BioSig Technologies, Inc.

2022 Annual Report to Stockholders

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2022

Commission File Number 001-38659

BIOSIG TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

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

55 Greens Farms Road, 1st Floor		
Westport, CT	**06880**	**(203) 409-5444**
(Address of principal executive offices)	(Zip Code)	(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal controls over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2022, based on the price at which the common stock was last sold on such date, is $28,093,855. 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 30, 2023, there were 66,857,687 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) 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.

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. BioSig is principally devoted to improving the standard of care in electrophysiology, or EP, with our PURE EP™ System's enhanced signal acquisition, digital signal processing, and analysis during catheter ablation of cardiac arrhythmias. The Company has generated minimal revenue to date and consequently its operations are subject to all risks inherent in business enterprise in early commercialization stage.

On November 7, 2018, we formed a subsidiary under the laws of the State of Delaware, originally under the name of NeuroClear Technologies, Inc., for the purpose of pursuing additional applications of the PURE EP™ signal processing technology outside of the field of cardiac electrophysiology. In March 2020, it was renamed ViralClear Pharmaceuticals, Inc. ("ViralClear"). As of March 30, 2023, the Company retains 69.08% ownership of ViralClear. ViralClear's Business Overview can be found on page 15.

On July 2, 2020, the Company formed an additional subsidiary, NeuroClear Technologies, Inc. ("NeuroClear"), a Delaware corporation, to pursue additional applications of the PURE EP™ signal processing technology outside of cardiac electrophysiology. We own 100% of the outstanding shares of common stock as of March 30, 2023 and the subsidiary is currently dormant. NeuroClear's Business Overview can be found on page 17.

Business Overview

BioSig Technologies is a medical device company commercializing an advanced digital signal processing technology platform to deliver insights to the treatment of cardiovascular arrhythmias. Through collaboration with physicians, experts, and healthcare leaders across the field of electrophysiology (EP), we are committed to addressing healthcare's biggest priorities — saving time, saving costs, and saving lives.

Our first product, the PURE EP™ System, is an FDA 510(k) cleared non-invasive class II device consisting of a unique combination of hardware and software designed to provide unprecedented signal clarity and precision for real-time visualization of intracardiac signals paving the way for personalized patient care. Integrating with existing systems in the EP lab, PURE EP™ is designed to accurately pinpoint even the most complex signals to maximize procedural success and efficiency.

PURE EP™ Software Version 6 with ACCUVIZ™ Module released late 2022, is the first to be designed and launched by the Company's new commercial and operations team and represents the most advanced iteration of the Company's digital signal processing technology. Software Version 6 delivers a new level of efficiency enabling unlimited, real-time analysis of intracardiac signals. In addition, the new ACCUVIZ™ Module introduces advanced signal processing automation, elevated visualization of clear cardiac signal information, and even smarter workflows.

PURE EP™ System's software includes our proprietary High Frequency Algorithm (HFA); a novel feature that identifies the key frequency components of cardiac data that can be difficult to identify within the traditional waveform presentation. We believe that a limitation of traditional systems is that they only display data as voltage over time. PURE EP™ adds visibility to cardiac frequency data. By focusing on signals above 200Hz, HFA aims to eliminate RF frequencies to retain clear focus on the signals targeted for ablation.

Other unique software functionalities—including Automatic Tachycardia Characterization (ATC) and TRUSOURCE™ Analysis & Report—aim to improve clinical workflow and deliver clear, actionable insights to today's electrophysiologist during cardiac catheter procedures.

By capturing critical cardiac signals—even the most complex, the PURE EP™ System is designed to enhance clinical decision-making and improve clinical workflow for all types of arrhythmias - even the most challenging procedures for cardiac arrhythmias, like ventricular tachycardia (VT) and atrial fibrillation (AF).

The PURE EP System is currently in a national commercial launch and in regular use at healthcare systems, such as Mayo Clinic, Texas Cardiac Arrhythmia Institute, Cleveland Clinic, and Kansas City Heart Rhythm Institute. In a blinded clinical study published in the Journal of Cardiovascular Electrophysiology, electrophysiologists rated PURE EP™ as equivalent or superior to conventional systems for 93.6% of signal samples, with 75.2% earning a superior rating.

More recently, results from a randomized study (Redo AF Sub Study), demonstrated the PURE EP™ System's potential to promote shorter procedural times and higher cost savings during catheter ablations. Study results demonstrated that the PURE EP™ System led to a mean procedure time reduction of 11.3 minutes. Given that the mean cost of operating room time is approximately $37 per minute (ClinicalTrials.gov Identifier: NCT04964440), the procedural time savings demonstrated by the PURE EP™ System suggest potential cost savings of approximately $418.10 per procedure. While this suggests that PURE EP™ might promote shorter procedural times, further studies are underway.

In July 2022, we entered into our first national purchasing agreement with HCA Management Services, L.P. whereby Kansas City Heart Rhythm Institute at Overland Park Regional Medical Center in Kansas City, Missouri acquired our PURE EP System under the terms of the new agreement with a 30-month lease of the system. Following Overland Park, the San Antonio Methodist Hospital purchased the PURE EP System under the same terms in October 2022.

In August 2022, we installed a second evaluation system at the Cleveland Clinic - both Main and Fairview campuses of Cleveland Clinic's Heart, Vascular & Thoracic Institute are now evaluating PURE EP™. The additional installation will support the medical center's clinical evaluation of the PURE EP™ System and expand physician access to our signal processing technology. Additionally, we recently expanded our clinical footprint in the Midwest with evaluation agreements at leading medical centers in Illinois and Wisconsin.

On January 10, 2023, we announced that Bellin Health entered into an agreement to acquire a PURE EP™ System. Through a formal evaluation, Bellin reported that clear cardiac signals positively impacted procedural efficiency resulting in cost savings per procedure.

In addition to clinical evaluation, we have conducted pre-clinical evaluation with the PURE EP™ System under several protocols at Mayo Clinic in Rochester, Minnesota (including novel research programs such as Artificial Intelligence, or AI, and repolarization), we also conducted studies at Mount Sinai Hospital in New York, New York, the University of Pennsylvania, and Cleveland Clinic. We intend to continue additional research and development studies with our technology at institutions including Mayo Clinic and Cleveland Clinic – a Research Agreement was signed with the Cleveland Clinic to explore expanded applications for our digital signal processing technology.

Over 3,000 procedures have been performed using the PURE EP™ System with more than 80 physicians at 21 hospitals across the United States.

Our patent portfolio now includes 25 (issued/allowed) issued utility patents (18 utility patents where BioSig is at least one of the applicants). Thirty four additional U.S. and foreign utility patent applications are pending covering various aspects of our PURE EP System for recording, measuring, calculating and displaying of electrocardiograms during cardiac ablation procedures (thirty four U.S. and foreign utility patent applications where either BioSig, Mayo, or both is at least one of the applicants). Two of these pending U.S. patent applications are directed to artificial intelligence (AI). We also have 30 issued worldwide design patents, which cover various features of our display screens and graphical user interface for enhanced visualization of biomedical signals (30 design patents where BioSig is at least one of the applicants). Finally, of the 34 patent applications mentioned above, we have licenses to 7 patents and 13 additional worldwide utility patent applications from Mayo Foundation for Medical Education and Research that are pending (7 patents and 13 applications where only Mayo is the applicant). These patents and applications are generally directed to electroporation and stimulation.

Recent Developments

Appointment of Chief Financial Officer

On February 2, 2023, we appointed Mr. Steve Buhaly as our Chief Financial Officer of the Company, whose employment commenced on February 6, 2023. Mr. Buhaly brings to the Company over thirty years of experience in finance, accounting, general management, product development and manufacturing. In connection with his appointment, Mr. Buhaly's annual base salary will be $100,000, less applicable payroll deductions and tax withholdings.

Private Placements

During the period from November 2022 through March 2023, we completed nine private placement transactions were we sold shares and warrants to certain institutional and accredited investors, consisting of (i) an aggregate of 14,203,367 shares of our common stock, at purchase prices ranging from $0.41 to $1.10928 per share, and (ii) warrants to purchase up to an aggregate of 5,330,949 shares of our common stock at exercise prices ranging from $0.4455 to $1.04678 with a weighted average exercise price of $0.71858 per share, for aggregate consideration of approximately $9.78 million.

In addition, pursuant to certain tail provisions in an engagement agreement, dated October 11, 2022, we had entered into with Laidlaw & Company (UK) Ltd. ("Laidlaw"), we issued to Laidlaw warrants to purchase an aggregate of 393,638 shares of common stock in connection with the transactions noted above.

In addition, pursuant to certain compensation provisions in an engagement agreement, dated February 24, 2023, we had entered into with Laidlaw & Company (UK) Ltd. ("Laidlaw"), we issued to Laidlaw warrants to purchase an aggregate of 117,076 shares of common stock in connection with the transactions noted above.

During October and November 2022, we sold 1,847,565 shares of our common stock for total net proceeds of approximately $990,000 under the At-the-Market Sales Agreement, or Sales Agreement, with Virtu Americas LLC, dated May 17, 2022. The Sales Agreement was terminated on November 30, 2022, effective December 1, 2022.

Our Industry

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

Catheter ablation is performed by an electrophysiologist (a specially trained cardiologist) in a specialized room in an EP lab. According to Health Research International, it is estimated that there are 7,340 global EP labs performing catheter ablations, each typically with an EP recording system costing an average of $160,000. According to Future Market Insights, global electrophysiology equipment and recording systems market value is worth $6.1 billion in 2022 (of which we estimate our addressable market to be $1.6 billion); and experts predict it is expected to be worth $17.55 billion by 2032, a CAGR of 10.94 percent.

Heart problems, including atrial fibrillation, cardiac arrest and heart failure, are on the rise among millennials because of unhealthy lifestyle choices like not getting enough exercise, smoking, and drinking too much alcohol. In addition, the growing geriatric population is susceptible to cardiovascular diseases which also may contribute to an increased demand in ablation procedures in forthcoming years. According to the World Health Organization, the number of individuals aged 65 years and over is projected to increase from 524 million in 2010 to 1.5 billion by 2050. Aging typically leads to several changes in heart and blood vessels, which result in an increased risk of cardiac disorders. Accordingly, as cardiac ablation is a safe and highly effective treatment for irregular heart rhythm, we believe population aging and lifestyle choices will drive the product demand in the future. Along with the expected increased disease burden, we believe that product advancements will significantly drive the industry expansion. Industry players operating in the market are continuously developing newer technologies to offer more successful outcomes, and the expected significant investment in research and development activities by these players is anticipated to lead to new product launches, thereby expanding the product availability.

Catheter Ablation of AF and VT

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

For patients who are candidates for ablation, an EP study is necessary to define the targeted sites for the ablation procedure. Two common, yet complex, conditions for which ablation procedures are performed are AF and VT. Most cardiac arrhythmias are well understood, and ablation simply requires destroying a small area of heart tissue possessing electrical abnormality. In contrast, complex arrhythmias, such as AF and VT, have complex pathophysiology and, because knowledge of their origins and mechanisms are incomplete, ablation treatments for these arrhythmias are largely empirical. Furthermore, the length of these procedures, which typically last from 3-6 hours, exposes the physician and staff to extensive radiation, requiring them to wear heavy lead vests. Consequently, ablating AF and VT has been regarded as being extremely difficult. Therefore, access to these procedures has traditionally been limited to being performed by mainly well-trained cardiologists and high-volume centers. Particularly during ablations for persistent (chronic) AF, long procedures and extensive ablation are often required. These procedures could result in significant scarring and damage to heart tissue, although a study from a French Bordeaux group found “recovery of atrial contractile function” (the heart goes back to beating and contracting normally) in 98% of patients in sinus rhythm after six months of follow-up. However, less experienced centers that do extensive ablations do run the risk of compromising the pumping ability and transport function of the left atrium.

AF is the most common heart rhythm disorder in the world and increases the risk for stroke 5-fold. In 2017, there were a reported 37.57 million prevalent cases and 3.05 million incident cases of AF globally, contributing to over 287,000 deaths worldwide (*Global, regional, and national prevalence, incidence, mortality, and risk factors for atrial fibrillation, 1990–2017: results from the Global Burden of Disease Study 2017*). In 2020, the Centers for Disease Control and Prevention stated that it is estimated that 12.1 million people in the United States will have AF in 2030, more than 454,000 patients hospitalized annually as the primary diagnosis, and AF contributes to an estimated 158,000 deaths each year. An increasing proportion of diagnosed AF cases are now being treated via ablation, as both physician confidence and the devices used in these procedures improve. A growing amount of positive clinical data has demonstrated the efficacy of AF ablation when compared to the traditional first-line treatment of anti-arrhythmic drugs.

Recent studies suggest that COVID-19 may increase the risk of certain arrhythmias. In a meta-analysis of 19 observational studies with 21,653 patients hospitalized with COVID-19, the prevalence of AF was 11%. According to the studies, AF was higher in patients with severe versus non-severe COVID-19 (19% versus 3%).

In 2021, a meta-analysis of 6 randomized clinical trials involved 1,212 patients with AF (609 were randomized to AF ablation and 603 to drug therapy (AADs); mean age, 56 years). Compared with AADs, catheter ablation use was associated with reductions in recurrent atrial arrhythmia (32.3% vs 53%; risk ratio (RR), 0.62; 95% CI, 0.51-0.74; P < .001; I2 = 40%), with a number needed to treat with ablation to prevent 1 arrhythmia of 5. Use of ablation was also associated with reduced symptomatic atrial arrhythmia (11.8% vs 26.4%; RR, 0.44; 95% CI, 0.27-0.72; P = .001; I2 = 54%) and hospitalization (5.6% vs 18.7%; RR, 0.32; 95% CI, 0.19-0.53; P < .001) with no significant difference in serious adverse events between the groups (4.2% vs 2.8%; RR, 1.52; 95% CI, 0.81-2.85; P = .19). In this meta-analysis of randomized clinical trials including first-line therapy of patients with paroxysmal AF, catheter ablation compared with antiarrhythmic drugs was associated with reductions in recurrence of atrial arrhythmias and hospitalizations, with no difference in major adverse events.

The AF Ablation Long Term Registry is an international registry of 3,630 patients who underwent AF ablation between 2012 and 2015 – the study reported a 41% rate of repeat ablation at 3 years post ablation. At 12-month follow-up, the outcome was judged to have been successful in 74% of patients. However, almost 50% of the patients were still taking an antiarrhythmic drug. AF recurrences were less common in patients with paroxysmal (31%) than with persistent (40%) or long-standing persistent (44%) AF.

According to the Heart Rhythm Society, VT is the most dangerous arrhythmia since it may result in ventricular fibrillation, a rapid chaotic heartbeat in the lower chambers of the heart which can often result in sudden cardiac death. Because the fibrillating muscle cannot contract and pump blood to the brain and vital organs, ventricular fibrillation is the number one cause of sudden cardiac death which accounts for approximately 300,000 deaths in the U.S. each year. VT is typically treated with implantable cardioverter defibrillators, or ICDs, or a combination of ablation along with an ICD.

Catheter ablation of VT has historically been used primarily for drug refractory ventricular arrhythmias in patients with ICDs. However, advances in electro-anatomical mapping systems, techniques to identify ablation sites during sinus rhythm, and the use of hemodynamic support devices has broadened the applicability of catheter ablation for ventricular arrhythmias. When performed in centers with high procedural volumes, the rates of complications remain relatively low. However, success rates have historically been quite variable and highly dependent on the specific ablation approach adopted. Additionally, catheter ablation has evolved into an important treatment option for patients with scar-related heart disease presenting with VT or VF. An individual's success rate of catheter ablation for VT is determined by the amount of infarct-related scar burden, represented as low-voltage signals; the experience of the team and center will influence outcomes. In patients with recurrent VT or VF despite complete revascularization and optimal medical treatment, radiofrequency catheter ablation should be considered. Recurrent VF episodes may be triggered by PVCs arising from partially injured Purkinje fibers or ventricular myocardium injured by ischemia and/or reperfusion. Precise catheter mapping and successful ablation of triggers for VT or VF, or myocardial substrate sustaining VT or VF, is a complex and demanding procedure according to the *2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC).*

We believe that ablation will continue to be a preferred treatment for AF and VT. This increase in demand for ablation procedures has also increased the demand for technological advances in medical devices essential to ablation procedures. Improvements are needed to help reduce the periprocedural complications and decrease costly lengths of stay in patients undergoing catheter ablation procedures, adding focus to improving outcomes at low volume hospitals and among patients at high risk due to comorbidities. We believe that the PURE EP™ System may have a meaningful impact on assisting ablation strategies especially for repeat ablations and for those with significant scarring as it was developed to reveal the high frequency and very small amplitude of intracardiac signals important for identifying ablation targets.

EP Lab Environment and EP Recording Systems

The electrophysiology (EP) laboratory can be an extraordinarily noisy environment which degrades the quality of cardiac signals. Examining the causes of signal loss, or noise, in electrophysiological recordings can be time consuming and a series of trial-and-error exercises (Yasar, Nafi, "Causes of Noise in Electrophysiological Recordings", June 28, 2021). Noise from the lab environment can substantially interfere with the conventional system's ability to process and visualize low amplitude intracardiac signals – resulting in blind spots and loss of relevant data.

The cost of delivering high quality care to patients requires doing more with less — including the integration of innovative technology and continued learning. The potential for signal attenuation can introduce misleading physiologic fractionation, leading to greater time spent in expensive environments with no clarity on how to improve this. While catheter advancements have yielded many advantages in EP cases, the burden of capturing clarity of the signal (i.e. "chasing the signal") remains on the shoulders of EPs as they rely on antiquated signal technology. We believe this can result in inefficiencies that create a clinical and economic burden. The shape and amplitude of electrocardiograms, unipolar and bipolar electrograms, and, consequently, reconstructed endocardial and epicardial maps, are influenced not only by electrophysiological and structural characteristics of the myocardial tissue involved, but with characteristics of the recording system. Amplitude and morphology of electrocardiogram and intracardiac signals are significantly affected by filters used to remove noise. Because of the number of amplitude and interval measurements made during an EP study, it is imperative that the recording system faithfully acquires surface electrocardiogram and intracardiac electrograms. We believe that the recording systems that are currently available on the market are ineffective in preserving the optimal amount of original information contained in the cardiac signals.

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

Generally, some current electrophysiology recording systems can effectively support the treatment of arrhythmias such as atrial flutter and supraventricular tachycardia, which show up as large-amplitude, low-frequency signals. However, more complex and prevalent arrhythmias, such as AF and VT, which are characterized by low-amplitude, high-frequency signals, have not found an effective evaluation of all relevant signals. This signal detection, acquisition, and isolation can be further complicated by equipment line noise and pacing signals. Current EP recorders use low-pass, high-pass, and notch filters to remove noise and artifacts from the various electrical signal information. Unfortunately, conventional filtering techniques can alter signals and make it difficult or impossible to see low-amplitude, high-frequency signals that can be inherent in cardiac monitoring, the visualization of which signals could help treat atrial fibrillation and ventricular tachycardia. It has been recently recognized that the assurance of waveform integrity, such as for the noise-free acquisition of intracardiac and ECG signals in an EP environment, had not been previously accomplished due to contamination of various signals by artifacts and noise.

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

Our Product

The patented PURE EP™ System is designed to address long-standing limitations that slow and disrupt cardiac catheter ablation procedures, such as environmental lab noise from other equipment, signal saturation, slow signal recovery, and inaccurate display of fractionated potentials. PURE EP™ is a signal processing platform that combines advanced hardware and software to address known challenges associated to signal acquisition, to enable electrophysiologists to see more signals and analyze them in real-time. The device aims to minimize noise and artifacts from cardiac recordings and acquire high-fidelity cardiac signals. Improving fidelity of acquired cardiac signals may potentially increase the diagnostic value of these signals, thereby possibly improving accuracy and efficiency of the EP studies and ablation procedures.

Cardiac catheter ablation is a procedure that involves delivery of energy through the tip of a catheter that scars or destroys heart tissue to correct heart rhythm disturbances. In August 2018, we received 510(k) clearance from the FDA to market our PURE EP™ System.

Our PURE EP™ System can record raw (unaltered) cardiac signals with multiple display options, low noise, and a large input signal dynamic range. This is achieved using a low-noise amplifier topology with minimal filtering to band-limit the signal and a high-resolution A/D converter. In addition, the PURE EP™ System can provide large-signal (e.g., from a defibrillator) input protection and radio frequency (RF) signal (e.g., from ablation) noise suppression. There is no need for gain switching in this architecture, and the full range of input signals is digitized with high resolution.

Our PURE EP™ System was designed to be useful in arrhythmia diagnosis. For example, in atrioventricular reentrant tachycardia (AVRT) & AV nodal reentrant tachycardia (AVNRT), EP physicians often look for a slow pathway potential or accessory pathway potentials that are not easy to detect. Furthermore, during pacing maneuvers, important diagnostic signals may be buried inside the saturation artifact from the pacing electrode. The wide dynamic range of the PURE EP™ System may allow for better differentiation of those signals, as there is no system saturation and a quicker recovery to baseline.

We are focused on improving intracardiac signal acquisition and enhancing diagnostic information for catheter ablation procedures for all arrhythmias, especially complex types like ventricular tachycardia, VT and atrial fibrillation, AF. VT is a fast, abnormal heart rate in the heart's lower chambers. VT does not give your heart enough time to fill with blood before it contracts again. This can affect blood flow to the rest of your body and is potentially life-threatening. AF is the most common cardiac arrhythmia associated with a fivefold risk of stroke. AF occurs when the upper chambers of the heartbeat irregularly, and do not pump all of the blood to the lower chambers, causing some blood to pool and potentially form clots. If a clot breaks loose, it can travel through the bloodstream to the brain and lead to a stroke. Strokes related to AF are often more severe compared to strokes with other underlying causes.

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

- ***Less noise*****:** PURE EP™'s low-noise proprietary architecture was engineered to enable acquisition of high-fidelity signals in the original, unfiltered format. PURE EP's Main System Unit (MSU) topology incorporates advanced shielding and very low noise front-end components.

- ***Wider range*****:** An expanded dynamic range retains cardiac signal details and reduces saturation. PURE EP™ combines a low-noise signal architecture with a fixed range up to 500mV, so signals are rarely clipped or limited by quantization noise.

- ***Higher definition:*** PURE EP™ supports a large frequency bandwidth and linear signal acquisition to accurately display complex fractionated signals, even at lower amplitudes and higher frequencies.

- ***Unipolar signals*****:** PURE EP™ incorporates an innovative WCT+™ design for acquiring unipolar signals, relying on a common front-end circuitry similar to how bipolar intracardiac signals are acquired.

- ***Customizable software and filters*****:** PURE EP™ offers software modules and specialty digital filters, so electrophysiologists can customize their interface and optimize signals for mapping, signal interpretation and during therapy delivery.

- ***Seamless integration*****:** PURE EP™ integrates with existing EP labs and workflows. It is compatible and complementary with EP recording systems, mapping systems, robotic equipment, and multi-display panels.

PURE EP™ Software Version 6 with ACCUVIZ™ Module released late 2022, is the first to be designed and launched by the Company's new commercial and operations team and represents the most advanced iteration of the Company's digital signal processing technology. Software Version 6 delivers a new level of efficiency enabling unlimited, real-time analysis of intracardiac signals. In addition, the new ACCUVIZ™ Module introduces advanced signal processing automation, elevated visualization of clear cardiac signal information, and even smarter workflows.

We believe that PURE EP™'s features may allow physicians to better determine precise ablation targets, strategy, and end point of procedures with the objective of reducing the need for patients to undergo multiple procedures, and to allow for less experienced EP physicians to perform more complex procedures. The PURE EP™ System is intended to operate in conjunction with the existing EP lab equipment.

Initial Analysis

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

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

Proof of Concept Testing

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

Prototype Testing

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

Clinical Evaluations

In February 2019, we conducted the first clinical cases with our PURE EP™ System. The observational patient cases were performed by Andrea Natale, M.D., F.A.C.C., F.H.R.S., F.E.S.C., Executive Medical Director, Texas Cardiac Arrhythmia Institute at St. David's Medical Center in Austin, Texas. In April 2019, we announced the completion of our second set of observational patient cases, which were performed at Prisma Health at Greenville Health System in South Carolina by Andrew Brenyo, MD, FHRS. Dr. Brenyo used the PURE EP™ System during procedures on patients with ischemic ventricular tachycardias, AF, PVC, and atypical flutters.

In May 2019, we announced the completion of our third set of observational patient cases at Indiana University under the leadership of Prof. John M. Miller, M.D., and Dr. Mithilesh K. Das, MBBS. Drs. Miller and Das used the PURE EP™ System during procedures on patients with atypical flutter, atrioventricular nodal reentry tachycardia (AVNRT), AF, supraventricular tachycardia, premature ventricular contractions, and a rare case of dual septal pathway. In August 2019, observational patient cases at Santa Barbara Cottage Hospital in California were performed by Brett Andrew Gidney, M.D. The initial experience across these early evaluation centers showed the PURE EP™ System functions as designed with positive feedback from EP users about the improved signal detection and fidelity.

In November 2019, we commenced our first clinical study for the PURE EP™ System titled, "*Novel Cardiac Signal Processing System for Electrophysiology Procedures (PURE EP 2.0 Study)*." The PURE EP 2.0 Study was conducted at three U.S. hospitals: Texas Cardiac Arrhythmia Institute at St. David's Medical Center in Austin, Texas, Mayo Clinic in Jacksonville, Florida and Massachusetts General Hospital in Boston, Massachusetts.

In April 2021, we announced the completion of the enrollment in the PURE EP 2.0 Study. Intracardiac signal data of clinical interest were collected during 51 cardiac ablation procedures using the PURE EP™ System, the signal recording system, and the 3D mapping system at the same time stamps. The samples were randomized and subjected to blinded, head-to-head evaluation by three independent electrophysiologists to determine the overall quality and clinical utility of PURE EP™ signals when compared to conventional sources. Each reviewer responded to the same 235 signal comparisons using a 10-point rating scale.

