>Options Exercisable</b>	
<b>Exercise Price</b>	<b>Number of Options</b>	<b>Weighted Average Remaining Life In Years</b>	<b>Exercisable Number of Options</b>	
\$ 2.51-5.00	1,203,218	7.7	\$ 1,163,218	
5.01-7.500	1,812,610	3.5	1,724,728	
7.51-10.00	120,000	6.3	120,000	
	3,135,828	5.2	3,007,946	

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A summary of the stock option activity and related information for the 2012 Plan for the years ended December 31, 2018 and 2017 is as follows:

	Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2017	3,298,079	\$ 5.60	6.4	\$ -
Grants	672,360	3.75	10.0	\$ -
Exercised	-		-	-
Canceled	(566,308)	5.43		-
Outstanding at December 31, 2017	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	\$ 311,545
Exercisable at December 31, 2018	3,007,946	\$ 5.36	5.0	\$ 297,745

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 \$4.27 as of December 31, 2018, 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 from an index of historical stock prices of comparable entities until sufficient data exists to estimate the volatility using the Company's own historical stock prices. Management determined this assumption to be a more accurate indicator of value. 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, 2018 and 2017 was estimated using the Black-Scholes pricing model.

On February 8, 2017, the Company granted an aggregate of 52,000 options to purchase the Company stock in connection with the services rendered at the exercise price of \$3.875 per share for a term of ten years with vesting immediately.

On November 8, 2017, the Company granted 80,000 options to purchase the Company stock in connection with the services rendered at the exercise price of \$3.925 per share for a term of ten years with 20,000 vesting immediately and 20,000 vesting each anniversary through November 8, 2020.

On November 8, 2017, the Company granted 190,000 options to purchase the Company stock in connection with the services rendered at the exercise price of \$3.925 per share for a term of ten years with 95,000 vesting immediately and 95,000 at one year anniversary.

On November 24, 2017, the Company granted 20,000 options to purchase the Company stock in connection with the services rendered at the exercise price of \$3.625 per share for a term of ten years, vesting immediately.

On November 24, 2017, the Company granted 168,000 options to purchase the Company stock in connection with the services rendered at the exercise price of \$3.625 per share for a term of ten years with 48,000 vesting immediately; 20,000 vesting on two year anniversary and 100,000 performance contingent.



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On November 24, 2017, the Company granted 120,000 options to purchase the Company stock in connection with the services rendered at the exercise price of \$3.75 per share for a term of ten years with 60,000 vesting immediately and 60,000 performance contingent.

On December 22, 2017, the Company granted 42,360 options to purchase the Company stock in connection with the services rendered at the exercise price of \$3.425 per share for a term of ten years, vesting immediately.

The following assumptions were used in determining the fair value of employee and vesting non-employee options during the year ended December 31, 2017:

Risk-free interest rate	2.01% - 2.34%
Dividend yield	0%
Stock price volatility	95.72% to 107.17%
Expected life	5 – 10 years
Weighted average grant date fair value	\$ 2.925

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

The fair value of all options vesting during the year ended December 31, 2018 and 2017 of \$2,357,242 and \$1,269,591, respectively, was charged to current period operations. Unrecognized compensation expense of \$173,446 and \$979,812 at December 31, 2018 and 2017, respectively, will be expensed in future periods.

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*Restricted Stock*

The following table summarizes the restricted stock activity for the two years ended December 31, 2018:

Restricted shares issued as of January 1, 2017	135,000
Granted	-
Vested	(135,000)
Total restricted shares issued as of December 31, 2017	-
Granted	-
Vested	-
Vested restricted shares as of December 31, 2018	-
Unvested restricted shares as of December 31, 2018	-

Stock based compensation expense related to restricted stock grants was \$0 and \$93,261 for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, the stock-based compensation relating to restricted stock of \$-0- remains unamortized.

*Warrants*

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at December 31, 2018:

Exercise Price	Number Outstanding	Expiration Date
\$ 0.0025	153,328	January 2020
\$ 3.75	2,442,424	April 2019 to August 2021
\$ 4.375	666,606	May 2021
\$ 4.60	12,294	January 2020
\$ 4.875	412,943	February 2019 to September 2019
\$ 5.05	12,227	January 2020
\$ 6.85	217,958	July 2021 to August 2021
\$ 6.875	91,504	August 2019 to September 2019
\$ 9.175	33,960	January 2019
\$ 9.375	536,267	April 2019 to March 2020
	<u>4,579,511</u>	

On February 9, 2017, the Company exchanged 15,429 warrants with an exercise price of \$5.25 with 18,001 warrants with an exercise price of \$3.75, all other terms and conditions the same, to 2016 investors to adjust offered terms in connection with the Company's equity raise with other investors.

On February 10, 2017, the Company issued an aggregate of 120,253 warrants to purchase the Company's common stock at \$3.75 per share, expiring on February 10, 2020, in connection with the sale of the Company's common stock.

On March 10, 2017, the Company issued an aggregate of 78,864 warrants to purchase the Company's common stock at \$3.75 per share, expiring on March 10, 2020, in connection with the sale of the Company's common stock.

On March 15, 2017, the Company issued 252,000 warrants to purchase the Company's common stock at \$3.75 per share, expiring on March 15, 2020, to Mayo Foundation in connection with a know-how licensing agreement (See Note 10). The fair value of the of the issued warrants of \$543,927, determined using the Black-Scholes option model with an estimated volatility of 105.22%, risk free rate of 1.599%, dividend yield of -0- and fair value of the Company's common stock of \$1.37, was charged to current period operations as acquired research and development.

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On March 31, 2017, the Company issued an aggregate of 62,900 warrants to purchase the Company's common stock at \$3.75 per share, expiring on March 31, 2020, in connection with the sale of the Company's common stock.

On April 6, 2017, the Company issued an aggregate of 115,321 warrants to purchase the Company's common stock at \$3.75 per share, expiring on April 6, 2020, in connection with the sale of the Company's common stock.

On May 5, 2017, the Company issued an aggregate of 2,667 warrants to purchase the Company's common stock at \$3.75 per share, expiring on May 5, 2020, in connection with the sale of the Company's common stock.

On May 17, 2017, the Company issued an aggregate of 74,785 warrants to purchase the Company's common stock at \$3.75 per share, expiring on May 17, 2020, for placement agent services in connection with the sale of the Company's common stock.

On June 20, 2017, the Company issued 4,000 warrants to purchase the Company's common stock at \$3.75 per share, expiring on June 20, 2020, in connection with the sale of the Company's common stock.

On June 30, 2017, the Company issued an aggregate of 43,334 warrants to purchase the Company's common stock at \$3.75 per share, expiring on June 30, 2020, in connection with the sale of the Company's common stock.

On July 13, 2017, the Company issued an aggregate of 53,401 warrants to purchase the Company's common stock at \$3.75 per share, expiring on July 13, 2020, in connection with the sale of the Company's common stock.

On August 18, 2017, the Company issued an aggregate of 70,200 warrants to purchase the Company's common stock at \$3.75 per share, expiring on August 18, 2020, in connection with the sale of the Company's common stock.

On September 18, 2017, the Company issued an aggregate of 20,668 warrants to purchase the Company's common stock at \$3.75 per share, expiring on September 18, 2020, in connection with the sale of the Company's common stock.

On October 11, 2017, the Company issued an aggregate of 77,334 warrants to purchase the Company's common stock at \$3.75 per share, expiring on October 11, 2020, in connection with the sale of the Company's common stock.

On November 3, 2017, the Company issued an aggregate of 266,800 warrants to purchase the Company's common stock at \$3.75 per share, expiring on May 3, 2021, in connection with the sale of the Company's Series D preferred stock. The warrants contain certain anti-dilutive provisions (see Note 8).

On November 3, 2017, the Company issued an aggregate of 312,203 warrants to purchase the Company's common stock at \$3.75 per share, expiring on November 3, 2020 in exchange for the return and cancellation of previously issued 312,202 warrants. The transaction was in connection with the sale of the Series D preferred stock. Both the issued and canceled warrants contain certain anti-dilutive provisions (see Note 8).

On November 6, 2017, the Company issued an aggregate of 82,668 warrants to purchase the Company's common stock at \$3.75 per share, expiring on November 6, 2020, in connection with the sale of the Company's common stock.

On November 6, 2017, due to certain anti-dilutive provisions embedded in the November 3, 2017 warrants issued in connection with the sale of Series D preferred stock (see above), exercise price of the previously issued 266,800 warrants were reset to \$3.75 and an additional 44,467 warrants were issued with an exercise price of \$3.75 per share, expiring May 3, 2021.

On December 29, 2017, the Company issued an aggregate of 92,134 warrants to purchase the Company's common stock at \$3.75 per share, expiring on December 29, 2020, in connection with the sale of the Company's common stock.

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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.

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A summary of the warrant activity for the years ended December 31, 2018 and 2017 is as follows:

	Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2017	3,651,438	\$ 4.90	2.1	\$ 494,099
Grants	1,792,000	\$ 3.75	3.0	-
Exercised	-		-	-
Canceled/Expired	(327,633)	\$ 3.75	-	-
Outstanding at December 31, 2017	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
Vested and expected to vest at December 31, 2018	4,579,511	\$ 4.73	1.5	\$ 1,924,388
Exercisable at December 31, 2018	4,579,511	\$ 4.73	1.5	\$ 1,924,388

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 \$4.27 as of December 31, 2018, which would have been received by the warrant holders had those warrant holders exercised their warrants as of that date.

**NOTE 10 – 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.

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Upon adoption of ASC 825-10, there was no cumulative effect adjustment to beginning retained earnings and no impact on the consolidated financial statements.

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, 2018 and 2017, the Company did not have any items that would be classified as level 1 or 2 disclosures.

As of December 31, 2018 and 2017, the Company did not have any derivative instruments that were designated as hedges.