Results showed 93% consensus across the blinded reviewers with a 75% overall improvement in intracardiac signal quality and confidence in interpreting PURE EP signals over the signals from conventional sources. Further analysis of the responses from the blinded reviewers showed an 83% (p-value <0.001) improved confidence when interpreting complex multi-component signals, leading to a better understanding of the catheter position in relation to the ablation target. Additionally, there was a 73% (p-value <0.001) improved visualization of small, fractionated potentials increasing the proper analysis of scar and abnormal conduction tissue characteristics.

The study manuscript, "*Evaluation of a novel cardiac signal processing system for electrophysiology procedures: the PURE EP 2.0 study"* has been published in the Journal of Cardiovascular Electrophysiology and is available electronically with open access via the Wiley Online Library. The manuscript is co-authored by Amin Al-Ahmad, M.D., FHRS, Bradley Knight, M.D., FHRS, Wendy Tzou, M.D., FHRS, Robert Schaller, D.O., FHRS, Omar Yasin, M.D, Deepak Padmanabhan, M.D., Jason Zagrodsky, M.D., FHRS, Mohammed Bassiouny, M.D., J David Burkhardt, M.D., FHRS, Joseph Gallinghouse Jr., M.D., FHRS, Moussa Mansour, M.D., FHRS, Christopher McLeod, MBChB, Ph.D., FHRS and Andrea Natale, M.D., FHRS, the Principal Investigator of the study. The independent, blinded reviewers were Bradley P. Knight, M.D. (Northwestern University), Wendy Tzou, M.D. (University of Colorado), and Robert Schaller, M.D. (University of Pennsylvania).

In July 2022, we entered into our first national purchasing agreement with HCA Management Services, L.P. whereby Kansas City Heart Rhythm Institute at Overland Park Regional Medical Center in Kansas City, Missouri acquired our PURE EP System under the terms of the new agreement with a 30-month lease of the system. Following Overland Park, the San Antonio Methodist Hospital purchased the PURE EP System under the same terms in October 2022.

In August 2022, we installed a second evaluation system at the Cleveland Clinic - both Main and Fairview campuses of Cleveland Clinic's Heart, Vascular & Thoracic Institute are now evaluating PURE EP™. The additional installation will support the medical center's clinical evaluation of the PURE EP™ System and expand physician access to our signal processing technology. The PURE EP™ System was highlighted in a peer-reviewed case report by the Journal of Atrial Fibrillation & Electrophysiology (JAFIB-EP). This clinical abstract detailed the value of PURE EP™ and our High Frequency Algorithm (HFA) during pulmonary vein isolation procedures at Cleveland Clinic.

The PURE EP™ System was featured in an abstract presentation at the 15th Asia Pacific Heart Rhythm Society (APHRS) Scientific Session in Singapore. Results from the randomized study revealed the PURE EP™ System's potential to promote shorter procedural times and higher cost savings during catheter ablation procedures. *Reduced Time of Redo Atrial Fibrillation Procedures with PURE EP ™ Recording System ECG/EGM Visualization: A Randomized Study*. 20 patients with non-paroxysmal AF with post-ablation arrhythmia recurrence ("redo AF") were enrolled with the purpose of determining the difference in procedural times when comparing ablations guided by PURE EP™'s electrocardiogram (EGM) visualization to the conventional ECG recording system. The PURE EP™ System led to a mean procedure time reduction of 11.3 minutes - given that the mean cost of operating room time is approximately $37 per minute, PURE EP™ demonstrated a potential suggest potential cost savings of approximately $418.10 per procedure. Source: Gallinghouse, G. Joseph; Natale, Andrea; Al-Ahmad, Amin; Della Roca, Domenico Giovanni; Jones, Sterling; Firmstone, Samantha; Lewen, Jason. (2022).

On January 10, 2023, we announced that Bellin Health entered into an agreement to acquire a PURE EP™ System. Through a formal evaluation, Bellin reported that clear cardiac signals positively impacted procedural efficiency resulting in cost savings per procedure.

In addition to clinical evaluation, we have conducted pre-clinical evaluation with the PURE EP™ System under several protocols at Mayo Clinic in Rochester, Minnesota (including novel research programs such as Artificial Intelligence, or AI, and repolarization). We also conducted studies at Mount Sinai Hospital in New York, New York, the University of Pennsylvania, and Cleveland Clinic. We intend to continue additional research and development studies with our technology at institutions including Mayo Clinic and Cleveland Clinic. A Research Agreement was signed with the Cleveland Clinic to explore expanded applications for our digital signal processing technology.

Over 3,000 procedures have been performed using the PURE EP™ System with more than 80 physicians at 21 hospitals across the United States.

Commercialization of the PURE EP™ System

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

We have begun implementing a market development program to commercially launch our PURE EP System. We have installed PURE EP™ Systems at several medical centers of excellence throughout the U.S. during 2021 and 2022 (and will continue to do so in 2023) for clinical evaluation - whereby these systems are installed on a trial basis for system evaluations; data collection for our clinical trials; to gather and publish data in peer-reviewed journals and for presentations at cardiology conferences; and for potential demonstrations to other physicians to observe the technology.

Health systems, facilities, and physicians that have conducted or observed cases performed with our technology may potentially acquire the system. Sales of our systems consist of hardware, software, and a recurring revenue feature through a technical service contract, including software upgrades, and down the line, include the AI-driven algorithms and applications. We intend to support our commercial activities by growing clinical validation and educational and training programs, including establishing training hubs at our early hospital partners' facilities. With the increased commercialization activity planned, we also plan to continue to grow our clinical account management team to support the initial use of the system and assist with ongoing product training and education, and have begun hiring a regional sales team to escalate our commercialization efforts along with a technical support team.

Our commercial and clinical activities are led by our Chief Commercial Officer, Gray Fleming, an experienced EP sales professional who previously spent 17 years at Abbott Laboratories and St. Jude Medical; Zachary Koch, CCDS, CEPS Principal Advisor of Product Development, who spent 16 years at St. Jude Medical and Abbott EP, holding numerous positions across the company's clinical, sales, training, and commercial teams; and Katie Freshwater, VP, Marketing, with over 20 years of medtech sales and marketing experience at companies including Cardinal Health, Medtronic, and Kimberly-Clark Healthcare.

Our team is further complemented by Access Strategy Partners, Inc. (ASPI), a Boston-based consulting firm with a deep expertise in commercialization, contract management, execution, and value proposition optimization. The ASPI team is led by co-founder and president, Jim Walker, a healthcare executive with more than 30 years of experience in sales, marketing, sales operations, and national accounts management in some of the leading companies in the medical device sector, including Boston Scientific Corporation (BSC) and Johnson & Johnson. His experience spans domestic and international responsibilities, focusing on strategic market development and key customer management.

We believe we will have ample inventory to meet planned commercial placement requirements in 2023. We have made progress towards obtaining a European CE marking certificate for medical devices. In Q1 2022, we completed the quality management system audit for the International Organization for Standardization ("ISO") 13485:2016.

Technology and Development Plan

Our technology team consists of 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, Cleveland Clinic, and the Texas Cardiac Arrhythmia Institute in Austin, Texas. Currently, we are contract manufacturing the complete PURE EP™ System with Plexus Corp.

We intend to continue additional research studies with our technology at Mayo Clinic and Cleveland Clinic. On November 20, 2019, we entered into licensing agreements with Mayo Clinic to establish a new product pipeline to complement the PURE EP System and develop solutions for novel ways to treat autonomic nervous system disease. The research and development pipeline contemplated pursuant to these agreements includes hardware, software, and algorithmic solutions to be integrated into the PURE EP platform technology. We entered into a research agreement with Cleveland Clinic Foundation to investigate expanded clinical applications for the intracardiac signals acquired by PURE EP™ System. Under the terms of the research agreement, Cleveland Clinic will conduct physician initiated scientific research investigating PURE EP™'s potential to address common limitations of signal processing and signal use expansion during but not limited to electrophysiology ablation procedures. Results from this research could elucidate new clinical workflow methods impacting the ablation process for numerous arrhythmia types.

In January 2021, we entered into a research agreement with Mayo Clinic regarding an AI research Program for our Novel Signal Recording System. The program is a strategic collaboration with Mayo to develop a next-generation AI- and machine learning-powered software for our PURE EP™ System. The collaboration includes an R&D program that will expand our proprietary hardware and software with advanced signal processing capabilities and aim to develop novel technological solutions by combining the electrophysiological signals delivered by PURE EP™ and other data sources. The development program is under the leadership of Samuel J. Asirvatham, M.D., Mayo Clinic's Vice-Chair of Innovation and Medical Director, Electrophysiology Laboratory. We entered into a 10-year collaboration agreement with Mayo Clinic in March 2017 and in November 2019, we signed a patent and know-how license agreement with Mayo Foundation for Medical Education and Research in which such terms apply to this program. On April 9, 2021, and October 22, 2021, we conducted first pre-clinical data collection studies under our AI program at Mayo Clinic.

Competition

We are marketing the PURE EP™ System as an additional information system for the EP lab. In general, the EP market is characterized by intense competition. There are currently four large companies that share the majority of the EP recording market share in the US. They produce the following electrophysiology recording systems, with an average selling price of approximately $160,000 (source: DRG Medtech 360 Millennium report on EP Devices, issued in June 2019):

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

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

- HeNan HuaNan Medical Science and Technology Co., LTD. offers the GY-6000 multi-channel physiological recorder (not FDA approved).

- 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.

- CathVision is developing an EP recording system, ECGenius System™ and recently obtained FDA 510(k) clearance in May 2022.

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

Customers

In December 2020, we announced that three PURE EP™ Systems were contracted for purchase by St. David's Healthcare in Austin, Texas and were subsequently sold in February 2021. These units were our first commercial sales. We also sold three PURE EP™ Systems to Mayo Foundation for Medical Education and Research in 2021 and leased two PURE EP™ Systems in 2022, one in July 2022 to Overland Park Regional Medical Center and one in October 2022 to Methodist Hospital in San Antonio. In January 2023, we entered into an agreement with Bellin Health in Wisconsin to acquire a PURE EP™ System. We are in active discussions with several accounts about the acquisition of the PURE EP™ System. We anticipate our following customers will be medical centers of excellence and other healthcare facilities that operate EP labs within our targeted commercial launch markets in the Northeast, Florida, and Texas.

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 several distributors or manufacturers. Plexus Corp is our manufacturing partner for the complete PURE EP System.

Research and Development Expenses

Research and development expenses for the fiscal years ended December 31, 2022, and 2021 were $5,821,460 and $5,601,508, respectively.

ViralClear Business Overview

ViralClear Pharmaceuticals, Inc.

ViralClear Pharmaceuticals, Inc. ("ViralClear") is a majority-owned subsidiary of the Company originally known as NeuroClear Technologies, Inc. The subsidiary was established November 2018 to pursue additional applications of the PURE EP™ signal processing technology outside of EP. In March 2020, it was renamed ViralClear in connection with its prior objective to develop merimepodib, a broad-spectrum anti-viral agent that showed potential to treat COVID-19. We currently do not intend to further develop merimepodib and have discontinued our pharmaceutical operations. Since late 2020, ViralClear has been realigned with its original objective of pursuing additional applications of the PURE EP™ signal processing technology outside of cardiac electrophysiology with an initial emphasis on developing a novel nerve recording system. As of March 30, 2023, the Company retains 69.08% ownership of ViralClear.

Currently, ViralClear is an early stage medical device company that is developing N-SENSE™, a novel sensing technology platform for high-speed electroneurogram (ENG) recordings. The specifications for this new product were based on the core competencies of the PURE EP™ signal processing technology, such as broad dynamic range of recorded signals and low signal-to-noise ratio and adapted to address disorders of the autonomic nervous systems through recordings and analysis of action potentials, the impulses along the membrane of a muscle cell or a nerve cell. These impulses are considered to carry valuable clinical information but may be difficult to detect through conventional recording platforms.

ViralClear aims to address what we believe to be the two main challenges of bioelectronic medicine devices: achieving accurate and targeted stimulation of specific nerves in a nerve bundle and implementing an effective feedback loop that can self-adjust for the optimal amount and timing of stimulation. We believe that advancements in overcoming these challenges will improve the safety and efficacy of current treatments and contribute to the developments of new therapy lines.

On December 18, 2020, we signed a research agreement with the University of Minnesota launching a program to develop novel therapies to treat sympathetic nervous system disease. The program studies are expected to form a foundation for developing a new platform technology to address disorders of the autonomic nervous system. We intend to develop new intellectual properties and products, including new hardware, software, and algorithmic solutions, with the support of Plexus, a tier 1 US-based manufacturing partner and take it through FDA approval, manufacturing, and commercialization. The R&D program is led by Richard W. Bianco, Ph.D., Professor, Director of Experimental Surgical Services (ESS), Department of Surgery in the University of Minnesota Medical School, John W. Osborn, Ph.D., Professor, Department of Surgery and Director of the Minnesota Consortium for Autonomic Neuromodulation (MCAN) in the University of Minnesota Medical School.

In February 2021, we conducted our first preclinical experiment at the University of Minnesota. Further studies to record and evaluate relevant nerve activity were conducted in April and November 2021.

We have partnered with Plexus to design, develop, and manufacture N-SENSE™, a novel sensing and stimulation platform technology.

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

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

• Develop N-SENSE™, a novel nerve sensing and stimulation platform technology to be used in product candidates which qualify for a nerve mapping and stimulation treatments including, but not limited to, renal denervation, deep brain stimulation and vagus nerve stimulation.

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

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

• Renal denervation ("RDN"): RDN has been shown to reduce blood pressure and can be an effective treatment for resistant hypertension sufferers who have failed drug therapy. The technique has proven to be effective, but clinical endpoints are still suboptimal. RDN device market is expected to reach $7B by 2027 (CAGR 23.7%).[1]

- o *Potential Application:* A device that can measure sympathetic nerve activity will inform the need and potential benefit for performing a procedure. Additionally, a device that can stimulate and elicit a sympathetic response, such as blood pressure, will aid in the assessment of nerve denervation success, and help determine if additional ablation is necessary. Therefore, a device that can perform stimulation on a number of channels, and record nerve activity is needed.

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

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

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

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

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

Industry and Market Overview

The global neurostimulation devices market is predicted to grow at 15.23% CAGR during the forecast period with the market size reaching $18.667 billion by 2025 from $7.974 billion in 2019. North America is dominating the neurostimulation devices market with highest market share due to robust healthcare infrastructure, growing R&D activity and presence of major healthcare players. The neurostimulation market is primarily driven by deep brain and spinal cord stimulation. The overall neurostimulation market is expected to grow due to societal factors such as an increase in the geriatric population, as well as the associated increase in the prevalence of chronic diseases.

The segment of the neurostimulation market for central nervous system (CNS), which include nVNS and DBS, is projected to exceed $14.5 billion in 2029 from a market value of $5 billion in 2019.[2]

Non-invasive Vagus *Nerve Stimulation*

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

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

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[1]**Source:** iHealthcareAnalyst, Inc. Feb. 2020

[2]**Source**: *Bioelectronic Medicine 2019 – 2029. IDTechEx report, Dr. Nadia Tsao*.

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

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

Deep Brain Stimulation:

Deep brain stimulator market is one of the fastest growing sectors in the neurostimulation market worldwide, growing at 9.3% annually and expected to reach $2.3 billion in worldwide market size by 2028. According to the World Health Organization, globally, 264 million people suffer from depression while 50 million people suffer from epilepsy. Parkinson's disease and essential tremor are FDA-approved indications for DBS, and the deep brain stimulator market is largely dominated by Medtronic, Abbott, and Boston Scientific. These companies have been working on innovations in their electrodes to avoid stimulation of adjacent structures (electric field shaping) which are the root cause of unwanted side effects of DBS. The industry is working on decreasing the size of the implant of the DBS device, which may lead to a skull-mounted implant. Medtronic's Activa systems consist of dual-channel or single channel IPGs. Abbott sells two devices known as the Infinity DBS IPG and Brio Rechargeable IPG. The Infinity DBS IPG is designated to manage movement disorders including Parkinson's disease, essential tremor, and dystonia. It utilizes the Bluetooth technology to communicate with a controller and can receive updates through an application. The system allows for currents to be steered towards target areas while avoiding peripheral stimulation. The Brio Rechargeable IPG delivers constant currents to maintain the desired stimulation level. It has shown clinical efficacy in Parkinson's disease and dystonia. Boston Scientific offers the Vercise directional lead in unison with their Neural Navigator systems ranging from 8 to 16 electrode leads and a directional system. Medtronic's Percept PC Deep Brain Stimulation ("DBS") system includes their BrainSense technology making it the first and only DBS neurostimulation system that has the ability to chronically capture and record brain signals while providing therapy to patients with neurologic disorders associated with Parkinson's Disease ("PD"), among others.

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

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

On March 5, 2021, we announced that the U.S. Patent Office had allowed a utility patent which has been exclusively licensed from the Mayo Foundation for Medical Education and Research. The patent application number 16/805,017 entitled, *"Systems and Methods for Electroporation"* was filed on February 28, 2020. The patent describes and claims methods and materials for improving the treatment of hypertension via electroporation of nerves in the renal area. Electroporation is an emerging technique that has demonstrated efficacy in treatments for several critical conditions and is currently being evaluated for the treatments of autonomic nervous disorders, including hyper- and hypotension / syncope.

NeuroClear Business Overview

NeuroClear Technologies, Inc.

On July 2, 2020, the Company formed an additional subsidiary, NeuroClear Technologies, Inc. ("NeuroClear"), a Delaware corporation, to pursue additional applications of the PURE EP™ signal processing technology outside of cardiac electrophysiology. We own 100% of the outstanding shares of common stock as of March 30, 2022 and the subsidiary is currently dormant.

Our intention is to move the neurotech assets from ViralClear into NeuroClear where the current and future neurotech assets would be housed. We intend to further develop our nerve recording system and ultimately bring the technology to market under NeuroClear Technologies, Inc.

ViralClear will continue to have cash and a shareholder base. Given its corporate history and almost four years of segregated operations, we believe that this entity can be of great value to the shareholders as we evaluate emerging growth businesses across various industry segments that aim for a Nasdaq listing.

Intellectual Property

Patents

Our success depends in large part on our ability to establish and maintain the proprietary nature of our technology. 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.

Our patent portfolio now includes 25 (issued/allowed) issued utility patents (18 utility patents where BioSig is at least one of the applicants). Thirty four additional U.S. and foreign utility patent applications are pending covering various aspects of our PURE EP System for recording, measuring, calculating and displaying of electrocardiograms during cardiac ablation procedures (thirty four U.S. and foreign utility patent applications where either BioSig, Mayo, or both is at least one of the applicants). Two of these pending U.S. patent applications are directed to artificial intelligence (AI). We also have 30 issued worldwide design patents, which cover various features of our display screens and graphical user interface for enhanced visualization of biomedical signals (30 design patents where BioSig is at least one of the applicants). Finally, of the 34 patent applications mentioned above, we have licenses to 7 patents and 13 additional worldwide utility patent applications from Mayo Foundation for Medical Education and Research that are pending (7 patents and 13 applications where only Mayo is the applicant). These patents and applications are generally directed to electroporation and stimulation.

BioSig and ViralClear signed three patent and know-how license agreements with Mayo Foundation for Medical Education and Research in November 2019. Under the terms of such agreements, BioSig exclusively licensed additional patents and applications of the Mayo Clinic related to novel ways for ablation therapy and to treat autonomic nervous system disease including hardware, software and algorithmic solutions to be integrated into the PURE EP platform technology. BioSig intends to take the licensed intellectual properties and products, which have been developed by Mayo Clinic over the last decade, through FDA approval, manufacturing, and commercialization. The development program is run under the leadership of Dr. Asirvatham. On March 5, 2021, we announced that the U.S. Patent Office had allowed a utility patent that ViralClear has exclusively licensed from the Mayo Foundation for Medical Education and Research. The patent application number 16/805,017 entitled, *"Systems and Methods for Electroporation"* was filed on February 28, 2020. The patent describes and claims methods and materials for improving the treatment of hypertension via electroporation of nerves in the renal area. Electroporation is an emerging technique that has demonstrated efficacy in treatments for several critical conditions and is currently being evaluated for the treatments of autonomic nervous disorders, including hyper- and hypotension / syncope.

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 March 19, 2019.

On October 7, 2019, we filed a standard mark trademark application for “SEE MORE, CLEARLY” and received notice of acceptance of statement of use on February 25, 2023.

On October 22, 2020, we filed a standard mark trademark application for “WCT+” and we filed a statement of use on November 11, 2022.

On October 22, 2020, we filed a standard mark trademark application for “ACCUVIZ” and we filed a statement of use on November 11, 2022.

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; extensions for statements of use have been filed.

On October 4, 2019, we filed a stylized/design trademark application for “ALLIANCE FOR ADVANCING BIOELECTRONIC MEDICINE” and an extension for a statement of use has been filed.

On May 26, 2020, we filed a standard mark trademark application for “N-SENSE” and an extension for a statement of use has been filed.

On May 26, 2020, we filed a standard mark trademark application for "N-SENSE TECHNOLOGIES" and an extension for a statement of use has been filed.

In July 2021, we received EU certificates of registration for the following trademarks: ACCUVIZ, WCT+, and COMBIO.

In July 2021, we received UK certificates of registration for the following trademarks: SMARTFINDER, ACCUVIZ, WCT+, and COMBIO.

Government Regulation

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

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

FDA Regulation

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

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

FDA Pre-market Clearance and Approval Processes

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

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

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

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

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

510(k) Clearance Process

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

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

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

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

The Premarket Approval Pathway

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

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

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

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

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

Pervasive and continuing FDA regulation

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

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

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

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

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

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

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

- Fines, injunctions, and civil penalties;

- Mandatory recall or seizure of our products;

- Administrative detention or banning of our products;
- Operating restrictions, partial suspension or total shutdown of production;
- Refusing our request for 510(k) clearance or pre-market approval of new product versions;
- Revocation of 510(k) clearance or pre-market approvals previously granted; and
- Criminal penalties.

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

U.S. Healthcare Laws and Regulations

In the United States, there are various healthcare fraud and abuse laws that apply to medical device manufacturers, such as us, with respect to our financial relationships with hospitals, physicians, patients, 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. Federal and state anti-kickback laws prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. 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, and the federal safe harbors may not apply to state anti-kickback laws. Other provisions of state and federal law impose civil and criminal penalties for presenting, or causing to be presented, to third-party payors (including the government) 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. Violations of these laws can lead to civil and criminal penalties, including but not limited to punitive sanctions, damage assessments, money penalties, imprisonment, denial of payment, exclusion from participation in federal healthcare programs, or some combination thereof.

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 30, 2023, we had 47 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.

Corporate and Other Information

We were incorporated in Nevada 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. Our principal executive offices are located at 55 Green Farms Road, 1st Floor, Westport, Connecticut 06880 and our telephone number is (203) 409-5444. Our website address is www.biosig.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K is an inactive textual reference only.

We file or furnish electronically with the U.S. Securities and Exchange Commission (the "SEC") our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information. Our SEC filings are available to the public over the Internet at the SEC's website at http://www.sec.gov. We make available on our website at www.biosig.com, under "Investors," free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC.

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.

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making investment decisions regarding our common stock.

- There is substantial doubt about our ability to continue as a going concern.
- Because we are an early commercialization stage company with one product in commercialization process, we expect to incur substantial additional operating losses.
- Our PURE EP System and other product candidates are in continued development and may not be successfully developed or commercialized.
- 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 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.
- We may be unable to develop our existing or future technology.
- We may experience delays in any phase of the preclinical or clinical development of a product, including during its research and development.

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

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

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

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

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

- The EP market is highly competitive.

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

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

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

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

- We may face risks associated with future litigation and claims.

- The Company has concluded that there is a material weakness in its internal control over financial reporting, which, if not remediated, could materially adversely affect its ability to timely and accurately report its results of operations and financial condition. The accuracy of the Company's financial reporting depends on the effectiveness of its internal controls over financial reporting.

- 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.

- 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.

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

- If we fail to comply with our obligations under our license agreements, we could lose the rights to intellectual property that is important to our business.

- We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

- Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non-compliance with these requirements.

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

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

- Future sales of our common stock in the public market or other financings could cause our stock price to fall.

- If we sell additional equity or debt securities to fund our operations, it may impose restrictions on our business.

Risks Related to Our Business and Industry

There is substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has issued an opinion on our consolidated financial statements included in this Annual Report on Form 10-K that states that the consolidated financial statements were prepared assuming we will continue as a going concern. Our consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America applicable for a going concern, which assume that we will realize our assets and discharge our liabilities in the ordinary course of business. We have incurred substantial operating losses and have used cash in our operating activities for the past few years. As of and for the year ended December 31, 2022, we had a net loss of $27.3 million and net cash used in operating activities of $21.7 million. Our consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. We also cannot be certain that additional financing, if needed, will be available on acceptable terms, or at all, and our failure to raise capital when needed could limit our ability to continue our operations. There remains substantial doubt about our ability to continue as a going concern for the next twelve months from the date the consolidated financial statements were issued.

To date, we have experienced negative cash flow from development of our technology, as well as from the costs associated with building a sales force to market our product and services. We expect to incur substantial net losses for the foreseeable future in order to further develop and commercialize our product. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities and expanding our staff to sell and support our product. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability.

Because of the numerous risks and uncertainties associated with further development and commercialization of our technology and any future tests, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable, and you may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the development and commercialization in the medical device industry. We may never successfully commercialize our technology and our business may fail.

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

We are an early commercialization stage company and we expect to incur substantial additional operating expenses over the next several years as our marketing, commercialization, and customer development along with additional research and development increase for our PURE EP System and other product candidates. The amount of our future losses and when, if ever, we will achieve profitability are uncertain. Our products that have generated minimal commercial revenue, and, although we expect to generate revenues this year from the commercial sale of our PURE EP System, may not be able to generate sufficient revenues to fund our operating expenses, if any. Our ability to generate revenue and achieve profitability will depend on, among other things, the following:

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

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

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

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

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

As of December 31, 2022, our cash and cash equivalents were approximately $0.4 million. Based on our currently expected level of operating expenditures, we do not expect that our existing cash and cash equivalents will be sufficient to fund our operations in the near future. Our revenue is generated from sales of our PURE EP System, for which we made first commercial sale in February 2021, and other products we may develop. Future sales of these products, if any, will be subject to, among other things, commercial and market uncertainties that may be outside our control. If we fail to generate our intended revenues from these products, our results of operations and the value of our business and securities would be materially and adversely affected.