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

The derivative and warrant liability as of December 31, 2017, in the amount of \$685,922 and \$2,358,240, respectively, has a level 3 classification.

The following table provides a summary of changes in fair value of the Company's level 3 financial liabilities as of December 31, 2018:

	<b>Warrant Liability</b>	<b>Derivative</b>
Balance, December 31, 2016	\$ 1,937,234	\$ 288,934
Total (gains) losses		
Initial fair value of warrant liability at date of issuance	652,054	-
Initial fair value of derivative at date of issuance of Series D Preferred Stock	-	397,162
Transfers out due to conversion of Series C Preferred Stock	-	(20,757)
Mark to market to December 31, 2017	(231,048)	20,583
Balance, December 31, 2017	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		
	-	-
Gain (loss) on change in warrant and derivative liabilities for the year ended December 31, 2018	\$ -	\$ -

Fluctuations in the Company's stock price are a primary driver for the changes in the derivative valuations during each reporting period. As the stock price decreases for each of the related derivative instruments, the value to the holder of the instrument generally decreases, therefore decreasing the liability on the Company's balance sheet. Additionally, stock price volatility is one of the significant unobservable inputs used in the fair value measurement of each of the Company's derivative instruments.

#### **NOTE 11 – COMMITMENTS AND CONTINGENCIES**

##### *Operating leases*

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. In addition, the Company entered into a lease for storage space with the Los Angeles, California building commencing on December 1, 2017 and expiring on August 31, 2019 for approximately \$223 per month.

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 and expiring July 31, 2019 for \$979 per month.

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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 and expiring September 30, 2019 for \$2,000 per month.

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

<b>Year Ending December 31,</b>	
2019	222,919
2020	204,657
2021	111,713
	<u>\$ 539,289</u>

*Licensing agreements*

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 autonomies 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.

*Employment agreements*

On July 14, 2014, the Company's Board of Directors (the "Board") increased the size of the Board to eight members and appointed Gregory D. Cash and Patrick J. Gallagher as members of the Board, effective as of July 15, 2014, to serve for a term expiring at the Company's 2015 annual meeting of stockholders. In addition, the Board appointed Mr. Cash to serve as the Company's president and chief executive officer.

In connection with the appointment of Mr. Cash, on July 15, 2014 (the "Effective Date"), the Company entered into an employment agreement with Mr. Cash (the "Employment Agreement"). The Employment Agreement has an initial term of three years that expires on July 15, 2017. Under the Employment Agreement, Mr. Cash is entitled to an annual base salary of \$275,000. Upon the Company closing an equity or equity-linked financing with proceeds to the Company of at least \$3.5 million (a "Qualified Financing"), Mr. Cash's annual base salary will automatically increase to \$325,000 and he will receive (i) a one-time payment equal to the difference between the amount he would have earned if his base salary was \$325,000 and the amount he actually earned at his base salary of \$275,000 for the time period from the Effective Date until the closing of such Qualified Financing and (ii) a one-time cash bonus of \$30,000. If the Company does not complete a Qualified Financing within six months after the Effective Date, Mr. Cash's annual base salary will nonetheless increase to \$325,000 and he will receive the same one-time payment unless the Company reasonably determines that the failure to complete such Qualified Financing was within the reasonable control of Mr. Cash. Mr. Cash is also eligible to receive an annual bonus equal to at least 50% of the sum of his base salary and one-time payment, based on the achievement of reasonable performance criteria to be determined by the Board in consultation with Mr. Cash within 90 days of the Effective Date.

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In accordance with the Employment Agreement, on July 15, 2014, the Company granted Mr. Cash an incentive stock option to purchase 506,308 shares of the Company's common stock, made pursuant to an Incentive Stock Option Agreement. The option has an exercise price of \$5.525, which was the fair market value of the Company's common stock on the date of grant, and a term that expires ten years from the date of grant. The option will vest as follows (i) 216,990 shares of common stock will vest in eleven equal installments of 18,083 shares of common stock and one final installment of 18,077 shares of common stock on a quarterly basis with the first installment vesting on the Effective Date and subsequent installments vesting every three months thereafter; (ii) 72,330 shares of common stock will vest immediately upon completion of a Qualified Financing; (iii) 72,330 shares of common stock will vest upon the listing of the Company's common stock on a recognized U.S. national securities exchange (i.e., NYSE, MKT LLC, The Nasdaq Stock Market LLC or the New York Stock Exchange); (iv) 72,329 shares of common stock will vest upon the 510(k) clearance or any other type of clearance deemed necessary by the U.S. Food and Drug Administration of the Company's PURE (Precise Uninterrupted Real-time evaluations of Electrograms) EP technology platform; and (v) 72,329 shares of common stock will vest upon the Company achieving a market capitalization of \$150,000,000 and maintaining such market capitalization for at least 90 consecutive calendar days.

Effective July 15, 2017, the Company elected not to continue under the above described agreement and accordingly terminated employment with Mr. Cash.

As of December 31, 2018 and 2017, there are no outstanding employment agreements.

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, 2018.

**NOTE 12 – INCOME TAXES**

At December 31, 2018, the Company has available for federal income tax purposes a net operating loss carry forward of approximately \$34,000,000, 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, 2018, the Company has decreased the valuation allowance by \$1,000,000 from \$8,200,000 to \$7,200,000. 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 are 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.



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The effective rate differs from the statutory rate of 21% as of December 31, 2018 and 34% as of December 31, 2017 due to the following:

	<u>2018</u>	<u>2017</u>
Statutory rate on pre-tax book loss	(21.00)%	(34.00)%
(Gain) loss on change in fair value of derivatives	-%	(0.56)%
Stock based compensation	8.25%	12.72%
Fair value of warrant to acquire research and development	-%	1.46%
Other	0.04%	0.09%
Valuation allowance	12.71%	20.29%
	<u>0.00%</u>	<u>0.00%</u>

The Company's deferred taxes as of December 31, 2018 and 2017 consist of the following:

	<u>2018</u>	<u>2017</u>
Non-Current deferred tax asset:		
Net operating loss carry-forwards	\$ 7,200,000	\$ 8,200,000
Valuation allowance	(7,200,000)	(8,200,000)
Net non-current deferred tax asset	<u>\$ -</u>	<u>\$ -</u>

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 13 – SUBSEQUENT EVENTS**

##### *Options granted:*

On January 22, 2019, the Company granted an aggregate of 460,000 options to purchase the Company's common stock to key employees and consultants with an exercise price of \$4.33 per share, vesting over three years quarterly beginning April 1, 2019 and expiring ten years from issuance date.

On March 14, 2019, the Company granted an aggregate 345,000 options to purchase the Company's common stock to key employees and consultants with an exercise price of \$5.66 per share with 20,000 options vesting on the first anniversary of the Grant Date, 150,000 vesting over three years annually and 175,000 vesting over three years quarterly beginning April 1, 2019 and expiring ten years from issuance date.

##### *Restricted stock units granted:*

On February 28, 2019, the Company granted 70,000 restricted stock units for services to two key employees with one third vesting immediately and remainder vesting over two years on anniversary.

##### *Common stock*

On January 22, 2019, the Company issued 465,000 shares of its common stock for services rendered to key employees and a consultant.

On February 1, 2019, the Company issued 40,000 shares of its common stock for services rendered to key consultants.

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On February 28, 2019, the Company issued an aggregate of 23,332 shares of its common stock for previously issued restricted stock units to employees on February 28, 2019, 30,000 shares of its common stock for services rendered to a key consultant and 25,000 shares of its common stock as employee compensation.

In 2019, the Company issued an aggregate of 111,658 shares of its common stock in exchange for proceeds of \$418,718 from the exercise of warrants.

In 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 \$1,172 in expenses.

In connection with the securities purchase agreements, the Company entered into registration rights agreements pursuant to which the Company agreed to provide registration rights with respect to the common stock issued to the 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 within 90 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.

## **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.

Disclosure controls and procedures were not effective due primarily to a material weakness in the segregation of duties in the Company's internal control of financial reporting as discussed below.

#### *Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting 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 conducted an evaluation of the design and operation of our internal control over financial reporting as of December 31, 2018, 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, 2018, because management identified a material weakness in the Company's internal control over financial reporting related to the segregation of duties as described below.

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The Company concluded it is difficult with a very limited staff to maintain appropriate segregation of duties in the initiating and recording of transactions, thereby creating a segregation of duties weakness. Due to: (i) the significance of segregation of duties to the preparation of reliable financial statements; (ii) the significance of potential misstatement that could have resulted due to the deficient controls; and (iii) the absence of sufficient other mitigating controls, we determined that this control deficiency resulted in more than a remote likelihood that a material misstatement or lack of disclosure within the annual or interim financial statements may not be prevented or detected.

### *Management's Remediation Initiatives*

This Annual Report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to the rules of the SEC that permit the Company to provide only management's report in this Annual Report.

Management has evaluated, and continues to evaluate, avenues for mitigating our internal controls weaknesses, but mitigating controls to completely mitigate internal control weaknesses have been deemed to be impractical and prohibitively costly, due to the size of our organization at the current time. Management expects to continue to use reasonable care in following and seeking improvements to effective internal control processes that have been and continue to be in use at the Company. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks.

### **ITEM 9B – OTHER INFORMATION**

None.

**PART III****ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The following table sets forth information regarding our executive officers and the members of our board of directors.

<b>Name</b>	<b>Age</b>	<b>Position with the Company</b>
Kenneth L. Londoner	51	Chief Executive Officer, Executive Chairman and Director
Steve Chaussy	65	Chief Financial Officer
Donald E. Foley	67	Director
Roy T. Tanaka	70	Director
Andrew L. Filler	52	Director
Patrick J. Gallagher	54	Director
Seth H. Z. Fischer	62	Director
Jeffrey F. O'Donnell, Sr.	59	Director
David Weild IV	62	Director

Directors are elected at each annual meeting of our stockholders and hold office until their successors are elected and qualified or until their earlier resignation or removal. Officers are appointed by our board of directors and serve at the discretion of the board of directors.