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

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

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

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

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

We may experience delays in any phase of the preclinical or clinical development of a product, including during its research and development.

We may experience delays in any phase of the preclinical or clinical development of a product, including during its research and development. The completion of any of these studies may be delayed or halted for numerous reasons, including, but not limited to, the following:

- successful completion of the pre-clinical and clinical development of our products;

- the FDA or other regulatory authorities do not approve a clinical study protocol or place a clinical study on hold;
- patients do not enroll in a clinical study or results from patients are not received at the expected rate;
- patients discontinue participation in a clinical study prior to the scheduled endpoint at a higher than expected rate;
- patients experience adverse events from a product we develop;
- third-party clinical investigators do not perform the studies in accordance with the anticipated schedule or consistent with the study protocol and good clinical practices or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- third-party clinical investigators engage in activities that, even if not directly associated with our studies, result in their debarment, loss of licensure, or other legal or regulatory sanction;
- regulatory inspections of manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend the preclinical or clinical studies;
- changes in governmental regulations or administrative actions;
- the interim results of the preclinical or clinical study, if any, are inconclusive or negative; and
- the study design, although approved and completed, is inadequate to demonstrate effectiveness and safety.

If the preclinical and clinical studies that we are required to conduct to gain regulatory approval are delayed or unsuccessful, we may not be able to market any product that we develop in the future. Preclinical studies and clinical trials are expensive and difficult to design and implement and any delays or prolongment in our preclinical and clinical studies will require additional capital. There is no assurance that we will be able to acquire additional capital to support our studies. The failure to obtain additional capital would have a material adverse effect on the Company.

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

In November 2019, we commenced our first clinical study with PURE EP System and completed the clinical trial as of September 2021. 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 subsequent clinical trials may be delayed or halted for numerous reasons, including:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The EP market is highly competitive.

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

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

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

We may fail to attract and retain qualified personnel.

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

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

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

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

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

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

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

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

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

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

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

If healthcare providers are unable to obtain sufficient reimbursement or other financial incentives from third-party healthcare 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. Currently, the PURE EP System does not receive separate reimbursement from any third-party payor. Instead, healthcare providers typically receive reimbursement for the procedure in which our product is used. Future regulatory action by CMS or other governmental agencies, or unfavorable clinical data, among other things, may impact coverage and/or reimbursement policies for procedures performed using our products. If healthcare providers are unable to obtain adequate coverage of, or reimbursement for, procedures performed using our products, or if managed care organizations do not receive improved capitated payments due to more accurate patient risk assessment using our products, we may be unable to sell our products at levels that are sufficient to allow us to achieve and maintain profitability, and our business would suffer significantly.

We may face risks associated with future litigation and claims.

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

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

Our business is subject to cybersecurity risks.

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

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

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

We presently maintain insurance coverage to protect against cybersecurity risks. However, 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 healthcare laws, including fraud and abuse, false claims, and privacy laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation and enforcement. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.

We are subject, directly or indirectly, to various U.S. federal and state healthcare laws and regulations. These laws include fraud and abuse laws, such as 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, marketing and education programs. In addition, we may be subject, directly or indirectly, to patient privacy regulations by both the federal government and the states in which we conduct our business. The healthcare 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 healthcare program, such as the Medicare and Medicaid programs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the Healthcare Reform Law and judicial challenges have continued for over a decade. However, as of the Supreme Court's ruling ordering the dismissal of, arguably, the most promising case challenging the Healthcare Reform Law to-date in June 2021, it appears that the Healthcare Reform Law will remain in-effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business. Additionally, the Biden administration has introduced various measures in recent years, focusing on healthcare and medical-product pricing, in particular. It remains to be seen how these measures will affect our business and there is uncertainty as to what other healthcare programs and regulations may be implemented or changed at the federal and/or state level in the U.S., but, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the U.S. in the future. For example, any changes that reduce, or impede the ability of healthcare providers to obtain reimbursement for medical procedures in which the products we currently, or intend to, commercialize are used, or that reduce medical procedure volumes, could adversely affect our operations and/or future business plans. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for medical devices affected by the legislation. From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing coverage, reimbursement, pricing, and marketing of medical device products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

The COVID-19 pandemic may adversely affect our business.

In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, have imposed unprecedented restrictions on travel, quarantines, and other public health safety measures. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases. The COVID-19 pandemic may adversely impact our business plan as our clinical studies may be delayed as hospitals in the impacted regions may shift their resources to patients affected by the disease. The rapidly evolving nature of the circumstances is such that it is impossible, at this stage, to determine the full and overall impact the COVID-19 pandemic may have, but it could disrupt production and cause delays in the supply and delivery of products used in our research and development efforts, adversely affect our employees, and disrupt our operations, all of which may have a material adverse effect on our business. In addition, the pandemic may have an adverse effect on the ability of regulatory bodies to review submissions in a timely manner, grant approvals or supervise our candidates and products, and may further divert the attention and efforts of the medical community to coping with the coronavirus and disrupt the marketplace in which we operate and may have a material adverse effects on our operations. Patient enrollment in future clinical trials could be slowed, delayed, or suspended due to the pandemic as well.

Moreover, the COVID-19 pandemic has created significant economic uncertainty and volatility in the credit and capital markets. Management plans to secure the necessary financing through the issue of new equity and/or the entering into of strategic partnership arrangements; however, there is no assurance that our management will be able to obtain such financing on reasonable terms or at all. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital and on the market price of our common stock, and we may not be able to successfully raise capital through the sale of our securities. If we are unsuccessful in commercializing our products or raising capital, we may need to reduce activities, curtail or cease operations.

In addition, a significant resurgence of COVID-19 or other infectious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations.

As a smaller reporting company, we are subject to scaled disclosure requirements that may make it more challenging for investors to analyze our results of operations and financial prospects.

Currently, we are a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act. As a "smaller reporting company," we are able to provide simplified executive compensation disclosures in our filings and have certain other decreased disclosure obligations in our filings with the SEC, including being required to provide only two years of audited financial statements in annual reports. Consequently, it may be more challenging for investors to analyze our results of operations and financial prospects.

Furthermore, we are a non-accelerated filer as defined by Rule 12b-2 of the Exchange Act, and, as such, are not required to provide an auditor attestation of management's assessment of internal control over financial reporting, which is generally required for SEC reporting companies under Section 404(b) of the Sarbanes-Oxley Act. Because we are not required to, and have not, had our auditor's provide an attestation of our management's assessment of internal control over financial reporting, a material weakness in internal controls may remain undetected for a longer period.

The Company has concluded that there is a material weakness in its internal control over financial reporting, which, if not remediated, could materially adversely affect its ability to timely and accurately report its results of operations and financial condition. The accuracy of the Company's financial reporting depends on the effectiveness of its internal controls over financial reporting.

Internal controls over financial reporting can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements and may not prevent or detect misstatements. Failure to maintain effective internal controls over financial reporting, or lapses in disclosure controls and procedures, could undermine the ability to provide accurate disclosure (including with respect to financial information) on a timely basis, which could cause investors to lose confidence in the Company's disclosures (including with respect to financial information), require significant resources to remediate the lapse or deficiency, and expose it to legal or regulatory proceedings.

In connection with the audit of its December 31, 2022 financial statements, the Company's management identified inadequate identification, recording and reporting of stock based compensation due under consulting or other third-party contracts entered into by the Company, but not yet ratified by the Company's Board of Directors which resulted in deficiencies, which, in aggregate, amounted to a material weakness in the Company's internal control over financial reporting.

The Company's remediation efforts are ongoing and it will continue its initiatives to implement and document policies, procedures, and internal controls. Remediation of the identified material weakness and strengthening the internal control environment will require a substantial effort throughout 2023 and beyond, as necessary, and the Company will test the ongoing operating effectiveness of the new and existing controls in future periods. The material weakness cannot be considered completely remediated until the applicable controls have operated for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. The Company cannot guarantee that it will be successful in remediating the material weakness it identified or that its internal control over financial reporting, as modified, will enable it to identify or avoid material weaknesses in the future.

The Company cannot guarantee that its management will be successful in identifying and retaining appropriate personnel; that newly engaged staff or outside consultants will be successful in identifying material weaknesses in the future; or that appropriate personnel will be identified and retained prior to these deficiencies resulting in material and adverse effects on the Company's business.

There are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected.

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act of 2002 require us to identify material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Our management, including our chief executive officer and chief financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our 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. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon 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. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us and adversely affect how our stock trades. This could in turn negatively affect our ability to access equity markets for capital.

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. Our patent portfolio now includes 25 (issued/allowed) issued utility patents (18 utility patents where BioSig is at least one of the applicants). Thirty four additional U.S. and foreign utility patent applications are pending covering various aspects of our PURE EP System for recording, measuring, calculating and displaying of electrocardiograms during cardiac ablation procedures (thirty four U.S. and foreign utility patent applications where either BioSig, Mayo, or both is at least one of the applicants). Two of these pending U.S. patent applications are directed to artificial intelligence (AI). We also have 30 issued worldwide design patents, which cover various features of our display screens and graphical user interface for enhanced visualization of biomedical signals (30 design patents where BioSig is at least one of the applicants). Finally, of the 34 patent applications mentioned above, we have licenses to 7 patents and 13 additional worldwide utility patent applications from Mayo Foundation for Medical Education and Research that are pending (7 patents and 13 applications where only Mayo is the applicant). These patents and applications are generally directed to electroporation and stimulation.

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.

Furthermore, the issuance of a patent, while presumed valid and enforceable, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees.

Patent rights are territorial, and patent protection extends only to those countries where we have issued patents. Filing, prosecuting and defending patents on our products and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. Many countries, however, do not protect intellectual property to the same extent as the U.S. or Europe, and their litigation processes differ. Competitors may successfully challenge or avoid our patents, or manufacture products in countries where we have not applied for patent protection. Changes in the patent laws in the U.S. or other countries may diminish the value of our patent rights. As a result of these and other factors, the scope, validity, enforceability, and commercial value of our patent rights are uncertain and unpredictable.

Indeed, several companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for Biosig to stop the infringement, misappropriation or other violation of Biosig's intellectual property rights generally. Proceedings to enforce Biosig's intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of Biosig's business, could put Biosig's patents at risk of being invalidated or interpreted narrowly and Biosig's patent applications at risk of not issuing and could provoke third parties to assert claims against Biosig. Biosig may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful.

The patent positions of medical device companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. A third-party may submit prior art, or we may become involved in opposition, derivation, reexamination, inter partes review, post-grant review, supplemental examination, or interference proceedings challenging our patent rights or the patent rights of our licensors or development partners. The costs of defending or enforcing our proprietary rights in these proceedings can be substantial, and the outcome can be uncertain. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, or reduce our ability to manufacture or commercialize products. Furthermore, if the scope or strength of protection provided by our patents and patent applications is threatened, it could discourage companies from collaborating with us to license, develop or commercialize current or future products. The ownership of our proprietary rights could also be challenged.

Furthermore, our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product, particularly in litigation in countries other than the U.S. that do not provide an extensive discovery procedure. Any litigation to enforce or defend our patent rights, if any, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

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.

Our commercial success also depends upon our ability, and the ability of any third party with which we may partner, to develop, manufacture, market and sell our products, if approved, and use our patent-protected technologies without infringing the patents of third parties. We may not have identified all patents, published applications or published literature that affect our business by blocking our ability to commercialize our products, by preventing the patentability of one or more aspects of our products to us or our licensors, or by covering the same or similar technologies that may affect our ability to market our products. For example, we (or the licensor of a product to us) may not have conducted a patent clearance search sufficient to identify potentially obstructing third party patent rights. Moreover, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, or the USPTO, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside of the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. We cannot be certain that we or our licensors were the first to invent, or the first to file, patent applications covering our products. We also may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents.

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

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

We may not have sufficient resources to bring these actions to a successful conclusion. Any of these events could substantially harm our earnings, financial condition and operations.

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

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

- Mayo Clinic may not properly obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our advanced features or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity, and enforceability of our intellectual property;

- Mayo Clinic may own or co-own intellectual property covering our advanced features that results from our collaboration with them, and in such cases, we may not have the exclusive right or any right to commercialize such intellectual property or such product candidates or research programs; or

- We may be prevented from enforcing or defending any intellectual property that we contribute to or that arises out of the collaboration, if Mayo Clinic refuses to cooperate with such action.

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

If we fail to comply with our obligations under our license agreements, we could lose the rights to intellectual property that is important to our business.

Our current license agreements impose on us various development obligations, payment of royalties and fees based on achieving certain milestones as well as other obligations. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. In addition, if the licensor fails to enforce its intellectual property, the licensed rights may not be adequately maintained. The termination of any license agreements or failure to adequately protect such license agreements could prevent us from commercializing our products or possible future products covered by the licensed intellectual property. Any of these events could materially adversely affect our business, prospects, financial condition and results of operation.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Our employees may have been previously employed at other companies in the industry, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product(s), which would materially adversely affect our commercial development efforts.

Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the relevant patent agencies in several stages over the lifetime of the patents and /or applications. The relevant patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which the failure to comply with the relevant requirements can result in the abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and know-how which could have a material adverse effect on our business, prospects, financial condition and results of operation.

Risks Related to our Common Stock

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

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

- announcements of technological innovations, new products or product enhancements by us or others;
- actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in our business, operations or prospects;
- announcements of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments by us or our competitors;
- conditions or trends in the biotechnology industry;
- changes in the economic performance or market valuations of other biotechnology companies;
- general market conditions or domestic or international macroeconomic and geopolitical factors unrelated to our performance or financial condition;
- purchase or sale of our common stock by stockholders, including executives and directors;
- volatility and limitations in trading volumes of our common stock;
- changes in our capital structure or dividend policy, future issuances of securities, sales or distributions of large blocks of our common stock by stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- changes in earnings estimates or recommendations by security analysts, if our common stock is covered by analysts;
- the addition or departure of key personnel;
- disputes and litigation related to intellectual property rights, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

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

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

Moreover, the COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent months. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock.

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

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

Although our shares of common stock 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.

Future sales of our common stock in the public market or other financings could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, the perception that these sales might occur or other financings, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. A substantial majority of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act unless these shares are owned or purchased by "affiliates" as that term is defined in Rule 144 under the Securities Act. In addition, shares of common stock issuable upon exercise of outstanding options, restricted stock units and shares reserved for future issuance under our incentive stock plan will be eligible for sale in the public market to the extent permitted by applicable vesting requirements and, in some cases, subject to compliance with the requirements of Rule 144. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws.

If we sell additional equity or debt securities to fund our operations, it may impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, which may impose restrictive covenants that adversely impact our business. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to expand our operations or otherwise capitalize on our business opportunities due to such restrictions, our business, financial condition and results of operations could be materially adversely affected.

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

As of March 30, 2023, we have outstanding options to purchase 4,616,151shares of common stock, 430,835 restricted stock units and have reserved 4,052,945 shares of our common stock for further issuances pursuant to our 2023 Long-Term Incentive Plan. In addition, as of March 30, 2023, we may be required to issue 511,297 shares of our common stock for issuance upon conversion of outstanding convertible Series C preferred stock which includes accrued dividends as of March 30, 2023, and 8,867,786 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 30, 2023, three of our stockholders beneficially owned over 19.4% 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.

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.

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.

As of March 31, 2023, we were in compliance with all covenants of the Series C Preferred Stock.

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

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

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

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

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

The terms of our Series C Preferred Stock contain anti-dilution provisions, which provisions require the lowering of the conversion price to the purchase price of future offerings. If in the future we issue securities for less than the conversion of our Series C Preferred Stock then in effect, we will be required to further reduce the relevant conversion prices.

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.

General Risk Factors

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.

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 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.

ITEM 1B – UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2 – PROPERTIES

We maintain our principal executive office at 55 Greens Farms Road, Westport, Connecticut, where we sublease approximately 6,590 square feet of office space. This lease runs until December 31, 2024, with monthly payments of $14,828 from January 1, 2022 through December 31, 2022, $15,377 per month from January 1, 2023 through December 31, 2023 and $15,926 from January 1, 2024 through December 31, 2024 plus any additional utility expenses. We do not have an option to extend the lease. In connection with the lease, we paid a security deposit of $14,828. There is no option to extend the lease past its initial term.

In addition, we maintain our engineering offices at 12424 Wilshire Boulevard, Los Angeles, California, where we lease approximately 4,000 square feet of office space. This lease runs until July 31, 2025, with monthly payments of $14,124 from September 1, 2022 through June 30, 2023, $14,618 from July 1, 2023 through June 30, 2024 and $15,130 from July 1, 2024 through July 31, 2025. In connection with the lease, we paid a security deposit of $27,404. We have an option to extend past its lease term for three additional years.

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

ITEM 3 – LEGAL PROCEEDINGS

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

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

ITEM 4 – MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market for Common Stock

On October 29, 2014, our common stock commenced trading on OTCQB under the symbol "BSGM" and on September 21, 2018 we commenced trading on the Nasdaq Capital Market exchange under the same ticker symbol. Prior to October 29, 2014, there was no established trading price for our common stock. The last reported sales price of our common stock on the Nasdaq Capital Market on March 30, 2023, was $1.13 per share.

Holders of Record

As of March 30, 2023, there were approximately 325 holders of our common stock, as determined by counting our record holders and the number of participants reflected in a security position listing provided to us by the Depository Trust Company. Because the "DTC participants" are brokers and other institutions holding shares of our common stock on behalf of their customers, we do not know the actual number of unique shareholders represented by these record holders.

Dividends

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

ITEM 6 – RESERVED

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

Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide a reader of our financial statements with a narrative from the perspective of our management on our financial condition, results of operations, liquidity, and certain other factors that may affect our future results. 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* "*Note on Forward-Looking Statements.*"

Overview

BioSig Technologies is a medical device company commercializing an advanced digital signal processing technology platform to deliver insights to the treatment of cardiovascular arrhythmias. Through collaboration with physicians, experts, and healthcare leaders across the field of electrophysiology (EP), we are committed to addressing healthcare's biggest priorities — saving time, saving costs, and saving lives.

Our first product, the PURE EP™ System, is an FDA 510(k) cleared non-invasive class II device consisting of a unique combination of hardware and software designed to provide unprecedented signal clarity and precision for real-time visualization of intracardiac signals paving the way for personalized patient care. Integrating with existing systems in the EP lab, PURE EP™ is designed to accurately pinpoint even the most complex signals to maximize procedural success and efficiency.

PURE EP™ Software Version 6 with ACCUVIZ™ Module released late 2022, is the first to be designed and launched by the Company's new commercial and operations team and represents the most advanced iteration of the Company's digital signal processing technology. Software Version 6 delivers a new level of efficiency enabling unlimited, real-time analysis of intracardiac signals. In addition, the new ACCUVIZ™ Module introduces advanced signal processing automation, elevated visualization of clear cardiac signal information, and even smarter workflows.

PURE EP™ System's software includes our proprietary High Frequency Algorithm (HFA); a novel feature that identifies the key frequency components of cardiac data that can be difficult to identify within the traditional waveform presentation. We believe that a limitation of traditional systems is that they only display data as voltage over time. PURE EP™ adds visibility to cardiac frequency data. By focusing on signals above 200Hz, HFA aims to eliminate RF frequencies to retain clear focus on the signals targeted for ablation.

Other unique software functionalities—including Automatic Tachycardia Characterization (ATC) and TRUSOURCE™ Analysis & Report—aim to improve clinical workflow and deliver clear, actionable insights to today's electrophysiologist during cardiac catheter procedures.

By capturing critical cardiac signals—even the most complex, the PURE EP™ System is designed to enhance clinical decision-making and improve clinical workflow for all types of arrhythmias - even the most challenging procedures for cardiac arrhythmias, like ventricular tachycardia (VT) and atrial fibrillation (AF).

The PURE EP System is currently in a national commercial launch and in regular use at healthcare systems, such as Mayo Clinic, Texas Cardiac Arrhythmia Institute, Cleveland Clinic, and Kansas City Heart Rhythm Institute. In a blinded clinical study published in the Journal of Cardiovascular Electrophysiology, electrophysiologists rated PURE EP™ as equivalent or superior to conventional systems for 93.6% of signal samples, with 75.2% earning a superior rating.

More recently, results from a randomized study (Redo AF Sub Study), demonstrated the PURE EP™ System's potential to promote shorter procedural times and higher cost savings during catheter ablations. Study results demonstrated that the PURE EP™ System led to a mean procedure time reduction of 11.3 minutes. Given that the mean cost of operating room time is approximately $37 per minute (ClinicalTrials.gov Identifier: NCT04964440), the procedural time savings demonstrated by the PURE EP™ System suggest potential cost savings of approximately $418.10 per procedure. While this suggests that PURE EP™ might promote shorter procedural times, further studies are underway.

In July 2022, we entered into our first national purchasing agreement with HCA Management Services, L.P. whereby Kansas City Heart Rhythm Institute at Overland Park Regional Medical Center in Kansas City, Missouri acquired our PURE EP System under the terms of the new agreement with a 30-month lease of the system. Following Overland Park, the San Antonio Methodist Hospital purchased the PURE EP System under the same terms in October 2022.

In August 2022, we installed a second evaluation system at the Cleveland Clinic - both Main and Fairview campuses of Cleveland Clinic's Heart, Vascular & Thoracic Institute are now evaluating PURE EP™. The additional installation will support the medical center's clinical evaluation of the PURE EP™ System and expand physician access to our signal processing technology. Additionally, we recently expanded our clinical footprint in the Midwest with evaluation agreements at leading medical centers in Illinois and Wisconsin.

On January 10, 2023, we announced that Bellin Health entered into an agreement to acquire a PURE EP™ System. Through a formal evaluation, Bellin reported that clear cardiac signals positively impacted procedural efficiency resulting in cost savings per procedure.

In addition to clinical evaluation, we have conducted pre-clinical evaluation with the PURE EP™ System under several protocols at Mayo Clinic in Rochester, Minnesota (including novel research programs such as Artificial Intelligence, or AI, and repolarization), we also conducted studies at Mount Sinai Hospital in New York, New York, the University of Pennsylvania, and Cleveland Clinic. We intend to continue additional research and development studies with our technology at institutions including Mayo Clinic and Cleveland Clinic - a Research Agreement was signed with the Cleveland Clinic to explore expanded applications for our digital signal processing technology.

Over 3,000 procedures have been performed using the PURE EP™ System with more than 80 physicians at 21 hospitals across the United States.

Our patent portfolio now includes 25 (issued/allowed) issued utility patents (18 utility patents where BioSig is at least one of the applicants). Thirty four additional U.S. and foreign utility patent applications are pending covering various aspects of our PURE EP System for recording, measuring, calculating and displaying of electrocardiograms during cardiac ablation procedures (thirty four U.S. and foreign utility patent applications where either BioSig, Mayo, or both is at least one of the applicants). Two of these pending U.S. patent applications are directed to artificial intelligence (AI). We also have 30 issued worldwide design patents, which cover various features of our display screens and graphical user interface for enhanced visualization of biomedical signals (30 design patents where BioSig is at least one of the applicants). Finally, of the 34 patent applications mentioned above, we have licenses to 7 patents and 13 additional worldwide utility patent applications from Mayo Foundation for Medical Education and Research that are pending (7 patents and 13 applications where only Mayo is the applicant). These patents and applications are generally directed to electroporation and stimulation.

Critical Accounting Estimates

The following discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the U.S. The preparation of consolidated 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 consolidated financial statements. The consolidated financial statements include estimates based on currently available information and our judgment as to the outcome of future conditions and circumstances.

We believe the following critical accounting estimates affect our more significant judgments and estimates used in the preparation of our financial statements. Among the significant judgments made by management in the preparation of our financial statements are the following:

Revenue Recognition

We derive our revenue primarily from the sale of our medical device, the PURE EP™ System, as well as related support and maintenance services and software upgrades in connection with the system.

We recognize revenue in accordance with Accounting Standards Codification (ASC) 842, *Leases* ("ASC 842") for lease components and ASC 606, *Revenue from Contracts with Customers* ("ASC 606") for non-lease components. For medical device sales, the Company recognize revenue under ASC 606.

The core principle of ASC 606 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

Under ASC 606, we determine revenue recognition through the following five steps:

- Identify the contract with the customer;
- Identify the performance obligations in the contract;
- Determine the transaction price;
- Allocate the transaction price to the performance obligation in the contract; and
- Recognize revenue when, or as, the performance obligations are satisfied.

Performance obligations are the units of accounting for revenue recognition and generally represent the distinct goods or services that are promised to the customer. If we determine that it has not satisfied a performance obligation, we will defer recognition of the revenue until the performance obligation is deemed to be satisfied. Once the PURE EP system is delivered, installed, and accepted by the customer, our performance obligation is recognized. Support, maintenance, and software upgrades are performance obligations over a defined period and are recognized ratably over the contractual service period. Customers typically purchase these services with the initial sale of the PURE EP System and do not have the right to terminate their contracts unless we fail to perform material obligations.

We may execute more than one contract with a single customer. If so, it is evaluated whether the agreements were negotiated as a package with a single objective, whether the amount of consideration to be paid in one agreement depends on the price and/or performance of another agreement, or whether the goods or services promised in the agreements represent a single performance obligation. The conclusions reached can impact the allocation of the transaction price to each performance obligation and the timing of revenue recognition related to those arrangements.

We record accounts receivable for amounts invoiced to customers for which we have an unconditional right to consideration as provided under the contractual arrangement. Unbilled receivables, if any, include amounts related to our contractual right to consideration for completed performance obligations not yet invoiced. Deferred revenue includes payments received in advance of performance under the contract. Our unbilled receivables and deferred revenue are reported on an individual contract basis at the end of each reporting period. Unbilled receivables are classified as current or noncurrent based on the timing of when we expect to bill the customer. Deferred revenue is classified as current or noncurrent based on the timing of when we expect to recognize revenue.

Our unconditional right to consideration for goods and services transferred to the customer is included in accounts receivable, net (if any) in the Company's consolidated balance sheet.

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.

Results of Operations (000's)

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, 2022, Compared to Twelve Months Ended December 31, 2021

Revenues and Cost of Goods Sold. Revenue for the year ended December 31, 2022, totaled $286 comprised of product sales of $254 and recognized service revenue of $32 as compared to $441 comprised of product sales of $414 and recognized service revenue of $27 for the year ended December 31, 2021.

We derive our revenue primarily from the sale or lease of our medical device, PURE EP™ system, as well as related support and maintenance services and software upgrades in connection with the system.

Cost of sales for the year ended December 31, 2022, was $57 comprised of the delivered product and cost of services as compared to $199 for the year ended December 31, 2021.

Gross profit from the year ended December 31, 2022, was $229 or 80.0% as compared to $242 or 54.9% for the year ended December 31, 2021. In 2022, we increased our pricing for our PURE EP system from the initial introduction pricing of 2021.

Research and Development Expenses. Research and development expenses for the twelve months ended December 31, 2022, were $5,821, an increase of $219 or 3.9%, from $5,602 for the twelve months ended December 31, 2021. This increase is primarily due to increase in the BioSig segment research and development in 2022 as compared to 2021.

Research and development expenses were comprised of the following:

	2022	2021
Salaries and equity compensation	$ 3,770	$ 2,833
Consulting expenses	428	725
Research, clinical studies, and design work	935	1,159
Regulatory	54	142
Data/AI development	36	307
Product development and formulation	-	15
Acquired research and development	-	150
Travel, supplies, other	598	271
Total	$ 5,821	$ 5,602

Stock-based compensation for research and development personnel was $951 and $759 for the twelve months ended December 31, 2022, and 2021, respectively.

General and Administrative Expenses. General and administrative expenses for the twelve months ended December 31, 2022, were $21,380, a decrease of $6,473, or 23.2%, from $27,853 incurred in the twelve months ended December 31, 2021. This decrease is primarily due to reduction in equity-based and other compensation, professional services, consulting fees and travel, meals and entertainment costs.

Payroll related expenses (including equity compensation) decreased to $12,001 in the twelve months ended December 31, 2022, from $17,360 for the twelve months ended December 31, 2021, a decrease of $5,359, or 30.9%. This decrease is due to the value of the stock-based compensation decreasing to $3,582 in 2022, as a result of the vesting of stock and stock options issued to board members, officers, and employees, as compared to $9,062 of stock-based compensation in 2021, net with added additional personnel in 2022.

Professional services for the twelve months ended December 31, 2022, totaled $1,174, a decrease of $87, or 6.9%, over the $1,261 recognized for the twelve months ended December 31, 2021. Of professional services, legal fees totaled $782 for the twelve months ended December 31, 2022, a decrease of $161, or 17.1%, from $943 incurred for the twelve months ended December 31, 2021. The significant decrease in legal fees in 2022 is due to reduction in legal work in asset acquisitions, financing and in developing and registering patents. Accounting fees incurred in the twelve months ended December 31, 2022, amounted to $225, an increase of $46 or 25.7%, from $179 incurred for the same period in 2021. The significant increase due to increase in 2022 work relating to auditing and review work relating to ViralClear segment.

Consulting fees and marketing totaled $3,955 for the twelve months ended December 31, 2022, a decrease of $808 or 17.0%, from $4,763 for the twelve months ended December 31, 2021. The decrease primarily relates to reductions in fund raising and investor relations to support our efforts in market research and potential investor identification and key consultants in connection with our commercialization efforts, net increases in marketing activities.

Travel, meals and entertainment costs for the twelve months ended December 31, 2022, were $1,110, an increase of $100, or 9.9%, from $1,010 incurred during the twelve months ended December 31, 2021. The increase in 2022 was due to lifting of various restrictions imposed by the COVID-19 pandemic-related measures as compared to 2021.

Rent for the twelve months ended December 31, 2022, totaled $426, a decrease of $40, or 8.6%, from $466 incurred during the same period in 2021. In 2022, we incurred a rent reduction with our lease extension in our Los Angeles facility and closed our Minnesota office.

Depreciation and Amortization Expense. Depreciation and amortization expense for the twelve months ended 2022 totaled $293 as compared to $198 incurred during the same period in 2021. The increase is due primarily to additional manufacturing and testing equipment purchased in 2022.

Interest Income. Interest income for the twelve months ended December 31, 2022, totaled $3 as compared to $2 earned during the twelve months ended December 31, 2021. The increase in 2022 was due interest received under our lease agreements in 2022.

Gain on Settlement of Debt. On September 23, 2021, we negotiated a lawsuit settlement with Aurigene relating to certain milestone payments for manufacturing and services under a contract with our ViralClear subsidiary. In connection with the settlement, we recognized a gain on settlement of debt of $553 during the twelve months ended December 31, 2021, as compared to nil for the twelve months ended December 31, 2022.

Preferred Stock Dividend. Preferred stock dividend for the twelve months ended December 31, 2022 and 2021, totaled $9 Preferred stock dividends are related to the issuance of our Series C Preferred Stock from 2013 through 2015. In addition, the Series C Preferred stock conversion rate reset from $0.63 to $0.25 in 2022, therefore we recorded a noncash deemed preferred stock dividend of $210 during the year ended December 31, 2022.

Noncontrolling Interest. In 2019 and 2020, ViralClear sold shares of its common stock to fund its initial and ongoing operations. As of December 31, 2022, we had a majority interest in ViralClear of 69.08%. The proportionate loss attributed to noncontrolling interests for the twelve months ended December 31, 2022, was $210 as compared to $939 for 2021.

Net Loss Available to BioSig Technologies, Inc. Net loss available to common stockholders for the twelve months ended December 31, 2022, was $27,271 compared to a net loss of $31,926 for the twelve months ended December 31, 2021, a decrease of $4,655 or 14.6%. The primary reasons for the decrease, as described above, are the decreases in general and administrative expenses from 2022 to 2021.

Segment Results

The Company reports segment information based on the "management" approach. The management approach designates the internal reporting used by management for making decisions and assessing performance as the source of the Company's reportable segments.

Summary Statement of Operations for the year ended December 31, 2022, as compared to the year ended December 31, 2021, are detailed in Note 13 of the accompanying consolidated financial statements.

COVID-19

The full public-health impact of the COVID-19 pandemic is currently indeterminable and rapidly evolving, and the related health crisis has adversely affected and may continue to adversely affect the global economy, resulting in possibly delaying our commercialization objectives of the PURE EP Systems due to limited resources and accessibility of hospitals as they cope with the pandemic.

Liquidity and Capital Resources

We had an accumulated deficit as of December 31, 2022, of approximately $216 million, as well as a net loss of approximately $27 million and negative operating cash flows. We expect to continue incurring losses and negative cash flows from operations until our products (primarily PURE EP System) reach commercial profitability.

We have incurred net losses and negative cash flows from operations since inception and our expectation is that these conditions will continue for the foreseeable future. In addition, we will require additional financing to fund future operations. Although we have commercial products available for sale, we have not generated significant revenues to date, and there is no assurance that 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 additional products 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.

Our plans include the continued commercialization of the PURE EP System and other applications of our core technology and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. Our shift from a focus on technology development to commercialization has allowed us to reduce our annual expenses in a meaningful way. As a result of this transition, we have been able to achieve savings through reductions in executive and management compensation and a reduction of our utilization of external consultants and professional service providers. We believe these cost-saving measures combined with our expectations of positive trends in commercial activity create the potential for us to achieve a lower cash flow breakeven rate. There are no assurances, however, that we will be successful in obtaining the level of financing needed for our operations. The ongoing COVID-19 pandemic has resulted and continues to result in significant financial market volatility and uncertainty in recent months. In addition, U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine.

A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital and on the market price of our common stock, and we may not be able to successfully raise capital through the sale of our securities.

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 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, 2022, the aggregate stated value of our Series C Preferred Stock was $105. The triggering events include our being subject to a judgment of greater than $100 or our initiation of bankruptcy proceedings. If any of the triggering events contained in our Series C Preferred Stock occur, the holders of our Series C Preferred Stock may demand redemption, an obligation we may not have the ability to meet at the time of such demand. We will be required to pay interest on any amounts remaining unpaid after the required redemption of our Series C Preferred Stock, at a rate equal to the lesser of 18% per annum or the maximum rate permitted by applicable law.

We expect to incur losses from operations for the near future. We expect to incur increasing marketing and commercialization expenses related to our PURE EP system in addition to additional research and development costs relating to the PURE EP and other product candidates, 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.

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.

Equity Financing

On March 21, 2022, we closed a registered direct offering (the "Offering") of an aggregate of 2,613,130 shares of our common stock, at an offering price of $1.15 per share and (ii) warrants to purchase up to 2,613,130 shares of our common stock, at an exercise price of $1.40 per share, that will become exercisable six months after the date of issuance and will expire three and one-half years following the date of issuance, for gross proceeds of approximately $3.0 million before the deduction of fees and offering expenses.

The common stock and warrants were offered by us pursuant to a shelf registration statement on Form S-3 (File No. 333-251859) (the "Shelf Registration Statement"), previously filed with the SEC on December 31, 2020, and declared effective by the SEC on January 12, 2021, and a prospectus supplement, dated March 21, 2022, to the Shelf Registration Statement, filed with the SEC on March 22, 2022.

From June through December 2022, the Company entered into multiple Securities Purchase Agreements with certain institutional and accredited investors, pursuant to which the Company sold to the Investors an aggregate of 10,044,734 shares of common stock at an average purchase price of $0.5780 per share, and warrants to purchase up to 1,080,799 shares of common stock at an exercise price of $0.4455 per share, that will become exercisable six months after the date of issuance and will expire five and one-half years following the date of issuance, in exchange for aggregate consideration of $5,280,735, net of expenses of $525,607.

Pursuant to the Amended and Restated Underwriting Agreement, we issued to the Underwriter, or its designees warrants to purchase up to an aggregate 217,083 shares of common stock, or 5% of the number of common stock sold in a June 2023 offering. The underwriter warrants are exercisable following the date of issuance and ending five years from the date of the execution of the Underwriting Agreement, at a price per share equal to $0.90 per share (120% of the public offering price per share) and are exercisable on a "cashless" basis.

From January through March 2023, we entered into multiple Securities Purchase Agreements with certain institutional and accredited investors, pursuant to which we sold to the Investors an aggregate of 8,500,300 shares of common stock at an average purchase price of $0.80 per share, and warrants to purchase up to 4,250,150 shares of common stock at an average exercise price of $0.7728 per share, that will become exercisable six months after the date of issuance and will expire five and one-half years following the date of issuance, in exchange for aggregate consideration of $6,757,672, net of expenses of $471,967.

Pursuant to certain tail provisions in an engagement agreement, dated October 11, 2022 we had entered into with Laidlaw & Company (UK) Ltd., we issued to Laidlaw in connection with the 2023 PIPES, warrants to purchase 283,449 shares of common stock at an average exercise price of $0.7884 per share. The Laidlaw warrants becomes exercisable six months after the date of issuance and will expire five and one-half years following the date of issuance.

In addition, pursuant to certain compensation provisions in an engagement agreement, dated February 24, 2023, we had entered into with Laidlaw & Company (UK) Ltd. ("Laidlaw"), we issued to Laidlaw warrants to purchase an aggregate of 117,076 shares of common stock in connection with the transactions noted above.

At-the-Market Offering

On May 17, 2022, we entered into an ATM Sales Agreement (the "Sales Agreement") with Virtu Americas LLC to act as our sales agent or principal ("Agent"), with respect to the issuance and sale of up to $10.0 million of our of common stock, par value $0.001 per share (the "Shares"), from time to time in an at-the-market public offering.

Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Virtu Americas LLC may sell the common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act"). We may sell the common stock in amounts and at times to be determined by us from time to time subject to the terms and conditions of the Sales Agreement, but it has no obligation to sell any of the common stock under the Sales Agreement. We or Virtu Americas LLC may suspend or terminate the offering of common stock upon notice to the other party and subject to other conditions. Virtu Americas LLC will act as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of Nasdaq.

We paid Agent a commission of up to 2.5% of the gross proceeds from the sale of the common stock pursuant to the Sales Agreement.

The offering of common stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms.

The common stock was sold and issued pursuant our shelf registration statement on Form S-3 (File No. 333-251859), which was previously declared effective by the Securities and Exchange Commission, and a related prospectus.

From May 18, 2022 through November 29, 2022, we sold 3,084,791 shares of its common stock through the Sales Agreement for net proceeds of $2,069,582, after transactional costs of $121,926.

On November 30, 2022, we delivered written notice to the Agent to terminate the Sales Agreement, effective December 1, 2022 pursuant to Section 13(b) of the Sales Agreement. We were not subject to any termination penalties related to the termination of the Sales Agreement.

Twelve Months Ended December 31, 2022, Compared to Twelve Months Ended December 31, 2021

As of December 31, 2022, we had a working capital deficit of $(2,133), comprised of cash of $357, accounts receivable of $9, short term inventory of $336, net investments in leases of $101 and prepaid expenses of $325, which was offset by $2,852 of accounts payable and accrued expenses, accrued dividends on preferred stock issuances of $91, short term deferred revenue of $5 and short-term lease liabilities of $313. For the twelve months ended December 31, 2022, cash provided by financing activities totaled $10,571, comprised of proceeds from the sale of our common stock of $8,283, proceeds from At-the-market sale of our common stock of $2,070 and proceeds from the exercise of warrants of $218. In the comparable period in 2021, $9,004 was raised through the sale of our common stock, proceeds from At-the-market sale of our common stock of $1,300 and proceeds of $28 from the exercise of options. At December 31, 2022, we had cash of $357 compared to $11,659 at December 31, 2021. Our cash is held in bank deposit accounts. At December 31, 2022 and 2021, we had no convertible debentures outstanding.

Cash used in operations for the twelve months ended December 31, 2022, and 2021 was $21,705 and $26,399, respectively, which represent cash outlays for research and development and general and administrative expenses in such periods. The decrease in cash outlays principally resulted from reduced general and administrative expenses from 2021 to 2022.

Cash used in investing activities for the twelve months ended December 31, 2022, was $168, compared to $542 for the twelve months ended December 31, 2021. During the twelve months ended December 31, 2022, we purchased office furniture, manufacturing and testing equipment, computer equipment and leasehold improvements. For the twelve months ended December 31, 2021, we incurred $542 on purchases of office furniture, manufacturing equipment, computer equipment and leasehold improvements.

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, 2022, the aggregate stated value of our Series C Preferred Stock was $105,000. 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.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses* (Topic 326)*: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. ASU 2016-13 was effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption was permitted, including adoption in any interim period.

In February 2020, the FASB issued ASU 2020-02, *Financial Instruments-Credit Losses* (Topic 326) *and Leases* (Topic 842) - *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases* (Topic 842), which amended the effective date of the original pronouncement for smaller reporting companies. ASC 2016-13 and its amendments will be effective for annual and interim periods beginning after December 15, 2022 for smaller reporting companies. The Company does not expect to have a material impact on the Company's financial position, results of operations or cash flows upon adoption of this new standard.

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

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 Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of BioSig Technologies, Inc. (the "Company") as of December 31, 2022, the related consolidated statements of operations, changes in equity and cash flows for the year ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. 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 also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

We have served as the Company's auditor since 2020 (such date takes into account the acquisition of certain assets of Friedman LLP by Marcum LLP effective September 1, 2022).

Marlton, New Jersey
March 31, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of BioSig Technologies, Inc. and subsidiaries (the "Company") as of December 31, 2021, the related consolidated statements of operations, changes in equity, and cash flows for the year ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the year ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. 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 also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

/s/ Friedman LLP

We served as the Company's auditor from 2020 to 2022.

Marlton, New Jersey

March 31, 2022

BIOSIG TECHNOLOGIES, INC.
CONSOLIDATED BALANCE SHEETS
(In Thousands, Except Par Value and Share Amounts)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash	$ 357	$ 11,659
Accounts receivable	9	-
Inventory, short term	336	1,881
Net investment in leases, short term	101	-
Prepaid expenses and vendor deposits	325	354
Total current assets	1,128	13,894
Property and equipment, net	665	652
Right-to-use assets, net	705	604
Other assets:		
Inventory, long term	1,141	-
Net investment in leases, long term	120	-
Patents, net	307	326
Other assets	44	43
Total assets	$ 4,110	$ 15,519
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued expenses, including $120 and $86 to related parties as of December 31, 2022 and 2021, respectively	$ 2,852	$ 2,179
Deferred revenue, short term	5	32
Dividends payable	91	82
Lease liability, short term	313	283
Total current liabilities	3,261	2,576
Deferred revenue, long term	-	5
Lease liability, long term	452	373
Total long-term liabilities	452	378
Total liabilities	3,713	2,954
Commitments and contingencies (Note 12)		
Series C 9% Convertible Preferred Stock, $0.001 par value, $1,000 stated value, authorized 4,200 shares, 105 shares issued and outstanding; liquidation preference of $105 as of December 31, 2022 and 2021	105	105
Equity:		
Preferred stock, $0.001 par value, authorized 1,000,000 shares, designated 200 shares of Series A, 600 shares of Series B, 4,200 shares of Series C, 1,400 shares of Series D, 1,000 shares of Series E, 200,000 shares of Series F Preferred Stock, none issued	-	-
Common stock, $0.001 par value, authorized 200,000,000 shares, 54,610,638 and 35,567,180 issued and outstanding as of December 31, 2022 and 2021, respectively	55	36
Additional paid in capital	216,232	201,127
Accumulated deficit	(215,974)	(188,922)
Total stockholders' equity attributable to BioSig Technologies, Inc.	313	12,241
Non-controlling interest	(21)	219
Total equity	292	12,460
Total liabilities and equity	$ 4,110	$ 15,519

The accompanying notes are an integral part of these Consolidated Financial Statements

BIOSIG TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Par Value and Share Amounts)

	Year ended December 31, 2022	2021
Revenue:		
Product sales	$ 254	$ 414
Service	32	27
Total revenue	286	441
Cost of goods sold	57	199
Gross profit	229	242
Operating expenses:		
Research and development	5,821	5,602
General and administrative	21,380	27,853
Depreciation and amortization	293	198
Total operating expenses	27,494	33,653
Loss from operations	(27,265)	(33,411)
Other income (expense):		
Interest income, net	3	2
Gain on settlement of debt	-	553
Loss before income taxes	(27,262)	(32,856)
Income taxes (benefit)	-	-
Net loss	(27,262)	(32,856)
Non-controlling interest	210	939
Net loss attributable to BioSig Technologies, Inc.	(27,052)	(31,917)
Preferred stock dividend	(9)	(9)
Preferred stock deemed dividend	(210)	-
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ (27,271)	$ (31,926)
Net loss per common share, basic and diluted	$ (0.64)	$ (0.95)
Weighted average number of common shares outstanding, basic and diluted	42,632,595	33,511,941

The accompanying notes are an integral part of these Consolidated Financial Statements

BIOSIG TECHNOLOGIES, INC.
CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
YEARS ENDED DECEMBER 31, 2022 AND 2021
(In Thousands, Except Par Value and Share Amounts)

	Common stock		Additional Paid in	Accumulated	Non-controlling	
	Shares	Amount	Capital	Deficit	Interest	Total
Balance, December 31, 2020	30,764,792	$ 31	$ 181,344	$ (157,005)	$ 802	$ 25,172
Common stock issued for services	1,124,341	1	3,974	-	-	3,975
Common stock issued upon exercise of options at $2.96 per share	9,375	*	28	-	-	28
Sale of common stock, net transactional costs of $995	2,500,000	3	9,001	-	-	9,004
Sale of common stock under At-the-market offering, net of transaction expenses of $40	251,720	*	1,300	-	-	1,300
Change in fair value of modified options	-	-	313	-	8	321
Stock based compensation	916,952	1	5,176	-	348	5,525
Preferred stock dividend	-	-	(9)	-	-	(9)
Net loss	-	-	-	(31,917)	(939)	(32,856)
Balance, December 31, 2021	35,567,180	$ 36	$ 201,127	$ (188,922)	$ 219	$ 12,460
Common stock issued for services	1,930,000	2	2,107	-	-	2,109
Sale of common stock and warrants, net transactional costs of $528	12,657,864	13	8,270	-	-	8,283
Sale of common stock under At-the-market offering, net of transaction expenses of $96	3,084,791	3	2,067	-	-	2,070
Common stock issued upon exercise of warrants at $0.25 per share	873,000	1	217	-	-	218
Common stock issued in settlement of accounts payable	238,638	*	105	-	-	105
Change in fair value of modified options	-	-	15	-	-	15
Issuance of subsidiary stock in settlement of debt to parent	-	-	(292)		292	-
Stock based compensation	259,165	*	2,625	-	(322)	2,303
Accretion of deemed preferred stock dividend	-	-	210	-	-	210
Deemed preferred stock dividend	-	-	(210)	-	-	(210)
Preferred stock dividend	-	-	(9)	-	-	(9)
Net loss	-	-	-	(27,052)	(210)	(27,262)
Balance, December 31, 2022	54,610,638	$ 55	$ 216,232	$ (215,974)	$ (21)	$ 292

**

*- less than $1

BIOSIG TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands, Except Par Value and Share Amounts)

	Year ended December 31, 2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (27,262)	$ (32,856)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	293	198
Non-cash lease expense	373	441
Equity based compensation	4,412	9,500
Gain on settlement of debt	-	(553)
Change in fair value of modified options	15	321
Changes in operating assets and liabilities:		
Accounts receivable	(9)	-
Lease receivables	(220)	-
Inventory	284	(1,114)
Prepaid expenses and other	30	(50)
Deferred revenue	(32)	38
Deposits	-	60
Accounts payable and accrued expenses	776	(1,988)
Operating lease liabilities	(365)	(396)
Net cash used in operating activities	(21,705)	(26,399)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(168)	(542)
Net cash used in investing activity	(168)	(542)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock, net of issuance costs	8,283	9,004
Proceeds from sale of common stock under a At-the-market offering, net of issuance costs	2,070	1,300
Proceeds from exercise of warrants	218	-
Proceeds from exercise of options	-	28
Net cash provided by financing activities	10,571	10,332
Net decease in cash and cash equivalents	(11,302)	(16,609)
Cash, beginning of the period	11,659	28,268
Cash, end of the period	$ 357	$ 11,659
Supplemental disclosures of cash flow information:		
Cash paid during the period for interest	$ -	$ -
Cash paid during the period for income taxes	$ -	$ -
Noncash investing and financing activities:		
Common stock issued in settlement of debt	$ 105	$ -
Dividend payable on preferred stock charged to additional paid in capital	$ 9	$ 9
Series C convertible preferred stock deemed dividend	$ 210	$ -
Record right-to-use assets and related lease liability	$ 502	$ 800

The accompanying notes are an integral part of these Consolidated Financial Statements

NOTE 1 – NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business and organization

BioSig Technologies, Inc. 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 is principally devoted to improving the standard care in electrophysiology with our PURE EP System's enhanced signal acquisition, digital signal processing, and analysis during ablation of cardiac arrhythmias. The Company has generated minimal revenue to date and consequently its operations are subject to all risks inherent in business enterprises in early commercialization stage.

On November 7, 2018, the Company formed a subsidiary under the laws of the State of Delaware originally under the name of NeuroClear Technologies, Inc. which was renamed to ViralClear Pharmaceuticals, Inc. ("ViralClear") in March 2020. The subsidiary was established to pursue additional applications of the PURE EP™ signal processing technology outside of cardiac electrophysiology, and subsequently in 2020, was repurposed to develop merimepodib, a broad-spectrum anti-viral agent that showed potential for the treatment of COVID-19. Since late 2020, ViralClear has been realigned with its original objective of pursuing additional applications of the PURE EP™ signal processing technology outside of cardiac electrophysiology.

In 2019 and 2020, ViralClear sold an aggregate of 1,965,240 shares of its common stock to investors for net proceeds of $15.6 million and issued an aggregate of 894,869 shares of its common stock in connection with acquiring assets and with know-how agreements. As of December 31, 2022, the Company had a majority interest in ViralClear of 69.08%.

On July 2, 2020, the Company formed an additional subsidiary, NeuroClear Technologies, Inc., a Delaware corporation.

COVID-19

On March 11, 2020, the World Health Organization declared a pandemic related to the rapidly spreading coronavirus (COVID-19) outbreak, which has led to a global health emergency. The full public-health impact of the ongoing pandemic is currently indeterminable and rapidly evolving, and the related health crisis has adversely affected and may continue to adversely affect the global economy, resulting in delaying to our commercialization objectives of the PURE EP Systems into the end of 2022 and 2023.

Inflation Reduction Act of 2022

On August 16, 2022, the U.S. government enacted the Inflation Reduction Act of 2022 that includes, among other provisions, changes to the U.S. corporate income tax system, including a fifteen percent minimum tax based on "adjusted financial statement income," which is effective for tax years beginning after December 31, 2022, and a one percent excise tax on net repurchases of stock after December 31, 2022. The Company is continuing to evaluate the Inflation Reduction Act and its requirements, as well as the application to our business, but at this time does not expect the Inflation Reduction Act to have a material impact on our financial results.

NOTE 2 – GOING CONCERN AND MANAGEMENT'S LIQUIDITY PLANS

As of December 31, 2022, the Company had cash of $0.4 million and working capital deficit of $2.1 million. During the year ended December 31, 2022, the Company used net cash in operating activities of $21.7 million. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company's primary source of operating funds since inception has been cash proceeds from sale 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's plans include the continued commercialization of the PURE EP System and other applications of our core technology and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. The Company's strategic shift from a focus on technology development to commercialization will allow the Company to significantly reduce operating expenses.