**Biographical Information**

*Kenneth L. Londoner.* Mr. Londoner has served as our director since February 2009, as our executive chairman since November 2013 and our chief executive officer since July 2017. He previously served as our chairman and chief executive officer from February 2009 to September 2013. Mr. Londoner has served as the managing partner of Endicott Management Partners, LLC, a firm dedicated to assisting emerging growth companies in their corporate development, since February 2010. From April 2007 to October 2009, he served as executive vice president – corporate business development and senior director of business development and, from November 2009 to December 2010, he served as a consultant to NewCardio, Inc., a medical device designer and developer. Mr. Londoner also served as a director of chatAND Inc. from January 2012 to April 2015. Mr. Londoner is a co-founder and board member of Safe Ports Holdings, Charleston, South Carolina. Mr. Londoner also served as a director of MedClean Technologies, Inc. from November 2008 to September 2010. Mr. Londoner was an investment officer and co-manager of the Seligman Growth Fund, Seligman Capital Fund, and approximately \$2 billion of pension assets at J & W Seligman & Co, Inc. in New York from 1991 to 1997. Mr. Londoner graduated from Lafayette College in 1989 with a degree in economics and finance and received his MBA from New York University's Leonard N. Stern School of Business in 1994. We believe that Mr. Londoner's extensive experience in financial and venture capital matters, as well as his intimate knowledge of our company as its co-founder make him an asset to our board of directors.

*Steve Chaussy.* Mr. Chaussy has served as our chief financial officer on a full-time basis since January 2018. Mr. Chaussy served as our chief financial officer on a part time basis from May 2011 to January 2018. Since 2005, Mr. Chaussy has been the sole proprietor of Anna & Co., Inc., a consulting company that offers services to small publicly traded companies. Anna & Co., Inc. provides general financial and accounting services, with a special emphasis towards SEC reporting and compliance, to companies that lack sufficient resources to hire full-time employees to provide such services. From 2001 to 2005, Mr. Chaussy provided services as both a chief financial officer and as a consultant to small publicly traded companies. Prior to 2001, Mr. Chaussy served as chief financial officer for a large private distribution and wholesaling company, where he gained international experience. Mr. Chaussy is a graduate of Virginia Polytechnic Institute and State University and is a licensed certified public accountant in Virginia, California and Florida.

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*Donald E. Foley.* Mr. Foley has served as our director since October 2015. Mr. Foley was chairman of the board and chief executive officer of Wilmington Trust Corporation from 2010-2011. Prior to Wilmington Trust Corporation, Mr. Foley was senior vice president, treasurer and director of tax for ITT Corporation, a supplier of advanced technology products and services. Mr. Foley currently serves on the board of directors of AXA Equitable EQAT Mutual Funds and is an advisory board member of M&T Corporation Trust and Investment Committee. Mr. Foley also served on the boards of directors of M&T Corporation from 2011-2012 and of Wilmington Trust Company, Wilmington Funds and Wilmington Trust Corporation from 2007-2011. In addition, Mr. Foley serves as chairman of the board of trustees of the Burke Rehabilitation Hospital and Burke Medical Research Institute, as well as the W. Burke Foundation since 2009 during which time the Hospital merged with the MonteFiore Hospital System. Mr. Foley holds an M.B.A. from New York University, and a B.A. from Union College where he had served as a trustee, and as a chairman of the President's Council. He also served as a trustee of the Covent of the Sacred Heart; and currently serves as a trustee at the Sacred Heart Network of schools and chairman of the board at New Beginning Family Academy, a charter school in Bridgeport, CT. Mr. Foley brings extensive financial, economic, capital markets and executive leadership expertise to our board gained through his successful career on Wall Street and the Fortune 500.

*Roy T. Tanaka.* Mr. Tanaka has served as our director since July 2012. From 2004 until his retirement in September 2008, Mr. Tanaka served as the worldwide president of Biosense Webster, Inc., a Johnson & Johnson company, a market and technology leader in the field of electrophysiology. He joined Biosense Webster, Inc. as its U.S. president in 1997. Previously he held a variety of senior management positions at Sorin Biomedical, Inc., including president and chief executive officer, and leadership roles at CooperVision Surgical and Shiley, a division of Pfizer, Inc. He currently serves on the boards of directors of Epix Therapeutics Inc., a company developing technology to measure the temperature in a lesion during cardiac ablation procedures, and VytronUS Inc., a company developing ultrasound technology in the diagnosis and treatment of complex cardiac arrhythmias. In addition, Mr. Tanaka served as a director of Volcano Corporation until May 2014 and Tomo Therapy until its acquisition in June 2011. Mr. Tanaka brings broad experience in executive leadership in the medical device field. His operational expertise and knowledge of the regulatory environment, both in the U.S. and globally, also bring a valuable perspective.

*Andrew L. Filler.* Mr. Filler has served as our director since November 2017. Mr. Filler brings to BioSig over 20 years of experience in intellectual property for technology and medical device companies. He currently serves as Partner and General Counsel for Sherpa Technology Group since February 2014. In addition, Mr. Filler has served as General Counsel and Vice President of IP for Nanosys, Inc. from July 2004 until February 2014 and currently consults with Nanosys, Inc. on business and legal matters. Mr. Filler also served as chief intellectual property counsel at Caliper Technologies from January 2002 until June 2004, senior associate attorney at Weil, Gotshal & Manges from 1995 to 1997 and again from January 2000 until January 2002, and director of intellectual property at Corvascular from 1997 until 2000. We believe that Mr. Filler's extensive experience as an intellectual property lawyer and managing extensive intellectual property portfolios make him a valuable member of our board.

*Patrick J. Gallagher.* Mr. Gallagher has served as our director since July 2014. Mr. Gallagher, MBA, CFA, is an accomplished capital markets executive, advisor, and investor with a distinguished record of success in both the public and private markets. He has nearly 20 years of experience on Wall Street and extensive expertise in alternative investments, capital markets, and marketing. Since September 2014, Mr. Gallagher has served as senior managing director and head of healthcare sales at Laidlaw & Co. (UK) Ltd. Mr. Gallagher serves as a strategic consultant for Athenex, Inc., a biopharmaceutical firm focused on next-generation therapies in oncology and immunology and was the vice president of business development and investor relations from September 2012 to October 2013. He also sits on the board of directors of Cingulate Therapeutics since July 2013, a clinical stage biopharmaceutical company focused on innovative new products for ADHD, as well as Evermore Global Advisors, a global money manager since May 2015. In November 2010, he was appointed by broker Concept Capital, a division of Sanders Morris Harris, as a Managing Director and the head of institutional sales. In 2001, Mr. Gallagher co-founded BDR Research Group, LLC, an independent sell-side research firm specializing in healthcare investing, financing and operations, and served as its chief executive officer until November 2010. Prior to 2001, he held various sales positions at investment and research firms Kidder Peabody, PaineWebber and New Vernon Associates. Mr. Gallagher is a CFA charter holder, received his MBA from Pennsylvania State University and holds a B.S. degree in finance from the University of Vermont. We believe that Mr. Gallagher's experience in capital markets and marketing, with extensive expertise concentrated in the life sciences space, make him a valuable resource on our board.

*Seth H. Z. Fischer.* Mr. Fischer has served as our director since May 2013. He most recently served as the Chief Executive Officer and as a director of Vivus, Inc., a publicly traded biopharmaceutical company commercializing and developing innovative, next-generation therapies to address unmet needs, with currently marketed products in metabolic disease and sexual health from September 2013 - December 2017. Prior to Vivus, Mr. Fischer served in positions of increasing responsibility with Johnson & Johnson, a public healthcare company, from 1983 until his retirement in 2012. Mr. Fischer served as Company Group Chairman, Johnson & Johnson, and Worldwide Franchise Chairman, Cardiovascular Devices, Cordis Corporation, from 2008 to 2012, which included responsibility for Cordis and Biosense Webster, and as Company Group Chairman, North America Pharmaceuticals from 2004 to 2007, which included responsibility for Ortho-McNeil Pharmaceuticals, Janssen, McNeil Pediatrics, and Scios. Prior to this position, He served as President of Ortho-McNeil Pharmaceuticals from 2000 to 2004, with his operating responsibilities encompassing the commercialization of products in multiple therapeutic categories including epilepsy, migraine, analgesic, anti-infective, cardiovascular, neurologic, psychiatric and women's health areas. Mr. Fischer currently serves as a member of the board of directors Agile Therapeutics, Inc., a public pharmaceutical company focused on women's health. He also serves on the board of directors of Marinus Pharmaceuticals, Inc., a public biopharmaceutical company focused on epilepsy and neuropsychiatric disorders. From April 2013 to September 2013, Mr. Fischer served on the board of directors of Trius Therapeutics, Inc., a public pharmaceutical company, until it was acquired by Cubist Pharmaceuticals, now a wholly owned subsidiary of Merck & Co., Inc. Mr. Fischer holds a Bachelor of General Studies from Ohio University and served as a captain in the U.S. Air Force. Mr. Fischer brings extensive executive level strategic and operational experience to our Board needed for strategic planning, product development, commercialization and operations.