The Company will require additional financing to fund future operations. Further, although the Company began commercial operations, there is no assurance that the Company will be able to generate sufficient cash flow to fund operations. In addition, there can be no assurance that the Company's continuing research and development will be successfully completed or that any additional products 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 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Principals of consolidation

The accompanying consolidated financial statements include the accounts of BioSig Technologies, Inc. and its majority owned subsidiary, ViralClear Pharmaceuticals, Inc., and wholly owned subsidiary, NeuroClear Technologies, Inc. herein collectively referred to as the "Company" or "BioSig". All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of these 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, stock-based compensation and the valuation allowance related to deferred tax assets. Actual results may differ from these estimates.

Revenue Recognition

The Company derives its revenue primarily from the sale of its medical device, the PURE EP™ System, and well as related support and maintenance services and software upgrades in connection with the system.

The Company recognizes revenue in accordance with Accounting Standards Codification (ASC) 842, *Leases* ("ASC 842") for lease components and ASC 606, *Revenue from Contracts with Customers* ("ASC 606") for non-lease components. For medical device sales, the Company recognize revenue under ASC 606.

The core principle of ASC 606 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

Under ASC 606, the Company determines revenue recognition through the following five steps:

- Identify the contract with the customer;
- Identify the performance obligations in the contract;
- Determine the transaction price;
- Allocate the transaction price to the performance obligation in the contract; and
- Recognize revenue when, or as, the performance obligations are satisfied.

Performance obligations are the units of accounting for revenue recognition and generally represent the distinct goods or services that are promised to the customer. If the Company determines that it has not satisfied a performance obligation, it will defer recognition of the revenue until the performance obligation is deemed to be satisfied. Once the PURE EP system is delivered, installed, and accepted by the customer, our performance obligation is recognized. Support, maintenance, and software upgrades are performance obligations over a defined period and are recognized ratably over the contractual service period. Customers typically purchase these services with the initial sale of the PURE EP System and do not have the right to terminate their contracts unless we fail to perform material obligations.

The Company may execute more than one contract with a single customer. If so, it is evaluated whether the agreements were negotiated as a package with a single objective, whether the amount of consideration to be paid in one agreement depends on the price and/or performance of another agreement, or whether the goods or services promised in the agreements represent a single performance obligation. The conclusions reached can impact the allocation of the transaction price to each performance obligation and the timing of revenue recognition related to those arrangements.

The Company records accounts receivable for amounts invoiced to customers for which the Company has an unconditional right to consideration as provided under the contractual arrangement. Unbilled receivables, if any, include amounts related to the Company's contractual right to consideration for completed performance obligations not yet invoiced. Deferred revenue includes payments received in advance of performance under the contract. Our unbilled receivables and deferred revenue are reported on an individual contract basis at the end of each reporting period. Unbilled receivables are classified as current or noncurrent based on the timing of when we expect to bill the customer. Deferred revenue is classified as current or noncurrent based on the timing of when we expect to recognize revenue.

The Company's unconditional right to consideration for goods and services transferred to the customer is included in accounts receivable, net (if any) in the Company's consolidated balance sheet.

In 2022, the Company entered two leases for our PURE EP system at a rate of $4,333 per month each. The term of the leases is for 30 months with an option provided to extend for an additional one year. The leases also have an option to purchase at the end of the lease at the fair market value. The Company accounts for the leases in accordance with ASC 842 and ASC 606.

The Company determined the leases meet the criteria of a sales-type lease whereby the present value of the future expected revenue (less the present value of the estimated unguaranteed residual value), cost of sales and profit and loss are recognized at the lease inception. Non-lease components are recognized under ASC 606. The discount rate utilized was the contract explicit rate of 2% per annum. (See Note 6 – Lease Receivables).

A reconciliation of contract liabilities with customers for the years ended December 31, 2022 and 2021, are presented below:

Year ended December 31,2022:

	Balance at December 31, 2021 (000's)	Consideration Received (000's)	Recognized in Revenue (000's)	Balance at December 31, 2022 (000's)
Product revenue	$ -	$ 254	$ (254)	$ -
Service revenue	37	-	(32)	5
Total	$ 37	$ 254	$ (286)	$ 5

Year ended December 31, 2021:

	Balance at December 31, 2020 (000's)	Consideration Received (000's)	Recognized in Revenue (000's)	Balance at December 31, 2021 (000's)
Product revenue	$ -	$ 414	$ (414)	$ -
Service revenue	-	64	(27)	37
Total	$ -	$ 478	$ (441)	$ 37

The table below summarizes our deferred revenue as of December 31, 2022 and 2021:

	December 31, 2022 (000's)	December 31, 2021 (000's)
Deferred revenue-current	$ 5	$ 32
Deferred revenue-noncurrent	-	5
Total deferred revenue	$ 5	$ 37

The Company had three customers which accounts for approximately 44.4%, 44.4% and 11.2% of our revenue in the year ended December 31, 2022 and two customers which accounted for approximately 68% and 32% of their revenue in the year ended December 31, 2021.

At December 31, 2022, the Company had two customers representing 52.2% and 47.8% of the outstanding accounts receivable. No outstanding accounts receivable at December 31, 2021.

The Company utilized one contract manufacturer for the manufacture and supply of the PURE EP system for the year ended December 31, 2022 and 2021.

Cost of Revenue

Cost of revenue consists primarily of the delivered cost of our medical device(s) sold or the leased under a sales-type lease.

Allowance for Doubtful Accounts

The Company adjusts accounts receivable down to net realizable value with its allowance methodology. In determining the allowance for doubtful accounts for estimated losses, aged receivables are analyzed periodically by management. Each identified receivable is reviewed based upon historical collection experience, financial condition of the customer and the status of any open or unresolved issues with the customer preventing the payment thereof. Corrective action, if necessary, is taken by the Company to resolve open issues related to unpaid receivables. The allowance for doubtful accounts was $0 at December 31, 2022 and 2021. The Company believes that its reserve is adequate, however results may differ in future periods. For the years ended December 31, 2022 and 2021, bad debt expense totaled $0.

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, 2022 and 2021, deposits in excess of FDIC limits were $0.05 million and $11.2 million, respectively.

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, 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 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 ASC 825-10, which permits entities to choose to measure many financial instruments and certain other items at fair value.

Inventory

The inventory is comprised of finished goods available for sale and are stated at the lower of cost or net realizable value using specific identification method for serial numbered inventory and first-in, first-out method for all other inventory for valuation. The inventory December 31, 2022 and 2021 was comprised of the following:

	December 31, 2022 (000's)	December 31, 2021 (000's)
Finished goods-total	$ 1,477	$ 1,881
Finished goods-short term	336	1,881
Finished goods-long term	$ 1,141	$ -

Prepaid Expenses and Vendor Deposits

Prepaid expenses and vendor deposits are comprised of prepaid insurance, operating expenses and other prepayments.

Leases (lessee)

The Company determines if a contractual arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, current operating lease liabilities, and noncurrent operating lease liabilities on the Company's consolidated balance sheet. The Company evaluates and classifies leases as operating or finance leases for financial reporting purposes. The classification evaluation begins at the commencement date and the lease term used in the evaluation includes the non-cancellable period for which the Company has the right to use the underlying asset, together with renewal option periods when the exercise of the renewal option is reasonably certain and failure to exercise such option which result in an economic penalty. All the Company's real estate leases are classified as operating leases. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the commencement date of the lease based on the present value of lease payments over the lease term.

The lease payments included in the present value are fixed lease payments. As most of the Company's leases do not provide an implicit rate, the Company estimates its collateralized incremental borrowing rate, based on information available at the commencement date, in determining the present value of lease payments. The Company applies the portfolio approach in applying discount rates to its classes of leases. The operating lease ROU assets include any payments made before the commencement date. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company does not currently have subleases. The Company does not currently have residual value guarantees or restrictive covenants in its leases.

Leases (lessor)

The Company classifies contractual lease arrangements entered as a lessor as a sales-type, direct financing or operating lease as described in ASC 842-Leases. For sales-type leases, the Company derecognizes the leased asset and recognizes the lease investment on the balance sheet.

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.

Other Assets:

Other assets are comprised of the following:

	December 31, 2022 (000's)	December 31, 2021 (000's)
Security deposits	$ 43	$ 42
Trademarks	1	1
Total other assets	$ 44	$ 43

Impairment of Long-lived Assets

The Company recognizes an impairment of long-lived assets used in operations, other than goodwill, when events or circumstances indicate that the asset might be impaired and the estimated undiscounted cash flows to be generated by those assets over their remaining lives are less than the carrying amount of those items. The net carrying value of assets not recoverable is reduced to fair value, which is typically calculated using the discounted cash flow method. The Company did not recognize and record any impairments of long-lived assets used in operations during the year ended December 31, 2022 and 2021.

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 $5.8 million and $5.6 million for the years ended December 31, 2022 and 2021, respectively.

Net Income (loss) Per Common Share

The Company computes earnings (loss) per share under Accounting Standards Codification subtopic 260-10, Earnings Per Share ("ASC 260-10"). Net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. 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, 2022 and 2021 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:

	December 31, 2022	December 31, 2021
Series C convertible preferred stock	655,619	83,468
Options to purchase common stock	4,555,484	4,568,484
Warrants to purchase common stock	4,217,111	818,910
Restricted stock units to acquire common stock	239,584	141,250
Totals	9,667,798	5,612,112

Stock Based Compensation

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

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.

Patents, Net

The Company capitalizes certain initial asset costs in connection with patent applications including registration, documentation and other professional fees associated with the application. Patent costs incurred prior to the Company's U.S. Food and Drug Administration ("FDA") 510(k) application on March 28, 2018 were charged to research and development expense as incurred. Commencing upon first in-man trials on February 18 and 19, 2019, capitalized costs are amortized to expense using the straight-line method over the lesser of the legal patent term or the estimated life of the product of 20 years. During the year ended December 31, 2022 and 2021, the Company recorded amortization of $19,006 and $19,006 to current period operations, respectively.

Warranty

The Company generally warrants its products to be free from material defects and to conform to material specifications for a period of up to two (2) years. Warranty expense is estimated based primarily on historical experience and is reflected in the consolidated financial statements.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions how to allocate resources and assess performance. The information disclosed herein represents all of the material financial information related to the Company's principal operating segments. (See Note 13 – Segment Reporting).

Non-controlling Interest

The Company's non-controlling interest represents the non-controlling shareholders ownership interests related to the Company's subsidiary, ViralClear. The Company reports its non-controlling interest in subsidiaries as a separate component of equity in the unaudited condensed consolidated balance sheets and reports both net loss attributable to the non-controlling interest and net loss attributable to the Company's common shareholders on the face of the unaudited condensed consolidated statements of operations. The Company's equity interest in ViralClear is 69.08% and the non-controlling stockholders' interest is 30.92% as of December 31, 2022. This is reflected in the consolidated statements of changes in equity.

Warrants

The Company accounts for stock warrants as either equity instruments, derivative liabilities, or liabilities in accordance with ASC 480, Distinguishing Liabilities from Equity (ASC 480), and ASC 815, Derivatives and Hedging (ASC 815), depending on the specific terms of the warrant agreement.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses* (Topic 326)*: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. ASU 2016-13 was effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption was permitted, including adoption in any interim period.

In February 2020, the FASB issued ASU 2020-02, *Financial Instruments-Credit Losses* (Topic 326) *and Leases* (Topic 842) - *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases* (Topic 842), which amended the effective date of the original pronouncement for smaller reporting companies. ASC 2016-13 and its amendments will be effective for annual and interim periods beginning after December 15, 2022 for smaller reporting companies. The Company does not expect to have a material impact on the Company's financial position, results of operations or cash flows upon adoption of this new standard.

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

NOTE 4 – PROPERTY AND EQUIPMENT

Property and equipment as of December 31, 2022 and 2021 is summarized as follows:

	December 31, 2022 (000's)	December 31, 2021 (000's)
Computer equipment	$ 397	$ 383
Furniture and fixtures	109	88
Manufacturing equipment	372	286
Testing/Demo equipment	304	145
Leasehold improvements	84	79
Total	1,266	981
Less accumulated depreciation	(601)	(329)
Property and equipment, net	$ 665	$ 652

Property and equipment are stated at cost and depreciated using the straight-line method over their estimated useful lives of 3 to 5 years. Leasehold improvements are depreciated over the related expected lease term. 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 $273,915 and $179,136 for year ended December 31, 2022 and 2021, respectively.

NOTE 5 – RIGHT TO USE ASSETS AND LEASE LIABILITY

On August 3, 2021, the Company entered into a sublease agreement whereby the Company leased approximately 6,590 square feet of office space at 55 Greens Farms Road, Westport, Connecticut commencing September 1, 2021 and expiring December 31, 2024 (40 months) at the initial rate beginning January 1, 2022 of $14,828 with escalating payments. In connection with the lease, the Company paid a security deposit of $14,232. There is no option to extend the lease past its initial term. At the lease commencement date, the Company estimated the lease liability and right-to-use assets at present value using the Company's incremental borrowing rate of 6.5% and determined their initial present values, at inception, of $492,876. In conjunction with the lease, the Company terminated, without penalty, the sublease at 54 Wilton Road, Westport, CT effective September 4, 2021 and removed the remaining right-to-use assets of $36,756 and related lease liability of $37,625 with a credit to rent expense of $868 relating to the lease termination.

On August 2, 2021, the Company exercised its option to extend its Rochester, Minnesota lease of approximately 1,400 square feet of office space for two additional years expiring on October 31, 2023 with a fixed monthly rate of $3,513, increasing to $3,618 for the second year. On January 18, 2023, effective November 1, 2022, the Company entered into a termination agreement with the lessor for a termination fee of $7,155. In connection with the termination, the Company removed the remaining right-to-use assets of $41,227 and related lease liability of $41,930 with a credit to rent expense of $703 relating to the lease termination.

On April 4, 2022, the Company entered into a Seventh Amendment to the Office Lease at 12424 Wilshire Blvd in Los Angeles dated August 9, 2011 (the "Seventh Amendment") – it is the Fifth Extended Term with respect to Suite 745 and the Expansion Term with respect to Suite 740 which is from July 1, 2022 until July 31, 2025 with a fixed monthly rent beginning at $14,124 and escalating yearly to $15,130 in the final year. The security deposit remains unchanged at $27,404.

The Company determined that the Seventh Amendment was a lease modification and accordingly reassessed the lease classification, remeasured the lease liability and adjusted the right-to-use asset. At April 4, 2022, the Company removed the remaining right-to-use net assets of $42,312 and related lease liability of $40,564 and recorded right-to-use assets and related lease liability of $502,445.

As of December 31, 2022, the Company had outstanding two leases with aggregate payments of $28,951 per month, expiring through July 31, 2025.

Right to use assets is summarized below:

	December 31, 2022 (000's)	December 31, 2021 (000's)
Right to use asset	$ 995	$ 803
Less accumulated amortization	(290)	(199)
Right to use assets, net	$ 705	$ 604

During the year ended December 31, 2022 and 2021, the Company recorded $438,129 and $479,746 as lease expense to current period operations, respectively.

Lease liability is summarized below:

	December 31, 2022 (000's)	December 31, 2021 (000's)
Total lease liability	$ 765	$ 656
Less: short term portion	(313)	(283)
Long term portion	$ 452	$ 373

Maturity analysis under these lease agreements are as follows (000's):

Year ended December 31, 2023	357
Year ended December 31, 2024	370
Year ended December 31, 2025	106
Total	833
Less: Present value discount	(68)
Lease liability	$ 765

Lease expense for the year ended December 31, 2022 and 2021 was comprised of the following:

	December 31, 2022 (000's)	December 31, 2021 (000's)
Operating lease expense	$ 373	$ 441
Short-term lease expense	37	39
Variable lease expense	28	-
Total	$ 438	$ 480

NOTE 6 – LEASE RECEIVABLES

In 2022, the Company entered into two leases for our PURE EP system at a rate of $4,333 per month each. The term of the leases is for 30 months with an option provided to extend for an addition one year. The leases also have an option to purchase at the end of the lease at the fair market value.

The Company determined the leases meet the criteria of a sales-type lease whereby the present value of the future expected revenue (less the present value of the estimated unguaranteed residual value), cost of sales and profit and loss are recognized at the lease inception. The discount rate utilized was the contract explicit rate of 2% per annum. The present value of the unguaranteed residual assets of $4 are included in net investment in leases in the balance sheet.

A reconciliation of lease receivables with customers for the year ended December 31, 2022 is presented below (none for 2021):

Year ended December 31, 2022:

	Balance at December 31, 2021 (000's)	Recognized in Revenue (000's)	Invoiced to Customer (000's)	Interest Earned (000's)	Unguaranteed Residual Assets (000's)	Balance at December 31, 2022 (000's)
Contract asset	$ -	$ 254	$ (39)	$ 2	$ 4	$ 221
Less current portion	-	-	-	-	-	(120)
Noncurrent portion	$ -	$ 254	$ (39)	2	$ 4	$ 101

Future cash flows under this lease agreement are as follows (000's):

Year ended December 31, 2023	$ 104
Year ended December 31, 2024	104
Year ended December 31, 2025	13
Present value of unguaranteed residual assets	4
Total	225
Less: Present value discount	(4)
Net investment in leases	$ 221

NOTE 7 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses at December 31, 2022 and 2021 consist of the following:

	December 31, 2022 (000's)	December 31, 2021 (000's)
Accrued accounting and legal	$ 646	$ 204
Accrued reimbursements and travel	33	56
Accrued consulting	546	264
Accrued research and development expenses	625	367
Accrued product purchases	-	1
Accrued marketing	256	38
Accrued office and other	220	84
Accrued payroll	513	552
Accrued settlement related to arbitration	13	613
	$ 2,852	$ 2,179

NOTE 8 – **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.

As a result of an amendment to the conversion price of our Series C Preferred Stock, the conversion price effective as of December 31, 2020 was $3.75 per share, subject to certain reset provisions. In 2021, the conversion price was reset from $3.75 per share to $2.27 per share and in 2022 reset to $0.25 per share. As such, the Company recorded a noncash deemed dividend of $209,682 during the year ended December 31, 2022.

The 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, 2022 and 2021, the aggregate stated value of our Series C Preferred Stock was $105,000. 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 the Company may not have the ability to meet at the time of such demand. The Company 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. Accordingly, the Company has classified the Series C Preferred Stock as a mezzanine obligation in the accompanying consolidated balance sheets.

Series C Preferred Stock issued and outstanding totaled 105 as of December 31, 2022 and 2021. As of December 31, 2022 and 2021, the Company has accrued $91,117 and $81,667 dividends payable on the Series C Preferred Stock.

NOTE 9 – STOCKHOLDER EQUITY

Shareholder rights plan

On July 14, 2020, our board of directors adopted a stockholder rights plan (the "Rights Plan") and declared a dividend of one preferred share purchase right for each outstanding share of BioSig's common stock to stockholders of record on July 27, 2020, and one right will be issued for each new share of common stock issued thereafter. Each right will initially trade with common stock, and will allow its holder to purchase from BioSig one one-thousandth of a share of Series F Junior Participating Preferred stock, par value $0.001 per share, for an exercise price of $50.00, once the rights become exercisable. In the event that a person or group acquires beneficial ownership of 12% or more of BioSig's then outstanding common stock, subject to certain exceptions, each right would entitle its holder (other than such person or members of such group) to purchase additional shares of BioSig's common stock having a market value of two times the exercise price of the right. In addition, at any time after a person or group acquires 12% or more of BioSig's outstanding common stock (unless such person or group acquires 50% or more), the Board may exchange one share of BioSig's common stock for each outstanding right (other than rights owned by such person or group, which would have become void). The Rights Plan could make it more difficult for a third party to acquire control of BioSig or a large block of our common stock without the approval of our board of directors. The rights expired on July 13, 2021.

Preferred stock

The Company is authorized to issue 1,000,000 shares of $0.001 par value preferred stock. As of December 31, 2022 and 2021, the Company has designated 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, 1,000 shares of Series E Preferred Stock and 200,000 shares of Series F Preferred Stock. As of December 31, 2022, and 2021, there were no outstanding shares of Series A, Series B, Series D, Series E and Series F preferred stock.

Common stock

The Company is authorized to issue 200,000,000 shares of $0.001 par value common stock. As of December 31, 2022 and 2021, the Company had 54,610,638 and 35,567,180 shares issued and outstanding, respectively.

2021:

In January 2021, the Company issued an aggregate of 658,868 shares of its common stock for services at a fair value previously recorded in 2020 of $2,658,224.

On July 2, 2021, the Company entered into securities purchase agreements with investors pursuant to which the Company issued 2,500,000 shares of common stock for aggregate proceeds of $9,004,033, net of $995,966 in expenses.

During the year ended December 31, 2021, the Company issued 1,124,341 shares of common stock for services at a fair value of $3,975,451.

During the year ended December 31, 2021, the Company issued 9,375 shares of common stock in exchange for proceeds of $27,750 from the exercise of options.

During the year ended December 31, 2021, the Company issued an aggregate of 258,084 shares of its common stock for vested restricted stock units.

At-The-Market Sale Agreement (2021)

On August 28, 2020, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC to act as the Company's sales agent and/or principal ("Jefferies" or the "Agent"), with respect to the issuance and sale of up to $45.0 million of the Company's shares of common stock from time to time in an at-the-market offering.

The Company paid Agent a commission equal to 3.0% of the gross proceeds from the sale of the shares pursuant to the Sales Agreement. The Company has also agreed to provide Jefferies with customary indemnification and contribution rights.

The offering of shares pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms.

The common stock was sold and issued pursuant the Company's shelf registration statement on Form S-3, which was previously declared effective by the Securities and Exchange Commission, and a related prospectus.

From January 15, 2021 through February 16, 2021, the Company sold 251,720 shares of its common stock through the Open Market Sales Agreement for net proceeds of $1,300,135, after transactional costs of $40,365.

On March 25, 2021, the Company delivered written notice to Jefferies to terminate the Sales Agreement effective as of April 8, 2021, pursuant to Section 7(b)(i) thereof. The Company was not subject to any termination penalties related to the termination of the Sales Agreement.

2022:

During the year ended December 31, 2022, the Company issued 1,930,000 shares of common stock for services at a fair value of $2,108,500.

During the year ended December 31, 2022, the Company issued an aggregate of 259,165 shares of its common stock for vested restricted stock units.

During the year ended December 31, 2022, the Company issued an aggregate of 238,638 shares of its common stock in settlement of outstanding accounts payable of $105,000.

On November 3, 2022, the Company reduced the exercise price of the March 21, 2022 issued warrants (see below) from an exercise price of $1.40 per share to $0.25 per share from November 4, 2022 through November 10, 2022. The Company issued an aggregate of 873,000 shares of Common Stock for warrants exercised for a total of $218,250.

At December 31, 2022, the Company accrued for 2,370,000 obligated, but unissued shares of common stock for services at a fair value of $1,060,740.

Sale of common stock

On March 21, 2022, the Company entered into a securities purchase agreement with several institutional and accredited investors, pursuant to which the Company sold in a registered direct offering an aggregate of 2,613,130 shares of the Company's common stock, at an offering price of $1.15 per share and warrants to purchase up to 2,613,130 shares of common stock at an exercise price of $1.40 per share, that are exercisable six months after the date of issuance and will expire three and one-half years following the date of issuance, for gross proceeds of approximately $3,005,000, net of expenses of approximately $5,000.

On June 24, 2022, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Laidlaw & Company (UK) Ltd. (the "Underwriter"), which was amended and restated on June 28, 2022 (the "Amended and Restated Underwriting Agreement"), relating to a best-efforts public offering (the "June 2022 Offering") of 4,341,667 shares of the Company's common stock. The public offering price of the common stock was $0.75 per share. After the underwriting discounts, which includes a reduced discount with respect to certain Company-introduced investors, and offering expenses, the Company received net proceeds from the offering of approximately $2,818,000.

Pursuant to the Amended and Restated Underwriting Agreement, the Company issued to the Underwriter, or its designees warrants to purchase up to an aggregate 217,083 shares of common stock, or 5% of the number of common stock sold in the offering.

On November 18, 2022, the Company entered into a Securities Purchase Agreement with certain accredited investors pursuant to which the Company sold to the investors an aggregate of 3,541,469 shares (the "Shares") of the Company's common stock at a purchase price of $0.41 per share, in exchange for aggregate consideration of $1,411,775, net of expenses of $40,225.

On December 21, 2022, the Company entered into a Securities Purchase Agreement with certain institutional and accredited investors pursuant to which the Company sold to the investors an aggregate of 2,161,598 shares of the Company's common stock at a purchase price of $0.51 per share, and warrants to purchase up to 1,080,799 shares of common stock at an exercise price of $0.45 per share, that are exercisable six months after the date of issuance and will expire five and one-half years following the date of issuance, in exchange for aggregate consideration of $1,050,960, net of expenses of $47,132.

ATM Sales Agreement

On May 17, 2022, the Company entered into an ATM Sales Agreement (the "Sales Agreement") with Virtu Americas LLC to act as the Company's sales agent or principal ("Agent"), with respect to the issuance and sale of up to $10.0 million of the Company's shares of common stock, from time to time in an at-the-market public offering.

The Company will pay Agent a commission of up to 2.5% of the gross proceeds from the sale of the common stock pursuant to the Sales Agreement.

From May 18, 2022 through November 29, 2022, the Company sold 3,084,791 shares of its common stock through the Sales Agreement for net proceeds of $2,069,582, after transactional costs of $121,926.

On November 30, 2022, the Company delivered written notice to the Agent to terminate the Sales Agreement, effective December 1, 2022 pursuant to Section 13(b) of the Sales Agreement. The Company is not subject to any termination penalties related to the termination of the Sales Agreement.

NOTE 10 – OPTIONS, RESTRICTED STOCK UNITS AND WARRANTS

BioSig Technologies, Inc.

2012 Equity Incentive Plan

On October 19, 2012, the Board of Directors of BioSig Technologies, Inc. approved the 2012 Equity Incentive Plan (the "Plan") and terminated the Long-Term Incentive Plan (the "2011 Plan"). The Plan (as amended) provides for the issuance of options, stock appreciation rights, restricted stock and restricted stock units to purchase up to 14,474,450 shares of the Company's common stock to officers, directors, employees and consultants of the Company. 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. On October 19, 2022, the 2012 Equity Incentive Plan expired.