*Jeffrey F. O'Donnell, Sr.* Mr. O'Donnell is currently our lead director since January 1, 2019 and has served as our director since February 2015; he had previously served as a director from October 2011 until February 2014. Mr. O'Donnell has extensive experience in the Healthcare industry, merging a solid, traditional corporate background with emerging growth experience. Jeff brings more than 20 years of Board and Chief Executive experience running emerging medical device firms. Businesses under his direct leadership have achieved over \$1.5 Billion in value creation from initial public offering of stock or mergers and acquisitions. Currently, Jeff is the Chief Executive Officer and a Director of Trice Medical. Trice is an emerging growth medical device company developing optical needles used by orthopedic surgeons to diagnose soft tissue damage of joints. In 2008, Jeff started and ran Embrella Cardiovascular, a medical device startup company, which was sold in 2011 to Edwards Lifesciences (NYSE: EW). Prior to Embrella Cardiovascular, Jeff served as President and CEO of PhotoMedex (NASDAQ: PHMD) from 1999 to 2009. Prior to PhotoMedex, Jeff was the President and CEO of Cardiovascular Dynamics. His team took CCVD public on NASDAQ in June of 1996 and purchased Radiance Medical Systems and Endologix (NASDAQ: ELGX). From 1994 to 1995 Jeff held the position of President and CEO of Kensey Nash Corporation (NASDAQ: KNSY). Additionally, he has held several senior sales and marketing management positions at Boston Scientific Corporation, Guidant Corporation and with Johnson & Johnson's Orthopedic Division. In 2005, Jeff was named LifeSciences CEO of the Year by Price Waterhouse Coopers. In 2011, Jeff was named the Greater Philadelphia Emerging Entrepreneur of The Year by Ernst & Young. In 2017, Jeff assumed the role of Chairman of the Board of Directors for SpectraWave, a cardiology device company. He joined the AdvaMed Accel Board of Directors in 2016 and serves as an observer on the Membership, Ethics and Technology and Regulatory committees of the AdvaMed Board. Previously, Jeff served as Chairman of the Board of Strata Skin Sciences (NASDAQ: SSKN) (2 years) as well as Director on the Board at Cardiac Science (7 yrs.) and Endologix (12 yrs.). Jeff is a graduate of LaSalle University in Philadelphia. Mr. O'Donnell brings his experience in the healthcare industry and cardiovascular space, along with his experience with emerging growth companies, which will make him a valuable member of our board of directors.

*David Weild IV.* Mr. Weild has served as a director since May 2015. Mr. Weild is founder, chairman and CEO of Weild & Co., Inc., parent company of the investment banking firm Weild Capital, LLC. Prior to Weild & Co., Mr. Weild was vice chairman of NASDAQ, president of PrudentialFinancial.com and head of corporate finance and equity capital markets at Prudential Securities, Inc. Mr. Weild holds an M.B.A. from the Stern School of Business and a B.A. from Wesleyan University. Mr. Weild is currently on the board of PAVmed. From September 2010 to June 2011, Mr. Weild served on the board of Helium.com, until it was acquired by R.R. Donnelly & Sons Co. Since 2003, Mr. Weild was a director and then chairman of the board of the 9-11 charity Tuesday's Children. He became chairman emeritus in late 2016 and still serves on the board. Mr. Weild brings extensive financial, economic, stock exchange, capital markets, and small company expertise to the Company gained throughout his career on Wall Street. He is a recognized expert in capital markets and has spoken at the White House, Congress, the SEC, OECD and the G-20 on how market structure can be bettered to improve capital formation and economic growth.

## **Family Relationships**

There are no family relationships among any of our officers or executive officers.

## **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and officers, and persons who own more than ten percent of our common stock, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. To our knowledge, based solely on a review of the copies of such reports furnished to us, during the fiscal year ended December 31, 2018, we believe that all filing requirements applicable to our officers, directors and greater than ten percent stockholders were complied with for the fiscal year ended December 31, 2018, except that, due to an administrative error, Form 4s were filed late for each of our directors on November 9, 2018 reporting long-term incentive awards made to such directors. In addition, two Form 4s were filed late for Mr. Londoner with respect to three transactions, one Form 4 was filed late for Mr. Gallagher with respect to one transaction, and one Form 4 was filed late for Mr. Filler with respect to one transaction..

## **Independent Directors**

Our board of directors has determined that each of Roy T. Tanaka, David Weild IV, Patrick J. Gallagher, Donald E. Foley, Seth H. Z. Fischer, Andrew L. Filler and Jeffrey F. O'Donnell, Sr. is independent within the meaning of Rule 5605(a)(2) of the NASDAQ Listing Rules and the rules and regulations promulgated by the Securities and Exchange Commission.

## **Committees of the Board of Directors**

Our board of directors has established an audit committee, a nominating and corporate governance committee and a compensation committee, each of which has the composition and responsibilities described below.

### *Audit Committee*

Our audit committee is currently comprised of Messrs. Weild, Gallagher and O'Donnell, each of whom our board has determined to be financially literate and qualifies as an independent director under Section 5605(a)(2) and Section 5605(c)(2) of the rules of the NASDAQ Stock Market. Mr. Weild is the chairman of our audit committee. In addition, Mr. Weild qualifies as a financial expert, as defined in Item 407(d)(5)(ii) of Regulation S-K.

### *Nominating and Corporate Governance Committee*

Our nominating and corporate governance committee is currently comprised of Messrs. Filler, Foley and Tanaka, each of whom qualifies as an independent director under Section 5605(a)(2) of the rules of the NASDAQ Stock Market. Mr. Filler is the chairman of our nominating and corporate governance committee.

### *Compensation Committee*

Our compensation committee is currently comprised of Messrs. O'Donnell and Gallagher, each of whom qualifies as an independent director under Section 5605(a)(2) of the rules of the NASDAQ Stock Market, an "outside director" for purposes of Section 162(m) of the Internal Revenue Code and a "non-employee director" for purposes of Section 16b-3 under the Securities Exchange Act of 1934, as amended, and does not have a relationship to us which is material to his ability to be independent from management in connection with the duties of a compensation committee member, as described in Section 5605(d)(2) of the rules of the NASDAQ Stock Market. Mr. O'Donnell is the chairman of our compensation committee.

## **Code of Ethics**

We have adopted a code of business conduct and ethics that applies to our officers, directors and employees, including our principal executive officer, principal financial officer and principal accounting officer. The full text of our Code of Business Conduct and Ethics is published on the Investors section of our website at [www.biosigtech.com](http://www.biosigtech.com). We intend to disclose any future amendments to certain provisions of the Code of Business Conduct and Ethics, or waivers of such provisions granted to executive officers and directors, on this website within four business days following the date of any such amendment or waiver.



**ITEM 11 - EXECUTIVE COMPENSATION**

**Compensation Philosophy and Practices**

We believe that the performance of our executive officers significantly impacts our ability to achieve our corporate goals. We, therefore, place considerable importance on the design and administration of our executive officer compensation program. This program is intended to enhance stockholder value by attracting, motivating and retaining qualified individuals to perform at the highest levels and to contribute to our growth and success. Our executive officer compensation program is designed to provide compensation opportunities that are tied to individual and corporate performance.

Our compensation packages are also designed to be competitive in our industry. The Compensation Committee from time-to-time consults with other advisors in designing our compensation program, including in evaluating the competitiveness of individual compensation packages and in relation to our corporate goals.

Our overall compensation philosophy has been to pay our executive officers an annual base salary and to provide opportunities, through cash and equity incentives, to provide higher compensation if certain key performance goals are satisfied.

The main principles of our fiscal year 2018 compensation strategy included the following:

- *An emphasis on pay for performance.* A significant portion of our executive officers' total compensation is variable and at risk and tied directly to measurable performance, which aligns the interests of our executives with those of our stockholders;
- *Performance results are linked to Company and individual performance.* When looking at performance over the year, we equally weigh individual performance as well as that of the Company as a whole. Target annual compensation is positioned to allow for above-median compensation to be earned through an executive officer's and the Company's extraordinary performance;
- *Equity as a key component to align the interests of our executives with those of our stockholders.* Our Compensation Committee continues to believe that keeping executives interests aligned with those of our stockholders is critical to driving toward achievement of long-term goals of both our stockholders and the Company; and

**Summary Compensation Table**

The following table provides certain summary information concerning compensation, for our last two fiscal years awarded to, earned by or paid to our named executive officers: (i) Kenneth L. Londoner, our chief executive officer, executive chairman and member of our board, and (ii) Steven Chaussy, our chief financial officer. We had no executive officers during our last completed fiscal year other than Mr. Londoner and Mr. Chaussy.

Name and principal position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)	Nonequity Incentive Plan Compensation (\$)	Change in	All Other Compensation (\$)	Total (\$)
							Pension Value and Nonqualified Deferred Compensation Earnings (\$)		
Kenneth L. Londoner, Chief Executive Officer, Executive Chairman and Director (5)	2018	654,167	200,000	1,381,800 (1)			-	-	- 2,235,967
	2017	435,000	-	758,500 (2)			-	-	- 1,193,500
Steven Chaussy, Chief Financial Officer	2018	318,750	95,000	442,500 (3)			-	-	- 856,250
	2017	180,833		380,000 (4)			-	-	- 560,833

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- (1) Represents (i) common stock award of 240,000 fully vested shares granted on May 4, 2018 and (ii) common stock award of 60,000 fully vested shares granted on November 6, 2018.
- (2) Represents (i) common stock award of 180,000 fully vested shares granted November 8, 2017 and (ii) a common stock award of 20,000 shares granted on November 9, 2017.
- (3) Represents a common stock award of 100,000 fully vested shares granted May 4, 2018.
- (4) Represents a common stock award of 100,000 fully vested shares granted November 8, 2017.
- (5) Mr. Londoner served as our Executive Chairman and Director through the entirety of our last two fiscal years. Mr. Londoner has served as our Chief Executive Officer since July 31, 2017.

### **Narrative Disclosure to Summary Compensation Table**

#### ***Executive Employment Agreements***

Mr. Londoner and Mr. Chaussy are at-will employees and neither have an employment agreement with us. Additionally, we do not have any agreements that would provide for payment to any of Mr. Londoner or Mr. Chaussy following, or in connection with the resignation, retirement or other termination of either of them, a change of control of us, or a change in either of their responsibilities following a change of control of us.

#### *Kenneth L. Londoner*

Mr. Londoner's salary, bonus and stock awards were determined by the Compensation Committee with consultation from members of the board of directors.

#### *Steve Chaussy*

Mr. Chaussy's salary, bonus and stock awards were determined by the chairman of the board with consultation from members of the board of directors.

#### *Retirement Plans*

As part of our overall compensation program, we provide all full-time employees, including our named executive officers, with the opportunity to participate in a defined contribution 401(k) plan. Our 401(k) plan is intended to qualify under Section 401 of the Internal Revenue Code so that employee pre-tax contributions and income earned on such contributions are not taxable to employees until withdrawn. Employees may elect to defer up to 100 percent of their eligible compensation (not to exceed the statutorily prescribed annual limit) in the form of elective deferral contributions to our 401(k) plan. Our 401(k) plan also has a "catch-up contribution" feature for employees aged 50 or older (including those who qualify as "highly compensated" employees) who can defer amounts over the statutory limit that applies to all other employees.

#### *Employee Benefits and Perquisites*

Along with all other full-time employees, Mr. Londoner and Mr. Chaussy are eligible to participate in our health and welfare plans which are comprised of medical and dental insurance benefits.

#### *No Tax Gross-Ups*

We do not make gross-up payments to cover our executives' personal income taxes that may pertain to any of the compensation paid by us.

**Outstanding Equity Awards at Fiscal Year End**

The following table sets forth information regarding equity awards that have been previously awarded to each of the named executive officers and which remained outstanding as of December 31, 2018.

Name	Number of Securities underlying Unexercised Options (#) Exercisable	Number of Securities underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$/Sh)	Option Expiration Date	Number of Shares or Units of Stock that have not Vested (#)	Market Value of Shares of Units That Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that Have Not Vested (#)	Equity Incentive Plan Awards: Market of Payout Value of Unearned Shares, Units or Other Rights that Have Not Vested (\$)
Kenneth Londoner	100,000	-	\$ 5.23	1/16/2020	-	\$ -	-	\$ -
Steven Chaussy	12,000	-	\$ 5.23	1/16/2020	-	\$ -	-	\$ -
	12,000	-	\$ 5.23	6/11/2023	-	\$ -	-	\$ -

**Director Compensation**

The following table sets forth summary information concerning the total compensation paid to our non-employee directors during the fiscal year ended December 31, 2018 for services to our company.

Name	Fees Earned or Paid in Cash (\$)	Equity Awards (\$)	Total (\$)
Donald E. Foley	\$ -	\$ 133,250 (1)	\$ 133,250
Roy T. Tanaka	\$ -	\$ 113,641 (2)	\$ 113,641
Andrew L. Filler	\$ -	\$ 317,191 (3)	\$ 317,191
Patrick J. Gallagher	\$ -	\$ 133,250 (4)	\$ 133,250
Seth H. Z. Fischer	\$ -	\$ 266,500 (5)	\$ 266,500
Jeffrey F. O'Donnell, Sr	\$ -	\$ 266,500 (6)	\$ 266,500
David Weild, IV	\$ -	\$ 227,281 (7)	\$ 227,281
<b>Total:</b>	\$ -	\$ 1,457,613	\$ 1,457,613

- (1) Represents (i) a common stock award of 25,000 fully vested shares granted on November 19, 2018
- (2) Represents (i) a stock option granted October 16, 2018 for the purchase of 34,566 shares of common stock, 17,283 vesting immediately and 17,283 vesting January 1, 2019, at an exercise price of \$5.09 and termination date of October 16, 2028
- (3) Represents (i) a stock option granted February 15, 2018 for the purchase of 20,000 shares of common stock, vesting immediately at an exercise price of \$3.55 and termination date of February 15, 2028 and (ii) a common stock award of 50,000 shares granted on November 6, 2018
- (4) Represents (i) a common stock award of 25,000 fully vested shares granted on November 20, 2018
- (5) Represents (i) a common stock award of 50,000 fully vested shares granted November 9, 2018
- (6) Represents (i) a common stock award of 50,000 fully vested shares granted November 6, 2018
- (7) Represents (i) a stock option granted October 16, 2018 for the purchase of 69,132 shares of common stock, 17,283 vesting immediately and 17,283 vesting January 1, 2019, 17,283 vesting on January 1, 2020 and 17,283 vesting on January 1, 2021 at an exercise price of \$5.09 and termination date of October 16, 2028

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

**Equity Compensation Plan Information**

The following table provides certain information as of December 31, 2018, with respect to our equity compensation plans under which our equity securities are authorized for issuance:

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,135,828	\$ 5.33	1,907,509
Equity compensation plans not approved by security holders	-	-	-
<b>Total</b>	<b>3,135,828</b>	<b>\$ 5.33</b>	<b>1,907,509</b>

**BioSig Technologies, Inc. 2012 Equity Incentive Plan**

On October 19, 2012, our board of directors approved the BioSig Technologies, Inc. 2012 Equity Incentive Plan (the “2012 Plan”), which provides for the grant of stock options, stock appreciation rights, restricted stock and restricted stock units to employees, directors and consultants, to be granted from time to time as determined by our board of directors or its designees. Our stockholders approved the 2012 Plan on October 17, 2012. An aggregate of 7,474,450 shares of common stock are reserved for issuance under the 2012 Plan. As of March 14, 2019, the number of options and restricted stock awards granted under the 2012 Plan are 6,581,128. The material features of the 2012 Plan are described below.

*Purpose.* The purpose of the 2012 Plan is to enable us to attract and retain the best available personnel for positions of substantial responsibility, provide additional incentive to employees, directors, and consultants, and to promote the success of the our business. The 2012 Plan provides for the granting of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, and restricted stock units, which may be granted singly, in combination, or in tandem, and which may be paid in cash, shares of common stock, or a combination of cash and shares of common stock, as described in more detail below.

*Effective Date and Expiration.* The 2012 Plan became effective on October 19, 2012 and will continue in effect for a term of 10 years from the later of (a) the plan’s effective date, October 19, 2012, or (b) the earlier of the most recent board of directors or stockholder approval of an increase in the number of shares reserved for issuance under the 2012 Plan.

*Share Authorization.* Subject to certain adjustments, the maximum aggregate number of shares of our common stock that may be delivered pursuant to awards under the 2012 Plan is currently 7,474,450 shares (which includes 600,000 shares of our common stock previously reserved for issuance for awards under our previous incentive plan, but never so issued or which expired or were terminated, forfeited, or repurchased by the Company), 100% of which may be delivered pursuant to incentive stock options.

Shares to be issued may be made available from authorized but unissued or reacquired shares of our common stock. If an award under the 2012 Plan is cancelled, forfeited to or repurchased by us, expires (in whole or in part), or is surrendered pursuant to an “Exchange Program” (as defined in the 2012 Plan), the shares subject to such cancelled, forfeited, repurchased, expired, or surrendered award may again be awarded under the 2012 Plan. With respect to stock appreciation rights, only shares of common stock actually issued pursuant to a stock appreciation right will cease to be available under the 2012 Plan, with the remaining shares of common stock subject to the stock appreciation right remaining available for future awards under the 2012 Plan. If shares of common stock are delivered to us in full or partial payment of the exercise price of a stock option or the tax withholding obligations related to awards granted under the 2012 Plan, the number of shares available for future awards under the 2012 Plan shall be reduced only by the net number of shares issued upon the exercise of the stock option or settlement of an award. Awards that may be satisfied either by the issuance of common stock or by cash or other consideration shall be counted against the maximum number of shares that may be issued under the 2012 Plan only to the extent the award is ultimately satisfied by the issuance of shares.

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*Administration.* The 2012 Plan may be administered by our board of directors or one or more of its committees as may be designated by the board of directors to administer the 2012 Plan (the “Administrator”). The Administrator will determine the persons to whom awards are to be made; determine the type, size, and terms of awards; construe and interpret the 2012 Plan and awards granted thereunder; establish and revise rules and regulations relating to the 2012 Plan; institute and determine the terms and conditions of an Exchange Program, and make any other determinations it believes necessary for the administration of the 2012 Plan. Subject to the provisions of the 2012 Plan, the Administrator’s decisions, determinations, and interpretations will be final and binding on all plan participants and any other award holders.

*Eligibility.* Employees (including any employee who is also a director or an officer), consultants, and non-employee directors of the Company who render services to the Company are eligible to participate in the 2012 Plan.

*Stock Options.* The Administrator may grant either incentive stock options (“ISOs”) qualifying under Section 422 of the Internal Revenue Code of 1986, as amended (the “Code”) or nonstatutory stock options, provided that only employees of the Company and its subsidiaries (excluding subsidiaries that are not corporations) are eligible to receive ISOs. Stock options may not be granted with an option price less than 100% of the fair market value of a share of common stock on the date the stock option is granted. If an ISO is granted to an employee who owns or is deemed to own more than 10% of the combined voting power of all classes of stock of the Company (or any parent or subsidiary), the option price shall be at least 110% of the fair market value of a share of common stock on the date of grant. The Administrator will determine the terms of each stock option at the time of grant, including, without limitation, the methods by or forms in which shares will be delivered to participants. The maximum term of each option, the times at which each option will be exercisable, and provisions requiring forfeiture of unexercised options at or following termination of employment or service generally are fixed by the Administrator, except that the Administrator may not grant stock options with a term exceeding ten years or, in the case of an ISO granted to an employee who owns or is deemed to own more than 10% of the combined voting power of all classes of stock of the Company (or any parent or subsidiary), a term exceeding five years.