2023 Long-Term Incentive Plan

On December 27, 2022, the Board of Directors of BioSig Technologies, Inc. approved the 2023 Long-Term Incentive Plan (the "2023 Plan"). The 2023 Plan provides for the issuance of options, stock appreciation rights, restricted stock and restricted stock units to purchase up to 5,265,945 shares, plus any prior plan awards of the Company's common stock to officers, directors, employees and consultants of the Company. 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. At December 31, 2022, there were 5,265,945 shares available under the 2023 Long-Term Incentive Plan.

Options

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 historical stock prices of the Company. The Company accounts for the expected life of options using the 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.

During the year ended December 31, 2022 and 2021, the Company granted an aggregate of 1,428,000 and 1,818,000 options to officers, directors and key consultants, respectively.

The following table presents information related to stock options at December 31, 2022:

	Options Outstanding			Options Exercisable
	Exercise Price	Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$	Under 1.00	398,000	9.7	200,000
	1.00-1.99	910,000	8.8	97,500
	2.00-2.99	875,375	8.7	641,374
	3.00-3.99	412,466	3.4	397,882
	4.00-4.99	1,165,916	5.1	1,049,853
	5.00-5.99	156,132	6.1	137,792
	6.00-6.99	356,542	4.5	354,868
	7.00-7.99	157,720	5.7	152,720
	Over 8.00	123,333	3.8	117,080
		4,555,484	6.7	3,149,069

A summary of the stock option activity and related information for the Plan for the two years ended December 31, 2022 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2021	3,568,497	$ 5.59	7.0	$ 110,961
Grants	1,818,000	$ 3.69	10.0	-
Exercised	(9,375)	$ 2.96		
Forfeited/expired	(808,638)	$ 6.19		
Outstanding at December 31, 2021	4,568,484	$ 4.57	6.9	$ -
Grants	1,428,000	$ 1.12	10.0	$ -
Forfeited/expired	(1,441,000)	$ 4.54		
Outstanding at December 31, 2022	4,555,484	$ 3.49	6.7	$ 3,000
Exercisable at December 31, 2022	3,149,069	$ 4.83	5.9	$ 3,000

The aggregate intrinsic value in the preceding tables represents the total pretax intrinsic value, based on options with an exercise price less than the stock price of BioSig Technologies, Inc. of $0.42 as of December 31, 2022, which would have been received by the option holders had those option holders exercised their options as of that date.

During the year ended December 31, 2021, the Company granted an aggregate of 1,818,000 options to purchase the Company's common stock in connection with services rendered at exercise prices from $2.44 to $4.97 per share for a term of ten years and with vesting from immediate to three years from the date of issuance.

During the year ended December 31, 2022, the Company granted an aggregate of 1,428,000 options to purchase the Company's common stock in connection with services rendered at exercise prices from $0.40 to $1.72 per share for a term of ten years and with vesting from immediate to three years from the date of issuance.

The following assumptions were used in determining the fair value of options during the years ended December 31, 2022 and 2021:

	2022	2021
Risk-free interest rate	1.17% - 4.06%	0.77% to 1.49%
Dividend yield	0%	0%
Stock price volatility	83.83% to 96.29%	82.50% to 95.98%
Expected life	5 – 10 years	5-10 years
Weighted average grant date fair value	$ 0.80	$ 2.55

On June 28, 2021, in connection with the exit of two members of the Company's board of directors, the Company extended the life of 145,000 previously issued director options from the contractual 90 days from termination of service to the earlier of the initial life or June 28, 2023. The change in estimated fair value of the modified options of $182,514 was charged to current period operations.

The following assumptions were used in determining the change in fair value of the modified options at June 28, 2021:

Risk-free interest rate	0.05% - 0.25%
Dividend yield	0%
Stock price volatility	88.57%
Expected life	0.25 – 2 years

On June 30, 2021, in connection with the resignation of a member of the Company's board of directors, the Company entered into a one-year consulting contract and extended the life of 221,240 previously issued director options from the contractual 90 days from termination of service to the earlier of the initial life or two years after service contract completion. The change in estimated fair value of the modified options of $111,402 was charged to current period operations.

The following assumptions were used in determining the change in fair value of the modified options on June 30, 2021:

Risk-free interest rate	0.06% - 0.46%
Dividend yield	0%
Stock price volatility	88.59%
Expected life	0.59 – 3 years

On March 16, 2022, in connection with the termination of a Company executive, the Company extended the life of 100,000 previously issued options from the contractual 90 days from termination of service to the earlier of the initial life or March 16, 2024. The change in estimated fair value of the modified options of $15,181 was charged to current period operations.

The following assumptions were used in determining the change in fair value of the modified options at March 16, 2022:

Risk-free interest rate	0.44% - 1.95%
Dividend yield	0%
Stock price volatility	83.86%
Expected life	0.25 – 2 years

The fair value of all options vesting during the year ended December 31, 2022 and 2021 of $1,829,233 and $3,357,274, respectively, was charged to current period operations. Unrecognized compensation expense of $1,373,155 at December 31, 2022 which the Company expects to recognize over a weighted average period of 1.00 years.

Warrants

The following table summarizes information with respect to outstanding warrants to purchase common stock of BioSig Technologies, Inc. at December 31, 2022:

Exercise Price	Number Outstanding	Expiration Date
$ 0.4066	250,000	November 2032
$ 0.4100	60,976	May, 2028
$ 0.4455	1,130,012	June 2028
$ 0.9000	217,083	June 2027
$ 1.4000	1,740,130	September 2025
$ 4.8000	250,000	February 2025 to July 2026
$ 6.16	568,910	November 2027
	4,217,111	

On July 7, 2021, BioSig Technologies, Inc. issued warrants to purchase 125,000 shares of its common stock at $4.80 per share, expiring on July 2, 2026, for placement agent services in connection with the sale of the company's common stock.

On March 21, 2022, the Company issued warrants to purchase 2,613,130 shares of its common stock at an exercise price of $1.40 per share, that are exercisable six months after the date of issuance and will expire three and one-half years following the date of issuance in connection with the sale of the Company's common stock.

On June 29, 2022, the Company issued warrants to purchase 217,083 shares of common stock at an exercise price of $0.90 per share and will expire five years following the date of the execution of the Underwriting Agreement in connection with the sale of common stock in the June 2022 Offering.

On November 18, 2022, the Company issued warrants to purchase 250,000 shares of common stock at an exercise price of $0.4066 for services. The warrants expire ten years following the date of issuance The fair value of $90,865, determined using the Black-Scholes Option method was charged to current period operations. The assumptions issued in the fair value determination was volatility: 96.26%, estimated life: 10 years and risk-free rate of 3.82%.

On November 18, 2022, the Company issued warrants to purchase 60,976 shares of common stock at an exercise price of $0.41 per share exercisable six months after the date of issuance and will expire five and one-half years following the date of issuance in connection with the sale of common stock in the November 2022 Offering. This Warrant was issued pursuant to that certain Engagement Agreement, by and between Laidlaw & Company (UK) Ltd. and the Company, dated as of October 11, 2022.

On December 27, 2022, the Company issued warrants to purchase 1,080,799 shares of its common stock at an exercise price of $0.4455 per share, that are exercisable six months after the date of issuance and will expire three and one-half years following the date of issuance in connection with the sale of the Company's common stock.

On December 27, 2022, the Company issued warrants to purchase 49,213 shares of common stock at an exercise price of $0.4455 per share exercisable six months after the date of issuance and will expire five and one-half years following the date of issuance in connection with the sale of common stock in the December 2022 Offering. This Warrant was issued pursuant to that certain Engagement Agreement, by and between Laidlaw & Company (UK) Ltd. and the Company, dated as of October 11, 2022.

A summary of the warrant activity for the two years ended December 31, 2022 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2021	1,446,200	$ 5.44	3.3	$ 1,500
Issued	125,000	$ 4.80	5.0	-
Expired	(752,290)	$ 5.00		
Outstanding at December 31, 2021	818,910	$ 5.74	5.3	$ -
Issued	4,271,201	$ 1.05	4.0	
Exercised	(873,000)	$ 0.25	-	-
Outstanding at December 31, 2022	4,217,111	$ 1.89	4.3	$ -
Vested and expected to vest at December 31, 2022	4,217,111	$ 1.89	4.3	$ 3,960
Exercisable at December 31, 2022	3,026,123	$ 2.46	3.9	$ 3,350

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 $0.42 of December 31, 2022, which would have been received by the warrant holders had those warrants holders exercised their options as of that date.

The fair value of warrants issued for services during the year ended December 31, 2022 and 2021 of $90,865 and $0, respectively, was charged to current period operations. Unrecognized compensation expense of $0 at December 31, 2022.

Restricted Stock Units

The following table summarizes the restricted stock activity for the two years ended December 31, 2022:

Restricted shares issued as of January 1, 2021	218,334
Granted	301,000
Vested and issued	(258,084)
Forfeited	(120,000)
Restricted shares issued as of December 31, 2021	141,250
Granted	387,500
Vested and issued	(259,165)
Forfeited	(30,001)
Vested restricted shares as of December 31, 2022	-
Unvested restricted shares as of December 31, 2022	239,584

In 2021, the Company granted an aggregate of 301,000 restricted stock units for services with vesting ranging from four months to three years.

On June 1, 2021, in connection with the termination of an employee, the Company accelerated vesting of 30,000 previously granted restricted stock units from a three-year period to fully vested. The change in vesting of the modified restricted stock unit resulted in a $109,725 charge to current period operations.

On June 30, 2021, in connection with the resignation of a member of the Company's board of directors, the Company accelerated vesting of 50,000 previously granted restricted stock units from a three-year period to fully vested. The change in vesting of the modified restricted stock unit resulted in a $232,375 charge to current period operations.

In 2022, the Company granted an aggregate of 387,500 restricted stock units for services with 375,000 vesting from four months to one year and 12,500 upon achievement of certain performance conditions.

Stock based compensation expense related to restricted stock grants was $358,931 and $950,281 for the year ended December 31, 2022 and 2021, respectively. As of December 31, 2022, the stock-based compensation relating to restricted stock of $107,655 remains unamortized.

ViralClear Pharmaceuticals, Inc.

2019 Long-Term Incentive Plan

On September 24, 2019, ViralClear's Board of Directors approved the 2019 Long-Term Incentive Plan (as subsequently amended, the "ViralClear Plan"). The ViralClear Plan was approved by BioSig as ViralClear's majority stockholder. The ViralClear Plan provides for the issuance of options, stock appreciation rights, restricted stock and restricted stock units to purchase up to 4,000,000 shares of ViralClear's common stock to officers, directors, employees and consultants of the ViralClear. Under the terms of the ViralClear Plan, ViralClear may issue Incentive Stock Options as defined by the Internal Revenue Code to employees of ViralClear only and nonstatutory options. The Board of Directors of ViralClear or a committee thereof administers the ViralClear Plan and determines the exercise price, vesting and expiration period of the grants under the ViralClear Plan.

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

Additionally, the vesting period of the grants under the ViralClear Plan will be determined by the administrator, in its sole discretion, with an expiration period of not more than ten years. There are 2,650,071 shares remaining available for future issuance of awards under the terms of the ViralClear Plan.

ViralClear Options

A summary of the stock option activity and related information for the ViralClear Plan for the two years ended December 31, 2022 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Outstanding at January 1, 2021	1,527,666	$ 5.00	4.0
Exercised	(550,000)	$ 5.00	
Forfeited/expired	(852,666)	$ 5.00	
Outstanding at December 31, 2021	125,000	$ 5.00	7.2
Forfeited/expired	(100,000)	$ 5.00	
Outstanding at December 31, 2022	25,000	$ 5.00	1.5
Exercisable at December 31, 2022	25,000	$ 5.00	1.5

The following table presents information related to stock options at December 31, 2022:

Options Outstanding			Options Exercisable
Exercise Price	Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$ 5.00	25,000	1.5	25,000

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

On July 1, 2021, ViralClear issued 206,250 shares of its common stock in exchange for the cashless exercise of 550,000 options previously granted on October 16, 2019.

On June 30, 2021, in connection with the resignation of a member of the Company's board of directors, the Company entered into a one-year consulting contract and extended the life of 25,000 previously issued director options from the contractual 90 days from termination of service to the earlier of the initial life or two years after service contract completion. The change in estimated fair value of the modified options of $26,577 was charged to current period operations.

The following assumptions were used in determining the change in fair value of the modified options at June 30, 2021:

Risk-free interest rate	0.07% - 0.46%
Dividend yield	0%
Stock price volatility	88.59%
Expected life	1.25 - 3 years

The fair value of all options vesting during the years ended December 31, 2022 and 2021 of $36,520 and $146,083, respectively, was charged to current period operations. Unrecognized compensation expense of $0 at December 31, 2022.

Warrants (ViralClear)

The following table presents information related to warrants (ViralClear) at December 31, 2022:

Exercise Price	Number Outstanding	Expiration Date
$ 5.00	473,772	November 2027
10.00	6,575	May 2025
	480,347	

Restricted stock units (ViralClear)

The following table summarizes the restricted stock activity for the two years ended December 31, 2022:

Restricted shares outstanding at January 1, 2021:	1,420,716
Issued	(40,000)
Forfeited	(62,037)
Restricted shares outstanding at December 31, 2021:	1,318,679
Forfeited	(240,000)
Total restricted shares outstanding at December 31, 2022:	1,078,679
Comprised of:	
Vested restricted shares as of December 31, 2022	678,679
Unvested restricted shares as of December 31, 2022	400,000
Total	1,078,679

Stock based compensation expense related to restricted stock unit grants of ViralClear was $(1,072,094) and $904,112 for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, the stock-based compensation relating to restricted stock of $58,140 remains unamortized.

NOTE 11 – NON-CONTROLLING INTEREST

On November 7, 2018, the Company formed a subsidiary, now known as ViralClear, to pursue additional applications of the PURE EP™ signal processing technology outside of cardiac electrophysiology, and subsequently in 2020, was repurposed to develop merimepodib, a broad-spectrum anti-viral agent that showed potential for the treatment of COVID-19. Since late 2020, ViralClear has been realigned with its original objective of pursuing additional applications of the PURE EP™ signal processing technology outside of cardiac electrophysiology.

On April 1, 2021, ViralClear issued an aggregate of 40,000 shares of its common stock in exchange for vested restricted stock units.

On July 1, 2021, ViralClear issued an aggregate of 206,250 shares of its common stock in exchange for the cashless exercise of 550,000 previously issued options.

On April 1, 2022, ViralClear issued 196,778 shares of its common stock to the Company in settlement of outstanding payables to BioSig Technologies.

As of December 31, 2022 and 2021, the Company had a majority interest in ViralClear of 69.08% and 68.44%, respectively.

A reconciliation of the ViralClear Pharmaceuticals, Inc. non-controlling loss attributable to the Company:

Net loss attributable to the non-controlling interest for the year ended December 31, 2022 (000's):

Net loss	$	(671)
Average Non-controlling interest percentage of profit/losses		31.24%
Net loss attributable to the non-controlling interest	$	(210)

Net loss attributable to the non-controlling interest for the year ended December 31, 2021 (000's):

Net loss	$	(3,077)
Average Non-controlling interest percentage of profit/losses		30.44%
Net loss attributable to the non-controlling interest	$	(939)

The following table summarizes the changes in non-controlling interest for the two years ended December 31, 2022 (000's):

Balance, January 1, 2021	$	802
Allocation of equity to non-controlling interest due to equity-based compensation issued		348
Allocation of equity to non-controlling interest due change in fair value of modified option		8
Net loss attributable to non-controlling interest		(939)
Balance, December 31, 2021		219
Allocation of equity to non-controlling interest due to subsidiary shares issued in settlement of debt to parent		292
Allocation of equity to non-controlling interest due to equity-based compensation issued		(322)
Net loss attributable to non-controlling interest		(210)
Balance, December 31, 2022	$	(21)

NOTE 12 — COMMITMENTS AND CONTINGENCIES

Operating leases

See Note 5 for operating lease discussion

Licensing agreements

Master Services Agreement

On January 1, 2022, the Company entered into a master services agreement with Access Strategy Partners Incorporated ("ASPI") whereby ASPI will provide commercial executives assigned with specific customer targets and develop sales and marketing plans that are mutually agreed to between ASPI and the Company and assist in their execution. The agreement expires two years from the effective date, with an addition one year extension option.

The Company is obligated to pay ASPI: i) a monthly service fee of $40,000 and ii) 10% commission on all New Account revenue, as defined, on a quarterly basis. At December 31, 2022 and 2021, accounts payable due under the contract was $80 and $0, respectively.

2017 Know-How License Agreement

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

The Company is obligated to pay to Mayo Foundation a 1% or 2% royalty payment on net sales of licensed products, as defined. At December 31, 2022 and 2021, accounts payable due under the contract was $4 and $1, respectively.

Patent and Know-How License Agreement – EP Software Agreement

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

In connection with the EP Software Agreement, the Company agreed to make earned royalty payments to Mayo in connection with the Company's sales of the licensed products to third parties and sublicense income received by the Company and to make milestone payments of up to $625,000 in aggregate. At December 31, 2022 and 2021, accounts payable due under the contract was $0.

Amended and Restated Patent and Know-How License Agreement – Tools Agreement

On November 20, 2019, the Company entered into an amended and restated patent and know-how license agreement (the "Tools Agreement") with Mayo. The Tools Agreement contains terms of license grant substantially identical to the EP Software Agreement, although it is for different patent rights and covers the field of electrophysiology systems. In June 2021, patent rights were issued ("Valid Claim") as defined whereby the Company paid milestone one of $75,000 during the 2021 year.

In connection with the Tools Agreement, the Company agreed to pay Mayo an upfront consideration of $100,000. The Company also agreed to make earned royalty payments to Mayo in connection with the Company's sales of the licensed products to third parties and sublicense income received by the Company and to make milestone payments of up to $550,000 in aggregate. At December 31, 2022 and 2021, accounts payable due under the contract was $0.

ViralClear Patent and Know-How License Agreement

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

In connection with the ViralClear Agreement, ViralClear agreed to make earned royalty payments to Mayo in connection with ViralClear's sales of the licensed products to third parties and sublicense income received by the Company and to make milestone payments of up to $700,000 in aggregate. In June 2021, patent rights were issued ("Valid Claim") as defined whereby the Company paid milestone one of $75,000 during the 2021 year. . At December 31, 2022 and 2021, accounts payable due under the contract was $0.

Trek Therapeutics, PBC

In the event of sublicensing, sale, transfer, assignment or similar transaction, ViralClear agreed to pay Trek 10% of the consideration received.

As part of the acquired assets, ViralClear received an assignment and licensing rights agreement from Trek with a third-party vendor regarding certain formulas and compounds usage. The agreement calls for milestone payments upon marketing authorization (as amended and defined with respect of product in a particular jurisdiction in the territory, the receipt of all approvals from the relevant regulatory authority necessary to market and sell such product in any such jurisdiction, excluding any pricing approval or reimbursement authorization) in any first and second country of $10 million and $5 million, respectively, in addition to 6% royalty payments. . At December 31, 2022 and 2021, accounts payable due under the contract was $0.

Defined Contribution Plan

Effective January 1, 2019, the Company established a qualified defined contribution plan (the "401(k) Plan") pursuant to Section 401(k) of the Code, whereby all eligible employees may participate. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) plan, subject to defined limitations. The Company is required to make contributions to the 401(k) Plan equal to 3 percent of each participant's eligible compensation, subject to limitations under the Code. For the year end December 31, 2022 and 2021, the Company charged operations $247,622 and $252,452, respectively, for contributions under the 401(k) Plan.

Purchase commitments

As of December 31, 2022, the Company had aggregate purchase commitments of approximately $1,882,530 for future services or products, some of which are subject to modification or cancellations.

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.

NOTE 13 – SEGMENT REPORTING

In accordance with ASC 280-10, the Company reports segment information based on the "management" approach. The management approach designates the internal reporting used by management for making decisions and assessing performance as the source of the Company's reportable segments. The Company has three reportable segments: BioSig Technologies, Inc. (parent), NeuroClear Technologies, Inc. and ViralClear Pharmaceuticals, Inc.

Information concerning the operations of the Company's reportable segments is as follows:

	Year Ended December 31, 2022 (000's)	Year Ended December 31, 2021 (000's)
Revenues (from external customers)		
BioSig	$ 286	$ 441
ViralClear	-	-
NeuroClear	-	-
	$ 286	$ 441

	Year Ended December 31, 2022 (000's)	Year Ended December 31, 2021 (000's)
Operating Expenses:		
BioSig	$ 26,819	$ 30,016
ViralClear	672	3,630
NeuroClear	3	7
	$ 27,494	$ 33,653

	Year Ended December 31, 2022 (000's)	Year Ended December 31, 2021 (000's)
Loss from Operations		
BioSig	$ (26,590)	$ (29,774)
ViralClear	(672)	(3,630)
NeuroClear	(3)	(7)
	$ (27,265)	$ (33,411)

	December 31, 2022 (000's)	December 31, 2021 (000's)
Total Assets		
BioSig	$ 4,051	$ 13,595
ViralClear	49	1,924
NeuroClear	10	-
	$ 4,110	$ 15,519

NOTE 14 – RELATED PARTY TRANSACTIONS

Accounts payable and accrued expenses include due to related parties comprised primarily director fees and travel reimbursements. Due to related parties as of December 31, 2022 and 2021 was $120,000 and $86,208, respectively.

During the year ended December 31, 2022 and 2021, the Company's Chief Financial Officer guaranteed issued corporate credit cards for no consideration.

NOTE 15 – INCOME TAXES

At December 31, 2022, the Company has available for federal income tax purposes a net operating loss carry forward of approximately $133,000,000, expiring in the year 2040, 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, 2022, the Company has increased the valuation allowance by $5,645,000 from $31,170,000 to $36,815,000. We have adopted the provisions of ASC 740-10-25, which provides recognition criteria and a related measurement model for uncertain tax positions taken or expected to be taken in income tax returns. ASC 740-10-25 requires that a position taken or expected to be taken in a tax return be recognized in the financial statements when it is more likely than not that the position would be sustained upon examination by tax authorities.

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

The Company is required to file income tax returns in the U.S. Federal various State jurisdictions. The Company is no longer subject to income tax examinations by tax authorities for tax years ending before December 31, 2016.

The effective rate differs from the statutory rate of 21% as of December 31, 2022 and 2021 due to the following:

	December 31, 2022	December 31, 2021
Statutory rate on pre-tax book loss	21.00%	21.00%
Other	(0.3)%	(1.3)%
Valuation allowance	(20.7)%	(19.7)%
	0.00%	0.00%

The Company's deferred taxes as of December 31, 2022 and 2021 consist of the following:

	December 31, 2022	December 31, 2021
Non-Current deferred tax asset:		
Net operating loss carry-forwards	$ 27,948,000	$ 24,308,000
Stock based compensation	7,814,000	6,862,000
Research and development costs	1,053,000	-
Valuation allowance	(36,815,000)	(31,170,000)
Net non-current deferred tax asset	$ -	$ -

NOTE 16 – FAIR VALUE MEASUREMENT

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

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

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

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

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

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

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

As of December 31, 2022, and 2021, the Company did not have any items that would be classified as level 1, 2 or 3 disclosures.

As of December 31, 2022, and 2021, the Company did not have any derivative instruments that were designated as hedges.

There were no derivative and warrant liabilities as of December 31, 2022 and 2021.

NOTE 17 – SUBSEQUENT EVENTS

Equity transactions:

Options:

On February 16, 2023, BioSig granted 250,000 options to purchase shares of its common stock to an officer. The options are exercisable at $1.25 per share for ten years with vesting in one year in equal quarterly installments.

Common stock issued:

From January through March 2023, the Company issued an aggregate of 121,249 shares of its common stock for restricted stock units and 3,625,500 shares of its common stock for services rendered, valued at $2,345,586, of which $1,060,740 was accrued as stock-based compensation at December 31, 2022.

Equity sales:

From January through March 2023, the Company entered into multiple Securities Purchase Agreements with certain institutional and accredited investors, pursuant to which the Company sold to the Investors an aggregate of 8,500,300 shares of common stock at an average purchase price of $0.80 per share, and warrants to purchase up to 4,250,150 shares of common stock at an average exercise price of $0.7884 per share, that will become exercisable six months after the date of issuance and will expire five and one-half years following the date of issuance, in exchange for aggregate consideration of $6,757,672, net of expenses of $471,967.

Pursuant to certain engagement agreements, dated October 11, 2022 and February 24, 2023 the Company had entered into with Laidlaw & Company (UK) Ltd., the Company issued to Laidlaw in connection with the 2023 PIPES, warrants to purchase 400,525 shares of common stock at an average exercise price of $0.7884 per share. The Laidlaw warrants becomes exercisable six months after the date of issuance and will expire five and one-half years following the date of issuance.

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

None.

ITEM 9A – CONTROLS AND PROCEDURES

Management's evaluation of disclosure controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(e) under the Exchange Act. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on management's evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are not designed at a reasonable assurance level and are not effective in providing reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's report on internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as a process designed by, or under the supervision of, a company's principal executive and principal financial officer and effected by the our board of directors, management and other personnel, 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 and includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made in accordance with authorizations of management and directors of the company; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible enhancements to controls and procedures.

Management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022, 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, 2022, because management identified that inadequate identification, recording and reporting of stock based compensation due under consulting or other third-party contracts entered into by the Company, but not yet ratified by the Company's Board of Directors which resulted in deficiencies, which, in aggregate, amounted to a material weakness in the Company's internal control over financial reporting.

The material weaknesses did not result in any identified misstatements to the consolidated financial statements and there were no changes to previously released financial results.

Management's Remediation Plan

In 2023, we have added additional measures including contract language with all future contracts to include a requirement that any stock-based compensation is subject to the Company's Board of Directors approval. We believe the added contract revisions will remediate the underlying deficiencies as identified by us. The remediation efforts will include an ongoing review of the implementation of additional controls to ensure all risks have been addressed.