The Administrator will determine the manner in which recipients of stock options may pay the option exercise price, which may include payment: (i) by cash, check, or promissory note, to the extent permitted by applicable laws; (ii) in shares of our common stock, provided such shares have a fair market value equal to the aggregate exercise price of the options exercised, and provided further that accepting such shares will not result in any adverse tax consequences to the Company, as the Administrator may determine in its sole discretion; (iii) under a cashless exercise program (whether through a broker or otherwise); (iv) by net exercise; (v) by such other methods of payment for the issuance of shares of common stock, to the extent permitted by applicable laws; or (vi) any combination of the foregoing.

*Stock Appreciation Rights.* The Administrator is authorized to grant stock appreciation rights (“SARs”) as a stand-alone award, or freestanding SARs, or in conjunction with options granted under the 2012 Plan, or tandem SARs. SARs entitle a participant to receive an amount, in cash, shares, or a combination thereof, equal to the excess of the fair market value of a share of common stock on the date of exercise over the fair market value of a share of common stock on the date of grant. The grant price of a SAR cannot be less than 100% of the fair market value of a share of common stock on the date of grant. The Administrator will determine the terms of each SAR at the time of the grant, including, without limitation, the methods by or forms in which shares will be delivered to participants. The maximum term of each SAR, the times at which each SAR will be exercisable, and provisions requiring forfeiture of unexercised SARs at or following termination of employment or service generally are fixed by the Administrator, except that no freestanding SAR may have a term exceeding ten years and no tandem SAR may have a term exceeding the term of the option granted in conjunction with the tandem SAR.

*Restricted Stock and Restricted Stock Units.* The Administrator is authorized to grant restricted stock and restricted stock units. Restricted stock consists of shares of common stock that may not be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated, and that may be forfeited in the event of certain terminations of employment or service prior to the end of a restricted period as specified by the Administrator in the applicable award agreement. Restricted stock units are the right to receive shares of common stock, cash, or a combination thereof at a future date in accordance with the terms of such grant upon the attainment of certain conditions specified by the Administrator, which include a substantial risk of forfeiture and restrictions on their sale or other transfer by the participant. The Administrator determines the eligible participants to whom, and the time or times at which, grants of restricted stock or restricted stock units will be made, the number of shares or units to be granted, the price to be paid, if any, the time or times within which the shares covered by such grants will be subject to forfeiture, the time or times at which the restrictions will terminate, and all other terms and conditions of the grants. Restrictions or conditions could include, but are not limited to, the attainment of certain Company-wide, business unit, or individual goals (including, without limitation, continued employment with or service to the Company), or any other basis determined by the Administrator in its discretion.

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*Vesting, Forfeiture, Assignment.* The Administrator, in its sole discretion, may determine that an award will be immediately vested in whole or in part, or that all or any portion may not be vested until a date, or dates, subsequent to its date of grant, or until the occurrence of one or more specified events, subject in any case to the terms of the 2012 Plan. If the Administrator imposes conditions upon vesting, then, except as otherwise provided below, subsequent to the date of grant, the Administrator may, in its sole discretion, accelerate the date on which all or any portion of the award may be vested.

The Administrator may impose on any award at the time of grant or thereafter, such additional terms and conditions as the Administrator determines, including, without limitation, terms requiring forfeiture of awards in the event of a participant's termination of employment or service. Except as otherwise determined by the Administrator, restricted stock will be forfeited upon a participant's termination of employment or service during the applicable restriction period.

Awards granted under the 2012 Plan generally are not assignable or transferable except by will or by the laws of descent and distribution, except that the Administrator may, in its discretion and pursuant to the terms of an award agreement, permit transfers of awards (i) by will, (ii) by the laws of descent and distribution, or (iii) as permitted by Rule 701 of the Securities Act of 1933, as amended.

*Adjustments Upon Changes in Capitalization.* In the event that any dividend or other distribution (whether in the form of cash, common stock, other securities, or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of shares of common stock or other securities of the Company, or other change in the corporate structure of the Company affecting shares of common stock occurs, then the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the 2012 Plan, will adjust the number and class of shares of common stock that may be delivered under the 2012 Plan and/or the number, class, and price of shares of common stock covered by each outstanding award. Notwithstanding the foregoing, no such adjustment shall be made or authorized to the extent that such adjustment would cause the 2012 Plan or any stock option to violate Section 422 of the Code or Section 409A of the Code. All such adjustments must be made in accordance with the rules of any securities exchange, stock market, or stock quotation system to which we are subject.

*Amendment or Discontinuance of the 2012 Plan.* The board of directors may at any time and from time to time, without the consent of the participants, alter, amend, revise, suspend, or discontinue the 2012 Plan in whole or in part, except that we will obtain stockholder approval of any plan amendment to the extent necessary and desirable to comply with the requirements relating to the administration of equity-based awards under U.S. state corporate laws, U.S. federal and state securities laws, the Code, any stock exchange or quotation system on which our common stock is listed or quoted, and the applicable laws of any foreign country or jurisdiction where awards are, or will be, granted under the 2012 Plan. Any amendments made shall, to the extent deemed necessary or advisable by our board of directors, be applicable to any outstanding awards theretofore granted under the 2012 Plan, notwithstanding any contrary provisions contained in any award agreement, provided that no amendment, alteration, suspension, or termination of the 2012 Plan will impair the rights of any participant unless mutually agreed to between the participant and the Administrator in a writing signed by both the participant and an authorized representative of the Company. Termination of the 2012 Plan will not affect the Administrator's ability to exercise its powers granted under the 2012 Plan with respect to awards granted under the 2012 Plan prior to the date of its termination.

## **SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

### **Common Stock**

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 14, 2019:

- by each person who is known by us to beneficially own more than 5.0% of our common stock;
- by each of our named executive officers and directors; and
- by all of our named executive officers and directors as a group.

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The percentages of common stock beneficially owned are reported on the basis of regulations of the Securities and Exchange Commission governing the determination of beneficial ownership of securities. Under the rules of the Securities and Exchange Commission, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. Except as indicated in the footnotes to this table, to our knowledge and subject to community property laws where applicable, each beneficial owner named in the table below has sole voting and sole investment power with respect to all shares beneficially owned and each person's address is c/o BioSig Technologies, Inc., 12424 Wilshire Blvd., Suite 745, Los Angeles, California 90025.

<u>Name of Beneficial Owner</u>	<u>Number of Shares of Common Stock Beneficially Owned (1)</u>	<u>Percentage Class (1)(2)</u>	<u>Number of Shares of Series C Preferred Stock Beneficially Owned</u>	<u>Percentage Class (14)</u>	<u>Total Voting Power</u>
<i>5% Beneficial Owners</i>					
Lora Mikolaitis	1,423,490 (3)	7.16%	-	-	7.16%
David Cherry	1,445,341 (4)	7.16%	-	-	7.16%
Kenneth Epstein	154,816 (15)	*	100	21.05%	*
Jerome B. Zeldis	248,782 (16)	1.25%	50	10.53%	1.25%
Ray Weber	16,960 (17)	*	45	9.47%	*
INTL FCStone Financial Inc C/F Raymond E Weber IRA	13,243 (18)	*	35	7.37%	*
Alliance Trust Company FBO Brian Mark Miller	37,166 (19)	*	100	21.05%	*
Fourfathom Capital, LLC	37,837 (20)		100	21.05%	*
Martin F. Sauer	21,995 (21)		25	5.26%	*
<i>Officers and Directors</i>					
Kenneth L. Londoner	2,165,167 (5)	10.92%	-	-	10.92%
Roy T. Tanaka	424,487 (6)	2.11%	-	-	2.11%
Seth H. Z. Fischer	296,768 (7)	1.49%	-	-	1.49%
Patrick J. Gallagher	151,065 (8)	*	-	-	*
Jeffrey F. O'Donnell, Sr.	401,920 (9)	2.02%	-	-	2.02%
Steve Chaussy	590,330 (10)	2.99%	-	-	2.99%
Andrew L. Filler	95,008 (11)	*	-	-	*
David Weild IV	194,566 (12)	*%	-	-	*
Donald E. Foley	247,000 (13)	1.25%	-	-	1.25%
All directors and executive officers as a group (9 persons)	4,566,311	23.00%	-	-	23.00%