As a result of the material weaknesses discussed above or of others, we may experience negative impacts on our ability to accurately report our results of operation and financial condition in a timely manner. If we do identify a material weakness in our internal control over financial reporting and are unsuccessful in implementing or following a remediation plan, or fail to update our internal control over financial reporting as our business evolves or to integrate acquired businesses into our controls system, if additional material weaknesses are found in our internal controls in the future, or if our external auditors cannot attest to the effectiveness of our internal control over financial review, if applicable, we may not be able to timely or accurately report our financial condition, results of operations or cash flows or to maintain effective disclosure controls and procedures. If we are unable to report financial information in a timely and accurate manner or to maintain effective disclosure controls and procedures, we could be subject to, among other things, regulatory or enforcement actions by the SEC, an inability for us to be accepted for listing on any national securities exchange in the near future, securities litigation and a general loss of investor confidence, any one of which could adversely affect our business prospects and the market value of our common stock. Further, there are inherent limitations to the effectiveness of any system of controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. We could face additional litigation exposure and a greater likelihood of an SEC enforcement or other regulatory action if further restatements were to occur or other accounting-related problems emerge.

The weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting identified in connection with the evaluation referred to above that occurred during our last completed fiscal quarter that has materially negatively affected, or is reasonably likely to materially affect, our internal control over financial reporting. As discussed above, management has remediation plans that will be implemented in 2023.

ITEM 9B – OTHER INFORMATION

None.

ITEM 9C – DISCLOSURES REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

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.

Name	Age	Position with the Company
Kenneth L. Londoner	55	Chief Executive Officer, Executive Chairman and Director
Steven Buhaly	66	Chief Financial Officer
John Sieckhaus	55	Chief Operating Officer
Michael Graydon "Gray" Fleming, Jr.	46	Chief Commercial Officer
David Weild IV	66	Director
Patrick J. Gallagher	58	Director
Donald E. Foley	71	Director
James J. Barry, PhD	63	Director
Frederick D. Hrkac	57	Director
James L. Klein	58	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.

On, February 6, 2023, Mr. Steve Chaussy resigned as Chief Financial Officer and on April 22, 2022 and April 28, 2022, Mr. Anthony Zook and Samuel Navarro resigned as members of the Company's board of directors, respectively.

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 served as the chief executive officer and president of ViralClear Pharmaceuticals, Inc., a majority-owned subsidiary of the Company ("ViralClear") from November 2018 through April 2020 and again since October 2020; and served as ViralClear's chairman of the board of directors from July 2019 through April 2020 and again since October 2020. Mr. Londoner has been serving as ViralClear's director since November 2018. 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.

Steven Buhaly. Mr. Buhaly has served as our chief financial officer since February 6, 2023. Mr. Buhaly has fifteen years of experience as a chief financial officer, having held this position at other companies including Planar Systems Inc. from 2000 to 2005, Longview Fibre Co. from 2006 to 2007, and most recently Qorvo Inc. from 2007 to 2016. Mr. Buhaly was the Chief Financial Officer at TriQuint Semiconductor, Inc. and continued to serve in that role following a merger with RF Micro Devices, Inc., which was then renamed as Qorvo Inc. Since retiring from Qorvo Inc. in mid-2016, he has worked as a freelance consultant and an angel investor. Mr. Buhaly holds a Bachelor of Science degree in Forest Engineering and a Master of Business Administration from University of Washington.

*John Sieckhau*s. Mr. Sieckhaus has served as our chief operating officer since March 2022. Mr. Sieckhaus brings to the Company 30 years in the healthcare industry, including 21 years at St. Jude Medical and Abbott Laboratories (NYSE: ABT). During his tenure with St. Jude Medical, Mr. Sieckhaus held commercial leadership positions of rising responsibility, including U.S. National Sales Leader, Senior Vice President & General Manager when he led sales and customer relationship management activities in the United States across all cardiovascular product lines. Mr. Sieckhaus's experience in building and leading high-performance teams, in addition to integrating multiple new and novel technologies and introducing them commercially, led to significant revenue growth for St. Jude Medical over his career. Most recently, Mr. Sieckhaus held the position of Vice President – Field Clinical Affairs for Abbott for the United States and CALA, where he created a world-class field clinical and monitoring team to support clinical trials across multiple business units within Abbott's Cardiovascular portfolio. Mr. Sieckhaus holds a Bachelor of Science degree in Biomedical Engineering from Johns Hopkins University.

Michael Graydon "*Gray*" *Fleming, Jr.* Mr. Fleming has served as of chief commercial officer since December 2021. Mr. Fleming brings to the Company over 20 years in the healthcare industry, including 17 years at Abbott Laboratories and St. Jude Medical. During his tenure at Abbott, Mr. Fleming held several commercial leadership positions, including Vice President of Cardiac Sales, when he led sales and customer relationship management activities in some of the most significant strategic areas of focus. Mr. Fleming's experience in delivering high-performing sales management initiatives led to substantial revenue growth with several key accomplishments, including the successful contracting of multiple leading IDN and GPO organizations. These initiatives resulted in some of the largest market share gains in the company's history while also delivery while also delivering substantial overhauls of historically underperforming regions throughout the Central Time Zone. Most recently, Mr. Fleming held the position of Chief Commercial Officer at Carecubes, a company created to provide a temporary and scalable negative pressure isolation technology solution based upon original joint request from the Defense Advanced Research Projects Agency (DARPA) and Centers for Disease Control and Prevention (CDC). Mr. Fleming holds a Bachelor of Business Administration degree with a Major in Marketing from Stephen F. Austin State University in Texas and a certificate in Leadership in Excellence and Development (LEAD) Program from the University of Texas.

David Weild IV. Mr. Weild has served as a director since May 2015. Mr. Weild is founder, chairman and chief executive officer of Weild & Co., Inc., an *Inc. 5000 Company* and 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 Scopus BioPharma and INX, LTD and previously served 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 continues to be involved as chairman emeritus. Mr. Weild brings extensive financial, economic, stock exchange, capital markets, and small company expertise to our Board 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, Organisation for Economic Co-operation and Development and the G-20 on how market structure can be bettered to improve capital formation and economic growth.

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 30 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. Further, he is a managing partner at Laidlaw Venture Partners where his roles include portfolio product, technology and company identification for investment as well as providing strategic and operational direction for companies across the entire portfolio. Since January 2018 Mr. Gallagher has served as chief executive officer of Voltron Therapeutics, Inc., a biopharmaceutical firm focused on developing and optimizing a novel Self Assembling Vaccine technology in a variety of indications, including in oncology and emerging infectious diseases. In September 2017, he was appointed chief executive officer of PD Theranostics, Inc., a predictive diagnostic technology company focused on refining, expanding, and integrating the data various imaging modalities can provide, greatly enhancing the current morphological assessment of tissue samples and subsequent clinical decisions. Additional roles include vice president of business development and investor relations for Kinex Pharmaceuticals (now Athenex), an oncology company, from September 2012 to October 2013; the board of directors of Cingulate Therapeutics, a clinical stage biopharmaceutical company focused on innovative new products for ADHD, since May 2012; and the board of directors of Algorithm Sciences, a company focused on rare cardiovascular diseases, since June 2019. Mr. Gallagher has also served on the board of directors of 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.

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. Prior experiences include executive positions with International Paper Company, Mobil Corporation and General Electric Company. Mr. Foley currently serves on the board of directors of Equitable EQAT and Wilmington Trust Mutual Fund Complexes. 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 served as an advisory board member of M&T Corporation Trust and Investment Committee, Goldman Sachs Asset Management Groups and Northern Trust Company. 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 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.

James J. Barry, Ph.D. Dr. Barry has served as our director since September 2021. Dr. Barry has more than 30 years of experience in the medical device industry as an executive and corporate board director. He is currently the Principal Owner at Convergent Biomedical Group LLC since January 2011, a company providing advisory services to the life sciences industry. Prior to Convergent, Dr. Barry was President and CEO at InspireMD, Inc. (Nasdaq: NSPR) from June 2016 to December 2019 and platform technology company, Arsenal Medical from August 2011 to December 2013. Dr. Barry spent the majority of his career at Boston Scientific (NYSE: BSX) from April 1992 to June 2010 with increasing roles of responsibility culminating as Sr. Vice President of Corporate Technology. While at Boston Scientific, Dr. Barry led the development and launch of the TAXUS drug-eluting coronary stent that achieved annual sales exceeding $3 billion. Dr. Barry is the author of multiple peer-reviewed publications and holds more than 40 U.S. and international patents. He holds a Ph.D. in Biochemistry from the University of Massachusetts-Lowell and a B.A. in Chemistry from St. Anselm College.

Frederick D. Hrkac. Mr. Hrkac has served as our director since April 2022. Mr. Hrkac has more than 30 years of experience in the medical device industry as an executive and corporate board director. He is currently serves on the board of Serres in Helsinki, Finland since September 2018, and Spineart in Geneva, Switzerland as chairman of the board since August 2017. In 2017, he served as senior vice president corporate development and from 2014-2016 served a senior vice president of global commercial operations of Biosensors International. From 2009-2011, Mr. Hrkac served as Europe, Middle East & Africa president of Boston Scientific where he was responsible for close to $2 billion of sales. From 2005-2009, Mr. Hrkac was an executive of Sorin Group CRM, Paris, France. And, from November 1990-April 2005 he lived in 6 different countries working as an executive for Johnson & Johnson including Biosense Webster, a Johnson & Johnson company having laid the groundwork strategically for the most successful J&J division of the last 20 years with sales growing from a few hundred million dollars to several billion dollars. Mr. Hrkac holds an Honors Bachelor of Business Administration from the Wilfrid Laurier University, Waterloo, Ontario Canada and currently resides in Zagreb, Croatia. Mr. Hrkac brings extensive expertise in global marketing and strategic business development, making him a valuable resource for our Board.

James L. Klein. Mr. Klein has served as our director since May 2022. Mr. Klein has more than 30 years of experience in the semi-conductor industry. He recently retired from Qorvo (previously TriQuint) where he was the President of Infrastructure and Defense Products (IDP) from 2015-2021 and prior to that the Vice President and General Manager of IDP from 2011-2015. Qorvo's IDP is leader in the development of radio frequency or RF semi-conductor products. Mr. Klein was also the president of Qorvo Biotechnologies (2020-2021). Qorvo Biotechnologies was focused on bringing innovative RF technology to the medical testing market. Mr. Klein spent the early part of his career at Texas Instruments (1988-1997) and Raytheon (1997-2011) - most of this part of his career was focused on the development and deployment of advanced semi-conductor technologies. Mr. Klein has both a B.S. and M. S. in electrical engineering from Texas A&M University - he is an ongoing member and former chair of the department's External Advisory Council. Mr. Klein brings to the Company skills in organizational leadership, change management, technology development and growth strategies that lead to growth and value, making him a valuable resource for our Board.

Family Relationships

There are no family relationships amongst our directors and executive officers.

Delinquent Section 16(a) Reports

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, 2022, 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, 2022, except that, due to timing of receiving EDGAR codes, Form 3 reports were filed late for, John Sieckhaus (March 21, 2022), Frederick Hrkac (April 28, 2022) and Gray Fleming (April 28, 2022).

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 was established in accordance with section 3(a)(58)(A) of the Exchange Act and is currently comprised of Messrs. Weild, Klein and Gallagher, 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 an audit committee 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. Foley, Hrkac and Weild, each of whom qualifies as an independent director under Section 5605(a)(2) of the rules of the NASDAQ Stock Market. Mr. Hrkac is the chairman of our nominating and corporate governance committee.

Compensation Committee

Our compensation committee is currently comprised of Messrs. Foley, Barry 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. Foley 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.biosig.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 2022 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; and
- *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.

On February 2, 2023, we entered into a General Release and Severance Agreement with Steve Chaussy, former Chief Financial Officer of the Company, pursuant to which Mr. Chaussy's employment with the Company will terminate at such point when his services are no longer required. On February 2, 2023, the Board appointed Mr. Steve Buhaly as the new Chief Financial Officer of the Company, whose employment commenced on February 6, 2023.

Summary Compensation Table

The following table sets forth the names and positions of: (i) each person who served as our principal executive officer during the year ended December 31, 2022; (ii) our most highly compensated executive officers, other than our principal executive officer, who was serving as an executive officer, as determined in accordance with the rules and regulations promulgated by the SEC, as of December 31, 2022, with compensation of $100,000 or more, and (iii) an additional individual for whom disclosure would have been provided pursuant to clause (ii) but for the fact that the individual was not serving as our executive officer at December 31, 2022 (collectively our "Named Executive Officers"):

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($) (1)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Kenneth L. Londoner, Chief Executive Officer, Executive Chairman and Director (20)	2022	865,667 (2)	125,000 (3)	504,000 (4)	-	177,030 (5)	1,671,697
	2021	840,000 (6)	105,000	1,197,000 (7)	119,633 (8)	93,381 (9)	2,355,014
Steven Chaussy, Former Chief Financial Officer (21)	2022	498,333 (10)	85,000 (11)	252,000 (12)	-	6,000 (13)	841,333
	2021	480,000 (14)	125,000	598,500 (15)	-	6,000 (16)	1,209,500
John R Sieckhaus, Chief Operating Officer (22)	2022	219,693	-	70,000 (17)	315,862 (18)	-	605,555
Gray Fleming, Chief Commercial Officer (23)	2022	400,000	-	-	-	-	400,000
	2021	28,974	-	-	597,053 (19)	-	626,027

(1) In accordance with SEC rules, this column reflects the aggregate fair value of the stock awards or option awards, as applicable, granted during the respective fiscal year computed as of their respective grant dates in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for share-based compensation transactions. The assumptions made in the valuation of the share-based payments are contained in Notes 9 and 10 to our financial statements for the fiscal year ended December 31, 2022 in this annual report.
(2) Represents (i) salary of $690,667 from Company and (ii) salary of $175,000 from ViralClear.
(3) Represents bonus of $125,000 from ViralClear.
(4) Represents a common stock award of 400,000 fully vested shares granted on April 5, 2022.
(5) Represents (i) director fees of $60,000 from company; (ii) director fees of $105,030 from ViralClear, (iii) $12,000 auto allowance in lieu for reimbursement of mileage.
(6) Represents (i) salary of $665,000 from Company and (ii) salary of $175,000 from ViralClear.
(7) Represents a common stock award of 300,000 fully vested shares granted on January 5, 2021.

(8) Represents a stock option granted December 28, 2021 for the purchase of 75,000 shares of common stock, vesting immediately at an exercise price of $2.44 and termination date of December 28, 2031.
(9) Represents (i) director fees of $80,000, (ii) $12,000 auto allowance in lieu for reimbursement of mileage, (iii) $1,381 personal part of business travel expenses.
(10) Represents (i) salary of $398,333 from Company and (ii) salary of $100,000 from ViralClear.
(11) Represents bonus of $85,000 from ViralClear
(12) Represents a common stock award of 200,000 fully vested shares granted April 5, 2022.
(13) Represents an auto allowance in lieu of reimbursement for mileage.
(14) Represents (i) salary of $380,000 from Company and (ii) salary of $100,000 from ViralClear.
(15) Represents a common stock award of 150,000 fully vested shares granted on January 5, 2021.
(16) Represents an auto allowance in lieu of reimbursement for mileage.
(17) Represents a common stock award of 50,000 fully vested shares granted March 21, 2022
(18) Represents a stock option granted March 30, 2022 for the purchase of 350,000 shares of common stock, vesting 1/3 on one year anniversary and remainder quarterly over the next two years at an exercise price of $1.30 and termination date of March 30, 2032
(19) Represents a stock option granted December 15, 2021 for the purchase of 350,000 shares of common stock, vesting 1/3 on one year anniversary and remainder quarterly over the next two years at an exercise price of $2.58 and termination date of December 15, 2031
(20) 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.
(21) Mr. Chaussy served as our Chief Financial Officer through the entirety of our last two fiscal years. Mr. Chaussy has served as our Chief Financial Officer since January 1, 2018. On February 6, 2023, Mr. Chaussy retired as Chief Financial Officer.
(22) Mr. Sieckhaus served as of Chief Operating Officer from March 21, 2022, date of hire.
(23) Mr. Fleming served as of Chief Commercial Officer from December 6, 2021, date of hire.

Narrative Disclosure to Summary Compensation Table

Executive Employment Agreements

Messrs. Londoner, Chaussy, Sieckhaus and Fleming are at-will employees, and do not have employment agreements with us. Additionally, we do not have any agreements that would provide for payment to any of Messrs. Londoner, Chaussy, Sieckhaus or Fleming following, or in connection with the resignation, retirement, or other termination of any of them, a change of control of us, or a change in either of their responsibilities following a change of control of us.

On February 2, 2023, we entered into a General Release and Severance Agreement (the "Release Agreement") with Mr. Chaussy, pursuant to which Mr. Chaussy's employment with the Company will terminate at such point when his services are no longer required (the "Separation Date"). For more detailed discussion of the Release Agreement, please see below under "Executive Employment Agreements – Steve Chaussy" in this Form 10-K.

Mr. Londoner and Mr. Chaussy received additional equity awards during 2020 from ViralClear for their roles as executive officers at ViralClear. For more detailed discussion of such awards, please see under the section titled "Certain Relationships and Related Transactions" in this Form 10-K.

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.

Mr. Londoner also serves as the director of ViralClear, and from September 24, 2019 to April 28, 2020 and again since October 30, 2020, Mr. Londoner serves as the chairman of the board of directors and chief executive officer of ViralClear. Mr. Londoner receives $175,000 annually from ViralClear for his services (which was partially paid in 2020). Mr. Londoner has received and may be granted awards under the ViralClear Plan.

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.

Steve Chaussy also serves as the chief financial officer of ViralClear and, commencing on September 24, 2019, receives an annual salary of $100,000 from ViralClear (which was partially paid in 2020). Mr. Chaussy has received and may be granted awards under the ViralClear Plan.

On February 2, 2023, we entered into the Release Agreement with Mr. Chaussy, pursuant to which Mr. Chaussy's employment with the Company will terminate at the Separation Date. Pursuant to the Release Agreement, we agreed, among other things, to: (i) continue to pay Mr. Chaussy's base salary through the Separation Date, less applicable taxes and other withholdings, payable in equal installments in accordance with our normal payroll policies; (ii) continued participation through the Separation Date in our current employee benefit plans in which Mr. Chaussy has elected to participate and in accordance with the terms and conditions of such benefit plans; (iii) to grant Mr. Chaussy 200,000 restricted shares (the "Tranche A Awarded Shares") of our common stock, pursuant to the terms and conditions of the 2023 Long-Term Incentive Plan and our standard Restricted Stock Award Agreement (the "RSA Agreement"); and (iv) upon the successful filing of this Annual Report on Form 10-K with the U.S. Securities and Exchange Commission on or before April 14, 2023, pay a cash bonus of $200,000 to Mr. Chaussy as severance pay over six months, beginning on the Separation Date. Pursuant to the Release Agreement and provided that Mr. Chaussy executes and does not revoke the Supplemental Release Agreement (as defined in the Release Agreement) before the expiration of the consideration period set forth therein, we also agreed to grant Mr. Chaussy an additional 125,000 restricted shares of our common stock (the "Tranche B Awarded Shares", and together with the Tranche A Awarded Shares, the "Awarded Shares"), pursuant to the terms and conditions of the 2023 Long-Term Incentive Plan and the RSA Agreement. The Awarded Shares will be fully vested on the date of grant. In consideration of the foregoing, Mr. Chaussy agreed to a release of claims against the Company including all of its affiliates, parent companies, subsidiary companies, employees, owners, directors, officers, principals, agents, insurers, and attorneys regarding, among other things, claims arising out of (i) his hiring, compensation, benefits, and employment with the Company, and (ii) his separation from employment with the Company. Mr. Chaussy also agreed to a customary covenant not to sue and a nondisclosure and confidentiality covenant. Please see our Current Report on 8-K filed with the SEC on February 7, 2023, as amended on February 7, 2023 for a copy of the full Release Agreement.

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, Messrs. Londoner, Chaussy, Sieckhaus and Fleming are eligible to participate in our health and welfare plans which are comprised of medical, vision, life, and dental insurance benefits and an FSA plan.

Pursuant to the Release Agreement described above, Mr. Chaussy has continued participation through the Separation Date in our current employee benefit plans in which Mr. Chaussy has elected to participate and in accordance with the terms and conditions of such benefit plans.

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, 2022.

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(1) 75,000(1)	- -	$ 4.66 $ 2.44	4/14/2030 12/28/2031	- -	$ - $ -	- -	$ - $ -
Steven Chaussy	12,000(2)	-	$ 5.23	6/11/2023	-	$ -	-	$ -
John Sieckhaus	-	350,000(3)	$ 1.30	3/30/2032	-	$ -	-	$ -
Gray Fleming	116,666(4)	233,334	$ 2.58	12/15/2031	-	$ -	-	$ -

(1) Each of these options vested immediately
(2) Each of these options vested immediately
(3) Each of these options vest 1/3 on first anniversary and remainder quarterly over the next two years
(4) Each of these options vest 1/3 on first anniversary and remainder quarterly over the next two years

For more detailed discussion of such equity awards and our equity compensation plans, please see under the section titled "ITEM 12 – SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS" in this Form 10-K.

Director Compensation

The following table presents the total compensation for each person who served as a non-employee director of our Board during the fiscal year ended December 31, 2022. Other than as set forth in the table and described more fully below, we did not pay any compensation, reimburse any expense of, make any equity awards or non-equity awards to, or pay any other compensation to any of the other members of our Board in such period.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($) (1)	Option Awards ($) (1)	All Other Compensation ($) (1)(2)	Total ($)
Donald E. Foley	$ 40,000	$ 20,000(2)	$ -	$ -	$ 60,000
Patrick J Gallagher	$ 30,000	$ 15,000(3)	$ -	$ -	$ 45,000
David Weild, IV	$ 40,000	$ 20,000(4)	$ -	$ -	$ 60,000
Samuel E. Navarro⸸	$ 15,000	$ -	$ -	$ -	$ 15,000
James J. Barry PhD	$ 30,000	$ 15,000(5)	$ -	$ -	$ 45,000
Anthony Zook^	$ 15,000	$ -	$ -	$ -	$ 15,000
Frederick Hrkac@	$ 15,000	$ 20,000(6)	$ 37,418(7)	$ -	$ 72,418
James Klein *	$ 15,000	$ 15,000(8)	$ 41,870(9)	$ -	$ 71,870
Total:	$ 200,000	$ 105,000	$ 79,288	$ -	$ 384,288

(1) In accordance with SEC rules, this column reflects the aggregate fair value of stock or option awards granted during the fiscal year ended December 31, 2022, computed as of their respective grant dates in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for share-based compensation transactions.
(2) Represents a common stock award of 45,455 fully vested shares granted November 23, 2022. As of December 31, 2022, Mr. Foley had 45,455 outstanding stock awards of shares of common stock.
(3) Represents a common stock award of 34,091 fully vested shares granted November 23, 2022. As of December 31, 2022, Mr. Gallagher had 34,091 outstanding stock awards of shares of common stock.
(4) Represents a common stock award of 45,455 fully vested shares granted November 23, 2022. As of December 31, 2022, Mr. Weild had 45,455 outstanding stock awards of shares of common stock.
(5) Represents a common stock award of 34,091 fully vested shares granted November 23, 2022. As of December 31, 2022, Mr. Barry had 34,091 outstanding stock awards of shares of common stock.
(6) Represents a common stock award of 45,455 fully vested shares granted November 23, 2022. As of December 31, 2022, Mr. Hrkac had 45,455 outstanding stock awards of shares of common stock.
(7) Represents a stock option granted April 22, 2022 for the purchase of 50,000 shares of common stock, 50% vesting immediately and 50% vesting on April 22, 2023 at an exercise price of $0.82 per share and termination date of April 22, 2032.
(8) Represents a common stock award of 34,091 fully vested shares granted November 23, 2022. As of December 31, 2022, Mr. Klein had 34,091 outstanding stock awards of shares of common stock.
(9) Represents a stock option granted May 2, 2022 for the purchase of 50,000 shares of common stock, 50% vesting immediately and 50% vesting on May 2, 2023 at an exercise price of $0.87 per share and termination date of May 2, 2032.

^ Effective April 22, 2022, Mr. Zook resigned from the Board.

⸸ Effective April 28, 2022, Mr. Navarro resigned from the Board.

@ Effective April 28, 2022, Mr. Hrkac was appointed to the Board.

* Effective May 2, 2022, Mr. Klein was appointed to the Board.

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, 2022, 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(1)	4,045,484	$	3.49	-
Equity compensation plans not approved by security holders(2)	25,000	$	1.50	2,650,071
Total	4,070,484	$	3.48	2,650,071

(1) Represents shares available for issuance under the 2012 Plan.
(2) Represents shares available for issuance under the ViralClear Plan.

BioSig Technologies, Inc. 2012 Equity Incentive Plan (expired October 2022)

On October 19, 2012, our board of directors adopted the BioSig Technologies, Inc. 2012 Equity Incentive Plan (the "2012 Plan"), which provided 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. The 2012 Plan was amended at various times to, among other things, increase the number of shares of our Common Stock authorized under the plan. The 2012 Plan expired by its terms on October 17, 2022. As of December 28, 2022, the number of shares issuable upon exercise of outstanding options and underlying restricted stock awards granted under the 2012 Plan was 4,107,984. The material features of the 2012 Plan are described below:

Administration and Eligibility. The 2012 Plan was administered by our Board or the Compensation Committee of the Board (the "Administrator"). Employees (including any employee who was also a director or an officer), consultants, and non-employee directors of the Company who rendered services to the Company were eligible to participate in the 2012 Plan.

Stock Options. The Administrator could grant either incentive stock options ("ISOs") qualifying under Code Section 422, or nonstatutory stock options, provided that only employees of the Company and its subsidiaries (excluding subsidiaries that are not corporations) were eligible to receive ISOs. The Administrator determined the terms of each stock option at the time of grant, including, without limitation, the method of delivery of shares and provisions governing the term, exercise, and forfeiture of each option.

Restricted Stock and Restricted Stock Units. The Administrator was authorized to grant restricted stock and restricted stock units. The Administrator determined the eligible participants to whom, and the time or times at which, grants of restricted stock or restricted stock units were 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 would be subject to forfeiture; the time or times at which the restrictions would terminate; and all other terms and conditions of the grants.