\* Less than 1%

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- (1) Shares of common stock beneficially owned and the respective percentages of beneficial ownership of common stock assume the exercise of all options and other securities convertible into common stock beneficially owned by such person or entity currently exercisable or exercisable within 60 days of March 14, 2019, except as otherwise noted. Shares issuable pursuant to the exercise of stock options and other securities convertible into common stock exercisable within 60 days are deemed outstanding and held by the holder of such options or other securities for computing the percentage of outstanding common stock beneficially owned by such person, but are not deemed outstanding for computing the percentage of outstanding common stock beneficially owned by any other person.
- (2) These percentages have been calculated based on 19,718,900 shares of common stock outstanding as of March 14, 2019.
- (3) Comprised of (i) 42,500 shares of common stock, (ii) options to purchase 150,000 shares of common stock that are currently exercisable or exercisable within 60 days of March 14, 2019, and (iii) 1,230,990 shares of common stock held by Miko Consulting Group, Inc. Lora Mikolaitis has sole voting and dispositive power over the securities held for the account of Miko Consulting Group, Inc.
- (4) Comprised of (i) 165,877 shares of common stock and warrants to purchase 42,000 shares of common stock, (ii) 126,658 shares of common stock and warrants to purchase 63,329 shares of common stock held by Thomas David Cherry as Trustee of Cherry Family Trust, a trust for which David Cherry is deemed the beneficial owner, (iii) 687,151 shares of common stock and warrants to purchase 343,577 shares of common stock held by Cherry Pipes Ltd., and (iv) 11,165 shares of common stock and warrants to purchase 5,584 shares of common stock held by Helen Martin for which Mr. Cherry is deemed the beneficial owner. David Cherry has sole voting and dispositive power over the securities held for the account of Cherry Pipes Ltd.
- (5) Comprised of (i) 883,843 shares of common stock directly held by Mr. Londoner, (ii) 1,181,324 shares of common stock held by Endicott Management Partners, LLC, an entity for which Mr. Londoner is deemed the beneficial owner, (iii) options to purchase 100,000 shares of common stock that are currently exercisable. Mr. Londoner has sole voting and dispositive power over the securities held for the account of Endicott Management Partners, LLC.
- (6) Comprised of (i) 32,350 shares of common stock and (ii) options to purchase 392,137 shares of common stock that are currently exercisable.
- (7) Comprised of (i) 60,000 shares of common stock and (ii) options to purchase 236,768 shares of common stock that are currently exercisable.
- (8) Comprised of (i) 46,294 shares of common stock directly held by Mr. Gallagher, (ii) 2,400 shares of common stock held by Amy E Gallagher Educational Trust for which Mr. Gallagher is deemed the beneficial owner with sole voting and dispositive power over the securities held by the trust, (iii) 2,400 shares of common stock held by Hans Gallagher Educational Trust for which Mr. Gallagher is deemed the beneficial owner with sole voting and dispositive power over the securities held by the trust, (iv) options to purchase 95,971 shares of common stock that are currently exercisable or exercisable within 60 days of March 14, 2019, and (v) warrants to purchase 4,000 shares of common stock.
- (9) Comprised of (i) 243,600 shares of common stock and (ii) options to purchase 158,320 shares of common stock that are currently exercisable.
- (10) Comprised of (i) 566,330 shares of common stock and (ii) options to purchase 24,000 shares of common stock that are currently exercisable.
- (11) Comprised of (i) 67,608 shares of common stock, (ii) options to purchase 20,000 shares of common stock that are currently exercisable and (iii) warrants to purchase 2,400 shares of common stock.
- (12) Comprised of (i) 20,000 shares of common stock and (ii) options to purchase 174,566 shares of common stock that is currently exercisable.
- (13) Comprised of (i) 127,000 shares of common stock, (ii) options to purchase 120,000 shares of common stock that are currently exercisable or exercisable within March 14, 2019.
- (14) These percentages have been calculated based on 475 shares of Series C Preferred Stock outstanding as of March 14, 2019.



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- (15) Comprised of (i) 116,866 shares of common stock, (ii) 37,950 shares of common stock issuable upon the conversion of shares of our Series C Preferred Stock, including dividends accrued thereon as of March 14, 2019, and (iii) 16,652 shares of common stock issued upon the exercise of warrants issued in consideration of certain amendments made to our Securities Purchase Agreement and Registration Rights Agreement. Mr. Epstein's address is 4 Brightfield Lane, Westport, CT 06880.
- (16) Comprised of (i) 67,612 shares of common stock, (ii) 18,976 shares of common stock issuable upon the conversion of shares of our Series C Preferred Stock, including dividends accrued thereon as of March 14, 2019, (iii) 2,194 shares of common stock issuable upon the exercise of warrants purchased in two private placement transactions, and (iv) options to purchase 160,000 shares of common stock that are currently exercisable. Mr. Zeldis' address is 151 Library Place, Princeton, NJ 08540.
- (17) Comprised of shares of common stock issuable upon the conversion of shares of our Series C Preferred Stock, including dividends accrued thereon as of March 14, 2019. Ray Weber may also be deemed beneficial owner of shares held by Sterne Agee & Leach Inc C/F Raymond E Weber IRA. Mr. Weber's address is 27 Zabriskie St., Jersey City, NJ 07307.
- (18) Comprised of shares of common stock issuable upon the conversion of shares of our Series C Preferred Stock, including dividends accrued thereon as of March 14, 2019. This stockholder's address is 27 Zabriskie St., Jersey City, NJ 07307.
- (19) Comprised of shares of common stock issuable upon the conversion of shares of our Series C Preferred Stock, including dividends accrued thereon as of March 14, 2019. This stockholder's address is 60 Summit Avenue, Mill Valley, CA 94941.
- (20) Brian Miller, manager of Fourfathom Capital, LLC, has sole voting and dispositive power over the securities held for the account of this selling stockholder. Comprised of shares of common stock issuable upon the conversion of shares of our Series C Preferred Stock, including dividends accrued thereon as of March 14, 2019. This stockholder's address is 60 Summit Avenue, Mill Valley, CA 94941.
- (21) Comprised of shares of common stock issuable upon the conversion of shares of our Series C Preferred Stock, including dividends accrued thereon as of March 14, 2019. This stockholder's address is 1028 Steeplechase Dr. Lancaster, PA 17601.

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

### Certain Relationships and Related Transactions

Transactions with related persons are governed by our Code of Conduct and Ethics, which applies to all of our directors, officers and employees. This code covers a wide range of potential activities, including, among others, conflicts of interest, self-dealing and related party transactions. Waiver of the policies set forth in this code will only be permitted when circumstances warrant. Such waivers for directors and executive officers, or that provide a benefit to a director or executive officer, may be made only by our Board, as a whole, or the Audit Committee. Absent such a review and approval process in conformity with the applicable guidelines relating to the particular transaction under consideration, such arrangements are not permitted. All related party transactions for which disclosure is required to be provided herein were approved in accordance with our Code of Conduct and Ethics.

On November 1, 2017, in connection with Mr. Filler joining our Board of Directors, we 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 our intellectual property strategy.

In connection with the SOW, the Company paid Sherpa a fee of (i) \$200,000 in cash, of which \$25,000 was paid on January 1, 2018, and the remainder was paid in the first quarter of 2018 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 \$3.625 per share of common stock, of which 60,000 options vested immediately and 60,000 options vested at completion of performance-related conditions. Mr. Filler is the general counsel and partner of Sherpa. During the year ended December 31, 2018, the Company paid to Sherpa \$427,219 for patent costs, consulting fees and expense reimbursements. As of December 31, 2018 and 2017, there was an unpaid balance of \$0.

### Independent Directors

Our board of directors has determined that each of Roy T. Tanaka, David Weild IV, Patrick J. Gallagher, David E. Foley, Seth H. Z. Fischer, Andrew L. Filler and Jeffrey F. O’Donnell, Sr. is independent within the meaning of Rule 5605(a)(2) of the NASDAQ Listing Rules and the rules and regulations promulgated by the SEC. In making its independence determinations, the board of directors sought to identify and analyze all of the facts and circumstances related to any relationship between a director, his immediate family and our company and our affiliates and did not rely on categorical standards other than those contained in the NASDAQ rule referenced above.

## ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit Fees. The aggregate fees billed by our independent registered public accounting firm, for professional services rendered for the audit of our annual financial statements for the years ended December 31, 2018 and 2017, including review of our interim financial statements were \$75,000 and \$59,500, respectively.

Audit Related Fees. We incurred fees to our independent registered public accounting firm of \$21,650 and \$26,000 for audit related fees during the fiscal years ended December 31, 2018 and 2017, respectively, which related to consent for and review of registration statements filed by the Company with the SEC.

Tax Fees. We incurred fees to our independent registered public accounting firm of \$5,000 and \$3,500 for tax compliance, tax advice and tax planning during the fiscal years ended December 31, 2018 and 2017.

All Other Fees. We incurred fees to our independent registered public accounting firm of \$-0- and \$-0- for all other fees during the fiscal years ended December 31, 2018 and 2017, respectively.

Our audit committee pre-approves all auditing services and all permitted non-auditing services (including the fees and terms thereof) to be performed by our independent registered public accounting firm, except for de minimis non-audit services that are approved by the audit committee prior to the completion of the audit. The audit committee may form and delegate authority to subcommittees consisting of one or more members when appropriate, including the authority to grant pre-approvals of audit and permitted non-auditing services, provided that decisions of such subcommittee to grant pre-approval is presented to the full audit committee at its next scheduled hearing.

**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, 2018 and 2017  
Consolidated Statements of Operations for the years ended December 31, 2018 and 2017  
Consolidated Statement of Stockholders' Equity (Deficit) for the two years ended December 31, 2018  
Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017  
Notes to Consolidated Financial Statements

- (2) Financial Statement Schedules

None.

- (3) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
3.1	<a href="#">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)</a>
3.2	<a href="#">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)</a>
3.3	<a href="#">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)</a>
3.4	<a href="#">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)</a>
3.5	<a href="#">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)</a>
3.6	<a href="#">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)</a>
3.7	<a href="#">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)</a>
3.8	<a href="#">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)</a>
3.9	<a href="#">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)</a>
3.10	<a href="#">Certificate of Seventh 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 September 10, 2018)</a>
3.11	<a href="#">Bylaws of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.4 to the Form S-1 filed on July 22, 2013)</a>
10.1	<a href="#">BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form S-1 filed on July 22, 2013)</a>
10.2	<a href="#">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)</a>

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- 10.3 [Securities Purchase Agreement, dated September 19, 2011, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.3 to the Form S-1 filed on July 22, 2013\)](#)
- 10.4 [Securities Purchase Agreement, dated December 27, 2011, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.4 to the Form S-1 filed on July 22, 2013\)](#)
- 10.5 [Securities Purchase Agreement, dated February 6, 2013, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.5 to the Form S-1 filed on July 22, 2013\)](#)
- 10.6 [Office Lease Agreement, dated August 9, 2011, by and between BioSig Technologies, Inc. and Douglas Emmett 1993, LLC \(incorporated by reference to Exhibit 10.11 to the Form S-1 filed on July 22, 2013\)](#)
- 10.7 [Indemnity Agreement, dated May 2, 2013 by and between BioSig Technologies, Inc. and Seth H. Z. Fischer \(incorporated by reference to Exhibit 10.14 to the Form S-1 filed on July 22, 2013\)](#)
- 10.8 [Amendment Agreement No. 4 to Securities Purchase Agreement, dated October 14, 2013, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.23 to the Form S-1/A filed on January 21, 2014\)](#)
- 10.9 [Securities Purchase Agreement, dated December 31, 2013, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.24 to the Form S-1/A filed on January 21, 2014\).](#)
- 10.10 [Registration Rights Agreement, dated December 31, 2013, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.25 to the Form S-1/A filed on January 21, 2014\)](#)
- 10.11 [Amendment No. 1 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan \(incorporated by reference to Exhibit 10.27 to the Form S-1/A filed on March 28, 2014\)](#)
- 10.12 [Amendment Agreement No. 5 to Securities Purchase Agreement, dated March 24, 2014, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.28 to the Form S-1/A filed on March 28, 2014\)](#)
- 10.13 [Patent Assignment, dated March 17, 2014, by and among Budimir Drakulic, Thomas Foxall, Sina Fakhar and Branislav Vljajinic and BioSig Technologies, Inc. \(incorporated by reference to Exhibit 10.29 to the Form S-1/A filed on May 1, 2014\)](#)
- 10.14 [Securities Purchase Agreement, dated April 4, 2014, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.30 to the Form S-1/A filed on May 1, 2014\)](#)
- 10.15 [Registration Rights Agreement, dated April 4, 2014, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.31 to the Form S-1/A filed on May 1, 2014\)](#)
- 10.16 [Form of Warrant used in connection with April 4, 2014 private placement \(incorporated by reference to Exhibit 10.32 to the Form S-1/A filed on May 1, 2014\)](#)
- 10.17 [Securities Purchase Agreement, dated as of August 15, 2014, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 21, 2014\)](#)
- 10.18 [Registration Rights Agreement, dated as of August 15, 2014, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.3 to the Form 8-K filed on August 21, 2014\)](#)
- 10.19 [Form of Warrant used in connection with August 15, 2014 private placement \(incorporated by reference to Exhibit 10.2 to the Form 8-K filed on August 21, 2014\)](#)
- 10.20 [Form of Restricted Stock Award Agreement under the 2012 Equity Incentive Plan \(incorporated by reference to Exhibit 10.2 to the Form 8-K filed on September 5, 2014\)](#)
- 10.21 [Composite of Unit Purchase Agreement, dated December 19, 2014, as amended by Supplement No. 1, dated December 17, 2014, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.37 to the Form 10-K filed on February 20, 2015\)](#)
- 10.22 [Registration Rights Agreement, dated December 19, 2014, by and between BioSig Technologies, Inc. and certain purchasers set forth therein \(incorporated by reference to Exhibit 10.38 to the Form 10-K filed on February 20, 2015\)](#)
- 10.23 [Form of "B" Warrant used in connection with December 19, 2014 private placement \(incorporated by reference to Exhibit 10.40 to the Form 10-K filed on February 20, 2015\)](#)

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10.24	<a href="#"><u>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)</u></a>
10.25	<a href="#"><u>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)</u></a>
10.26	<a href="#"><u>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)</u></a>
10.27	<a href="#"><u>Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on October 29, 2015)</u></a>
10.28	<a href="#"><u>Unit Purchase Agreement, dated October 23, 2015, by and between BioSig Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on October 29, 2015)</u></a>
10.29	<a href="#"><u>Form of Warrant used in connection with October 23, 2015 private placement (incorporated by reference to Exhibit 10.3 to the Form 8-K filed on Form 8-K on October 29, 2015)</u></a>
10.30	<a href="#"><u>Registration Rights Agreement, dated October 23, 2015, by and between BioSig Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.04 to the Form 8-K filed on October 29, 2015)</u></a>
10.31	<a href="#"><u>Form of Subscription Agreement (incorporated by reference to the Item 1.01 – Entry Into a Material Definitive Agreement to the Form 8-K filed on November 3, 2016)</u></a>
10.32	<a href="#"><u>Unit Purchase Agreement, dated October 28, 2016, by and between BioSig Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to the Item 1.01 – Entry Into a Material Definitive Agreement to the Form 8-K filed on November 3, 2016)</u></a>
10.33	<a href="#"><u>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)</u></a>
10.34	<a href="#"><u>Registration Rights Agreement, dated October 28, 2016, by and between BioSig Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to the Item 1.01 – Entry Into a Material Definitive Agreement to the Form 8-K filed on November 3, 2016)</u></a>
10.35	<a href="#"><u>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)</u></a>
10.36	<a href="#"><u>General Release and Severance Agreement, dated May 31, 2017, by and between BioSig Technologies, Inc. and Greg Cash (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on June 2, 2017)</u></a>
10.37	<a href="#"><u>Restricted Stock Award Agreement, dated May 31, 2017, by and between BioSig Technologies, Inc. and Greg Cash (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on June 2, 2017)</u></a>
10.38	<a href="#"><u>Form of Unit Purchase Agreement, dated April 6, 2016, by and between BioSig Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.61 to the Form S-1/A filed on August 3, 2017)</u></a>
10.39	<a href="#"><u>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)</u></a>
10.40	<a href="#"><u>Form of Registration Rights Agreement, dated April 6, 2017, by and between BioSig Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.63 to the Form S-1/A filed on August 3, 2017)</u></a>
10.41	<a href="#"><u>Certificate of Designation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on November 9, 2017)</u></a>
10.42	<a href="#"><u>Form of Securities Purchase Agreement dated November 3, 2017, by and between BioSig Technologies, Inc. and certain accredited investors (incorporated by reference to Exhibit 10.1 to Form 8-K filed on November 9, 2017)</u></a>
10.43	<a href="#"><u>Form of Warrant A used in connection with November 3, 2017 sale of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 10.2 to Form 8-K filed on November 9, 2017)</u></a>
10.44	<a href="#"><u>Form of Warrant B used in connection with November 3, 2017 sale of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 10.3 to Form 8-K filed on November 9, 2017)</u></a>
10.45	<a href="#"><u>Form of Registration Rights Agreement dated November 3, 2017, by and between BioSig Technologies, Inc. and certain purchasers of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 10.4 to Form 8-K filed on November 9, 2017)</u></a>

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10.46	<a href="#"><u>Form of Securities Purchase Agreement dated February 16, 2018, by and between BioSig Technologies, Inc. and certain accredited investors (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on February 16, 2018).</u></a>
10.47	<a href="#"><u>Form of Warrant used in connection with February 16, 2018 sale of Series E Convertible Preferred Stock (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on February 16, 2018).</u></a>
10.48	<a href="#"><u>Form of Registration Rights Agreement dated February 16, 2018, by and between BioSig Technologies, Inc. and certain purchasers of Series E Convertible Preferred Stock (incorporated by reference to Exhibit 10.3 to the Form 8-K filed on February 16, 2018).</u></a>
10.49	<a href="#"><u>Form of Consent in connection with February 16, 2018 private placement (incorporated by reference to Exhibit 10.4 to the Form 8-K filed on February 16, 2018).</u></a>
10.50	<a href="#"><u>Form of Unit Purchase Agreement dated April 30, 2018, by and between BioSig Technologies, Inc. and certain accredited investors (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on May 1, 2018).</u></a>
10.51	<a href="#"><u>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).</u></a>
10.52	<a href="#"><u>Amendment No. 3 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).</u></a>
10.53	<a href="#"><u>Securities Purchase Agreement dated as of July 30, 2018, 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 August 16, 2018).</u></a>
10.54	<a href="#"><u>Form of Series A Common Stock Purchase Warrant in connection with the July 30, 2018 private placement (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on August 16, 2018).</u></a>
10.55	<a href="#"><u>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).</u></a>
10.56	<a href="#"><u>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).</u></a>
31.01	<a href="#"><u>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.</u></a>
31.02	<a href="#"><u>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.</u></a>
32.01	<a href="#"><u>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.</u></a>
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

## **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 15, 2019

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

Date: March 15, 2019

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.

<u>Name</u>	<u>Position</u>	<u>Date</u>
<u>/s/ DONALD E. FOLEY</u> Donald E. Foley	Director	March 15, 2019
<u>/s/ ANDREW L. FILLER</u> Andrew L. Filler	Director	March 15, 2019
<u>/s/ PATRICK J. GALLAGHER</u> Patrick J. Gallagher	Director	March 15, 2019
<u>/s/ ROY T. TANAKA</u> Roy T. Tanaka	Director	March 15, 2019
<u>/s/ SETH H. Z. FISCHER</u> Seth H. Z. Fischer	Director	March 15, 2019
<u>/s/ JEFFREY F. O'DONNELL, SR.</u> Jeffrey F. O'Donnell, Sr.	Director	March 15, 2019
<u>/s/ DAVID WEILD IV</u> David Weild IV	Director	March 15, 2019

**EXHIBIT 31.01**

**CERTIFICATION**

I, Kenneth L. Londoner, certify that:

1. I have reviewed this annual report on Form 10-K of BioSig Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonable likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 15, 2019

/s/ KENNETH L. LONDONER

Kenneth L. Londoner  
Chief Executive Officer



**EXHIBIT 31.02**

**CERTIFICATION**

I, Steven Chaussy, certify that:

1. I have reviewed this annual report on Form 10-K of BioSig Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonable likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 15, 2019

/s/ STEVEN CHAUSSY

Steven Chaussy  
Chief Financial Officer

**Exhibit 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**

I, Kenneth L. Londoner, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of BioSig Technologies, Inc. on Form 10-K for the fiscal year ended December 31, 2018 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of BioSig Technologies, Inc.

Date: March 15, 2019

By: /s/ KENNETH L. LONDONER

Name: Kenneth L. Londoner

Title: *Chief Executive Officer*

I, Steven Chaussy, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of BioSig Technologies, Inc. on Form 10-K for the fiscal year ended December 31, 2018 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of BioSig Technologies, Inc.

Date: March 15, 2019

By: /s/ STEVEN CHAUSSY

Name: Steven Chaussy

Title: *Chief Financial Officer*