Vesting, Forfeiture, Assignment. The Administrator, in its sole discretion, could determine that an award will be immediately vested in whole or in part, or that all or any portion could 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 imposed conditions upon vesting, then the Administrator may, in its sole discretion, accelerate the date on which all or any portion of the award may be vested.

BioSig Technologies, Inc. 2023 Long-Term Incentive Plan

Purpose. The purpose of the 2023 Plan is to enable us to remain competitive and innovative in our ability to attract and retain the services of key employees, key contractors, and outside directors of the Company and our subsidiaries. The 2023 Plan provides for the granting of incentive stock options, nonqualified stock options, stock appreciation rights ("SARs"), restricted stock, restricted stock units, performance awards, dividend equivalent rights, other awards, performance goals, and tandem awards which may be granted singly or in combination, or in tandem, and that may be paid in cash, shares of our Common Stock, or other consideration, or any combination thereof. The 2023 Plan is expected to provide flexibility to our compensation methods in order to adapt the compensation of our key employees, key contractors, and outside directors to a changing business environment, after giving due consideration to competitive conditions and the impact of applicable tax laws.

Effective Date and Expiration. The 2023 Plan was approved by our Board on December 27, 2022 (the "Effective Date") and approved by our stockholders at a special meeting held on February 7, 2023. The 2023 Plan will terminate on the tenth anniversary of the Effective Date, unless earlier terminated by our Board. No award may be granted under the 2023 Plan after its termination date, but awards made prior to the termination date may extend beyond that date in accordance with their terms.

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 2023 Plan is currently 5,265,945 shares, plus any Prior Plan Awards (as defined below), subject to adjustment in certain circumstances to prevent dilution or enlargement as described below. All of the shares available for issuance as an award under the 2023 Plan may be delivered pursuant to incentive stock options. "Prior Plan Awards" means (i) any awards granted pursuant to the BioSig Technologies, Inc. 2011 Long-Term Incentive Plan or the BioSig Technologies, Inc. 2012 Equity Incentive Plan that are outstanding on the Effective Date and that, on or after the Effective Date, (x) expire or otherwise terminate without having been exercised in full or without Common Stock being issued pursuant to such awards, (y) are forfeited, or (z) are repurchased by us.

Shares to be issued under the 2023 Plan may be made available from authorized but unissued shares of our Common Stock, Common Stock held in our treasury, or shares purchased by us on the open market or otherwise. During the term of the 2023 Plan, we will at all times reserve and keep enough shares available to satisfy the requirements of the 2023 Plan. Shares underlying awards granted under the 2023 Plan that expire or are forfeited, or terminated without being exercised, or awards that are settled for cash, will again be available for the grant of additional awards within the limits provided by in the 2023 Plan. If previously acquired shares of Common Stock are delivered to the Company in full or partial payment of the exercise price for the exercise of a stock option granted under the 2023 Plan, the number of shares of Common Stock available for future awards under the 2023 Plan shall be reduced only by the net number of shares of Common Stock issued upon exercise of the stock option. Awards that may be satisfied either by the issuance of shares of Common Stock or by cash or other consideration shall be counted against the maximum number of shares of Common Stock that may be issued under the 2023 Plan only during the period that the award is outstanding or to the extent the award is ultimately satisfied by the issuance of shares. An award will not reduce the number of shares that may be issued pursuant to the 2023 Plan if the settlement of the award will not require the issuance of shares, such as, for example, SARs that can only be satisfied by the payment of cash. Only shares forfeited back to the us or shares canceled on account of termination, expiration or lapse of an award, shares surrendered in payment of the exercise price of a stock option or shares withheld for payment of applicable employment taxes and/or withholding obligations resulting from the exercise of an option shall again be available for grant as incentive stock options under the 2023 Plan, but shall not increase the maximum number of shares that may be delivered pursuant to incentive stock options.

Administration. Under the terms of the 2023 Plan, the 2023 Plan will be administered by our Board or such committee of the Board as is designated by the Board to administer the 2023 Plan (the "Committee"), which, to the extent necessary to satisfy the requirements of Rule 16b-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), shall consist entirely of two or more "outside directors" as defined in Rule 16b-3 under the Exchange Act. At any time there is no Committee to administer the 2023 Plan, any reference to the Committee is a reference to our Board. The Committee will determine the persons to whom awards are to be made; determine the type, size, and terms of awards; interpret the 2023 Plan; establish and revise rules and regulations relating to the 2023 Plan and any sub-plans (including sub-plans for awards made to participants who do not reside in the United States); establish performance goals applicable to awards and certify the extent of their achievement; and make any other determinations that it believes are necessary for the administration of the 2023 Plan. The Committee may delegate certain of its duties to one or more of our officers as provided in the 2023 Plan.

Eligibility. The 2023 Plan provides for awards to the outside directors, officers, employees, and contractors of the Company and our subsidiaries. As of March 30, 2023, there were 47 employees, 6 directors, and approximately 15 consultants eligible to participate in the 2023 Plan. The Company's current Section 16 executive officers and each member of our Board are among the individuals eligible to receive awards under the 2023 Plan.

Stock Options. Subject to the terms and provisions of the 2023 Plan, options to purchase shares of our Common Stock may be granted to eligible individuals at any time and from time to time as determined by the Committee. Stock options may be granted as incentive stock options, which are intended to qualify for favorable treatment to the recipient under federal tax law, or as nonqualified stock options, which do not qualify for such favorable tax treatment. Subject to the limits provided in the 2023 Plan, the Committee determines the number of stock options granted to each recipient. Each stock option grant will be evidenced by a stock option agreement that specifies the stock option's exercise price, whether the stock options are intended to be incentive stock options or nonqualified stock options, the duration of the stock options, the number of shares to which the stock options pertain, and such additional limitations, terms, and conditions as the Committee may determine.

The Committee determines the exercise price for each stock option granted, except that the exercise price may not be less than 100% of the fair market value of a share of our Common Stock on the date of grant; provided, however, that if an incentive stock option is granted to an employee who owns or is deemed to own more than 10% of the combined voting power of all classes of our Common Stock (or of any parent or subsidiary), the exercise price must be at least 110% of the fair market value of a share of our Common Stock on the date of grant. All stock options granted under the 2023 Plan will expire no later than ten years (or, in the case of an incentive stock option granted to an employee who owns or is deemed to own more than 10% of the combined voting power of all classes of our Common Stock (or of any parent or subsidiary), five years) from the date of grant. Stock options are nontransferable except by will or by the laws of descent and distribution or, in the case of nonqualified stock options, as otherwise expressly permitted by the Committee. The granting of a stock option does not accord the recipient the rights of a stockholder, and such rights accrue only after the exercise of a stock option and the registration of shares of our Common Stock in the recipient's name.

Stock Appreciation Rights. The 2023 Plan authorizes the Committee to grant SARs, either as a separate award or in connection with a stock option. A SAR entitles the holder to receive from us, upon exercise, an amount equal to the excess, if any, of the aggregate fair market value of a specified number of shares of our Common Stock to which such SAR pertains over the aggregate exercise price for the underlying shares. The exercise price of a SAR shall not be less than 100% of the fair market value of a share of our Common Stock on the date of grant.

Each SAR will be evidenced by an award agreement that specifies the exercise price, the number of shares to which the SAR pertains, and such additional limitations, terms, and conditions as the Committee may determine. We may make payment of the amount to which the participant exercising SARs is entitled by delivering shares of our Common Stock, cash, or a combination of stock and cash as set forth in the award agreement relating to the SARs. SARs are not transferable except as expressly permitted by the Committee.

Restricted Stock. The 2023 Plan provides for the award of shares of our Common Stock that are subject to forfeiture and restrictions on transferability as set forth in the 2023 Plan, the applicable award agreement, and as may be otherwise determined by the Committee. Except for these restrictions and any others imposed by the Committee, upon the grant of restricted stock, the recipient will have rights of a stockholder with respect to the restricted stock, including the right to vote the restricted stock and to receive all dividends and other distributions paid or made with respect to the restricted stock on such terms as will be set forth in the applicable award agreement; provided, however, such dividends or distributions may, if provided in the applicable award agreement, be withheld by us for a participant's account until the restrictions lapse with respect to such restricted stock. During the restriction period set by the Committee, the recipient may not sell, transfer, pledge, exchange, or otherwise encumber the restricted stock.

Restricted Stock Units. The 2023 Plan authorizes the Committee to grant restricted stock units. Restricted stock units are not shares of our Common Stock and do not entitle the recipients to the rights of a stockholder, although the award agreement may provide for rights with respect to dividends or dividend equivalents. The recipient may not sell, transfer, pledge, or otherwise encumber restricted stock units granted under the 2023 Plan prior to their vesting. Restricted stock units will be settled in shares of our Common Stock, in an amount based on the fair market value of our Common Stock on the settlement date. If the right to receive dividends on restricted stock units is awarded, then, if provided in the applicable award agreement, such dividends may be withheld by us for a participant's account until the restrictions lapse with respect to such restricted stock units.

Dividend Equivalent Rights. The Committee may grant a dividend equivalent right either as a component of another award or as a separate award. The terms and conditions of the dividend equivalent right will be specified by the grant and, when granted as a component of another award, may have terms and conditions different from such other award. Dividend equivalent rights granted as a separate award also may be paid currently or may be deemed to be reinvested in additional Common Stock. Any such reinvestment will be at the fair market value at the time thereof. Dividend equivalent rights may be settled in cash or Common Stock.

Performance Awards. The Committee may grant performance awards payable at the end of a specified performance period in cash, shares of Common Stock, or other rights based upon, payable in, or otherwise related to our Common Stock. Payment will be contingent upon achieving pre-established performance goals (as described below) by the end of the applicable performance period. The Committee will determine the length of the performance period, the maximum payment value of an award, and the minimum performance goals required before payment will be made, so long as such provisions are not inconsistent with the terms of the 2023 Plan, and to the extent an award is subject to Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), are in compliance with the applicable requirements of Section 409A of the Code and any applicable regulations or authoritative guidance issued thereunder. In certain circumstances, the Committee may, in its discretion, determine that the amount payable with respect to certain performance awards will be reduced from the maximum amount of any potential awards. If the Committee determines, in its sole discretion, that the established performance measures or objectives are no longer suitable because of a change in our business, operations, corporate structure, or for other reasons that the Committee deems satisfactory, the Committee may modify the performance measures or objectives and/or the performance period.

Performance Goals. The 2023 Plan provides that performance goals may be established by the Committee in connection with the grant of any award under the 2023 Plan. Such goals shall be based on the attainment of specified levels of one or more business criteria, which may include, without limitation: cash flow; cost; revenues; sales; ratio of debt to debt plus equity; net borrowing, credit quality or debt ratings; profit before tax; economic profit; earnings before interest and taxes; earnings before interest, taxes, depreciation and amortization; gross margin; earnings per share (whether on a pre-tax, after-tax, operational or other basis); operating earnings; capital expenditures; expenses or expense levels; economic value added; ratio of operating earnings to capital spending or any other operating ratios; free cash flow; net profit; net sales; net asset value per share; the accomplishment of mergers, acquisitions, dispositions, public offerings or similar extraordinary business transactions; sales growth; price of our Common Stock; return on assets, equity or stockholders' equity; market share; inventory levels, inventory turn or shrinkage; total return to stockholders; or any other criteria determined by the Committee, in each case with respect to the Company or any one or more of our subsidiaries, divisions, business units, or business segments, either in absolute terms or relative to the performance of one or more other companies (including an index covering multiple companies).

Other Awards. The Committee may grant other forms of awards, based upon, payable in, or that otherwise relate to, in whole or in part, shares of our Common Stock, if the Committee determines that such other form of award is consistent with the purpose and restrictions of the 2023 Plan. The terms and conditions of such other form of award shall be specified in the grant. Such other awards may be granted for no cash consideration, for such minimum consideration as may be required by applicable law, or for such other consideration as may be specified in the grant.

Vesting of Awards; Forfeiture; Assignment. Except as otherwise provided below, the Committee, 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 2023 Plan.

The Committee may impose on any award, at the time of grant or thereafter, such additional terms and conditions as the Committee determines, including terms requiring forfeiture of awards in the event of a participant's termination of service. The Committee will specify the circumstances under which performance awards may be forfeited in the event of a termination of service by a participant prior to the end of a performance period or settlement of awards. Except as otherwise determined by the Committee, restricted stock will be forfeited upon a participant's termination of service during the applicable restriction period.

Awards granted under the 2023 Plan generally are not assignable or transferable except by will or by the laws of descent and distribution, except that the Committee may, in its discretion and pursuant to the terms of an award agreement, permit transfers of nonqualified stock options or SARs to: (i) the spouse (or former spouse), children, or grandchildren of the participant ("Immediate Family Members"); (ii) a trust or trusts for the exclusive benefit of such Immediate Family Members; (iii) a partnership in which the only partners are (a) such Immediate Family Members and/or (b) entities that are controlled by the participant and/or his or her Immediate Family Members; (iv) an entity exempt from federal income tax pursuant to Section 501(c)(3) of the Code or any successor provision; or (v) a split interest trust or pooled income fund described in Section 2522(c)(2) of the Code or any successor provision, provided that (x) there shall be no consideration for any such transfer, (y) the applicable award agreement pursuant to which such nonqualified stock options or SARs are granted must be approved by the Committee and must expressly provide for such transferability, and (z) subsequent transfers of transferred nonqualified stock options or SARs shall be prohibited except those by will or the laws of descent and distribution.

Change in Control. In connection with a change in control, outstanding awards may be converted into new awards, exchanged or substituted for with new awards, or canceled for no consideration, provided participants were given notice and an opportunity to purchase or exercise such awards, or cancelled and cashed out based on the positive difference between the per share amount to be received in connection with the transaction and the purchase/exercise price per share of the award, if any. The description of a change in control and its effects on awards granted under the 2023 Plan is qualified in its entirety by reference to the relevant terms and provisions of the 2023 Plan, which is attached as Annex A to our Proxy Statement filed with the SEC on December 29, 2022.

Recoupment for Restatements. The Company may recoup all or any portion of any shares of our Common Stock or cash paid to a participant in connection with an award, in the event of a restatement of our financial statements as set forth in our clawback policy as may be in effect from time to time.

Adjustments Upon Changes in Capitalization. In the event that any dividend or other distribution (whether in the form of cash, shares of our Common Stock, other securities, or other property), recapitalization, stock split, reverse stock split, rights offering, reorganization, merger, consolidation, split-up, spin-off, split-off, combination, subdivision, repurchase, or exchange of shares of our Common Stock or other securities, issuance of warrants or other rights to purchase shares of our Common Stock or other securities, or other similar corporate transaction or event affects the fair market value of an award, the Committee shall adjust any or all of the following so that the fair market value of the award immediately after the transaction or event is equal to the fair market value of the award immediately prior to the transaction or event: (i) the number of shares and type of Common Stock (or other securities or property) that thereafter may be made the subject of awards; (ii) the number of shares and type of Common Stock (or other securities or property) subject to outstanding awards; (iii) the exercise price of each outstanding stock option; (iv) the amount, if any, we pay for forfeited shares in accordance with the terms of the 2023 Plan; and (v) the number of or exercise price of shares then subject to outstanding SARs previously granted and unexercised under the 2023 Plan, to the extent that the same proportion of our issued and outstanding shares of Common Stock in each instance shall remain subject to exercise at the same aggregate exercise price; provided, however, that the number of shares of Common Stock (or other securities or property) subject to any award shall always be a whole number. Notwithstanding the foregoing, no such adjustment shall be made or authorized to the extent that such adjustment would cause the 2023 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 2023 Plan. Our Board may, at any time and from time to time, without the consent of participants, alter, amend, revise, suspend, or discontinue the 2023 Plan in whole or in part; provided, however, that (i) no amendment that requires stockholder approval in order for the 2023 Plan and any awards under the 2023 Plan to continue to comply with Sections 421 and 422 of the Code (including any successors to such sections or other applicable law) or any applicable requirements of any securities exchange or inter-dealer quotation system on which our Common Stock is listed or traded, shall be effective unless such amendment is approved by the requisite vote of our stockholders entitled to vote on the approval of the 2023 Plan; and (ii) unless required by law, no action by our Board regarding amendment or discontinuance of the 2023 Plan may adversely affect any rights of any participants or obligations of the Company to any participants with respect to any outstanding awards under the 2023 Plan without the consent of the affected participant.

Repricing of Stock Options or SARs. The Committee may not "reprice" any stock option or SAR without stockholder approval. For purposes of the 2023 Plan, "reprice" means any of the following or any other action that has the same effect: (a) amending a stock option or SAR to reduce its exercise price; (b) canceling a stock option or SAR at a time when its exercise price exceeds the fair market value of a share of our Common Stock in exchange for cash or a stock option, SAR, award of restricted stock, or other equity award; or (c) taking any other action that is treated as a repricing under generally accepted accounting principles, provided that nothing will prevent the Committee from (x) making adjustments to awards upon changes in capitalization, (y) exchanging or cancelling awards upon a merger, consolidation, or recapitalization, or (z) substituting awards for awards granted by other entities, to the extent permitted by the 2023 Plan.

ViralClear Pharmaceuticals, Inc. 2019 Equity Incentive Plan

On September 24, 2019, the board of directors (the "ViralClear Board") of ViralClear approved the ViralClear Plan, subject to stockholder approval, which provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights ("SARs"), restricted stock, and restricted stock units to key employees, key contractors, and outside directors of ViralClear, to be granted from time to time as determined by the ViralClear Board or its designee. An aggregate of 4,000,000 shares of the ViralClear common stock are reserved for issuance under the ViralClear Plan. The material features of the ViralClear Plan are described below.

Purpose. The purpose of the ViralClear Plan is to enable ViralClear to attract and retain the services of key employees, key contractors, and outside directors of ViralClear and its subsidiaries and to provide such persons with a proprietary interest in ViralClear. The ViralClear Plan provides for the granting of incentive stock options, nonqualified stock options, SARs, restricted stock, and restricted stock units, which may be granted singly, in combination, or in tandem; 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; and which will increase the interest of such persons in ViralClear's welfare, furnish an incentive to such persons to continue their services for ViralClear or its subsidiaries, and provide a means through which ViralClear may attract able persons as employees, contractors, and outside directors.

Effective Date and Expiration. The ViralClear Plan became effective on September 24, 2019 and will continue in effect for a term of 10 years, unless earlier terminated by the ViralClear Board.

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 ViralClear Plan is currently 4,000,000 shares, 100% of which may be delivered pursuant to incentive stock options.

Shares to be issued may be made available from authorized but unissued common stock, common stock held by ViralClear in its treasury, or common stock purchased by ViralClear on the open market or otherwise. During the term of the ViralClear Plan, ViralClear will at all times reserve and keep available the number of shares of common stock sufficient to satisfy the requirements of the ViralClear Plan. If an award under the ViralClear Plan is forfeited, expires, or is canceled, in whole or in part, then the number of shares of common stock covered by the award or stock option so forfeited, expired, or canceled may again be awarded pursuant to the provisions of the ViralClear Plan. In the event that previously acquired shares of common stock are delivered to ViralClear in full or partial payment of the exercise price for the exercise of a stock option granted under the ViralClear Plan, the number of shares of common stock available for future awards under the ViralClear Plan shall be reduced only by the net number of shares of common stock issued upon the exercise of the stock option. Awards that may be satisfied either by the issuance of shares of common stock or by cash or other consideration shall be counted against the maximum number of shares of common stock that may be issued under the ViralClear Plan only during the period that the award is outstanding or to the extent the award is ultimately satisfied by the issuance of shares of common stock. Awards will not reduce the number of shares of common stock that may be issued pursuant to the ViralClear Plan if the settlement of the award will not require the issuance of shares of common stock, as, for example, a SAR that can be satisfied only by the payment of cash. Notwithstanding any provisions of the ViralClear Plan to the contrary, only shares forfeited back to ViralClear, shares canceled on account of termination, expiration or lapse of an award, shares surrendered in payment of the exercise price of a stock option or shares withheld for payment of applicable employment taxes and/or withholding obligations resulting from the exercise of an option shall again be available for grant of incentive stock options under the ViralClear Plan, but shall not increase the maximum number of shares of common stock that may be delivered pursuant to awards under the ViralClear Plan as the maximum number of shares of common stock that may be delivered pursuant to incentive stock options.

Administration. The ViralClear Plan may be administered by our ViralClear Board or such committee of the ViralClear Board as is designated by it to administer the ViralClear Plan (the "Committee"). The ViralClear Board or the Committee will determine and designate the persons to whom awards are to be made and set forth the award period, date of grant, terms, provisions, limitations, and performance requirements of awards. The Committee will determine whether an award shall include one type of equity incentive, two or more equity incentives granted in combination, or two or more equity incentives granted in tandem. The ViralClear Board may authorize one or more officers of ViralClear to designate one or more employees as eligible persons to whom nonqualified stock options, incentive stock options, or SARs will be granted under the ViralClear Plan and determine the number of shares of common stock that will be subject to such stock options, incentive stock options, or SARs. The Committee will interpret the ViralClear Plan and award agreements; prescribe, amend, and rescind any rules and regulations, as necessary or appropriate for the administration of the ViralClear Plan; and establish performance goals for an award and certify the action as it deems necessary or advisable in the administration of the ViralClear Plan. The Committee may delegate to officers of ViralClear the authority to perform specified functions under the ViralClear Plan. With respect to restrictions in the ViralClear Plan that are based on the requirements of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), the rules of any exchange or inter-dealer quotation system upon which ViralClear's securities are listed or quoted, or any other applicable law, to the extent that any such restrictions are no longer required by applicable law, the Committee shall have the sole discretion and authority to grant awards that are not subject to such mandated restrictions and/or to waive any such mandated restrictions with respect to outstanding awards. Subject to the provisions of the ViralClear Plan, the ViralClear Board and Committee's decisions, determinations, and interpretations will be final, binding, and conclusive on all ViralClear Plan participants and any other award holders.

Eligibility. Employees (including any employee who is also a director or an officer), contractors, and outside directors of ViralClear whose judgment, initiative, and efforts contributed to, or may be expected to contribute to, the successful performance of ViralClear are eligible to participate in the ViralClear Plan, provided that only employees of a corporation shall be eligible to receive incentive stock options.

Grant of Awards. The grant of an award shall be authorized by the Committee and shall be evidenced by an award agreement setting forth the applicable award being granted; the total number of shares or units to be granted; the price to be paid, if any; the award period; the date of grant; and such other terms, provisions, limitations, and performance objectives, as are approved by the Committee. The Company shall execute an award agreement with a participant after the Committee approves the issuance of an award. Any award granted pursuant to the ViralClear Plan must be granted within 10 years of the date of adoption of the ViralClear Plan by the ViralClear Board. The ViralClear Plan shall be submitted to ViralClear's stockholders for approval; however, the Committee may grant awards under the ViralClear Plan prior to the time of stockholder approval. Any such award granted prior to such stockholder approval shall be made subject to such stockholder approval. The grant of an award to a participant shall not be deemed either to entitle the participant to, or to disqualify the participant from, receipt of any other award under the ViralClear Plan. If the Committee establishes a purchase price for an award, the participant must accept such award within a period of 30 days (or such shorter period as the Committee may specify) after the date of grant by executing the applicable award agreement and paying such purchase price. Any award under the ViralClear Plan that is settled in whole or in part in cash on a deferred basis may provide for interest equivalents to be credited with respect to such cash payment. Interest equivalents may be compounded and shall be paid upon such terms and conditions as may be specified by the grant.

Stock Options. The Committee may grant either incentive stock options, qualifying under Section 422 of the Code, or nonqualified stock options, provided that only employees of ViralClear are eligible to receive incentive stock options. The option price for any share of common stock which may be purchased under a nonqualified stock option for any share of common stock must be equal to or greater than the fair market value of such share on the date of grant. The option price for any share of common stock which may be purchased under an incentive stock option must be at least equal to the fair market value of such share on the date of grant. If an incentive stock option 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 ViralClear (or any parent or subsidiary), the option price shall be at least 110% of the fair market value of our common stock on the date of grant. No dividends may be paid or granted with respect to any stock option. No stock option shall be granted with a term of greater than 10 years from its date of grant; however, if an employee owns or is deemed to own more than 10% of the combined voting power of all classes of stock of ViralClear (or any parent or subsidiary), and an incentive stock option is granted to such employee, the term of such incentive stock option shall be no more than five years from the date of grant. The Committee may not grant incentive stock options under the ViralClear Plan to any employee that would permit the aggregate fair market value (determined on the date of grant) of the common stock with respect to which incentive stock options (under the ViralClear Plan and any other plan of ViralClear and its subsidiaries) are exercisable for the first time by such employee during any calendar year to exceed $100,000. To the extent any stock option granted under the ViralClear Plan that is designated as an incentive stock option exceeds this limit or otherwise fails to qualify as an incentive stock option, such stock option (or any such portion thereof) shall be a nonqualified stock option. In such case, the Committee shall designate which stock will be treated as incentive stock option stock by causing the issuance of a separate stock certificate and identifying such stock as incentive stock option stock on ViralClear's stock transfer records.

If a stock option is exercisable prior to the time it is vested, the common stock obtained on the exercise of the stock option shall be restricted stock that is subject to the applicable provisions of the ViralClear Plan and the award agreement. If the Committee imposes conditions upon exercise, then subsequent to the date of grant, the Committee may, in its sole discretion, accelerate the date on which all or any portion of the stock option may be exercised. No stock option may be exercised for a fractional share of common stock. The granting of a stock option shall impose no obligation upon the participant to exercise that stock option. The Committee will determine the manner in which recipients of stock options may pay the option exercise price, which may include payment by cash or check, bank draft, or money order payable to the order of ViralClear; by delivery of common stock owned by the participant on the exercise date, valued at its fair market value on the exercise date, and which the participant has not acquired from ViralClear within six months prior to the exercise date; by delivery (including by FAX or electronic transmission) to ViralClear or its designated agent of an executed irrevocable option exercise form (or, to the extent permitted by ViralClear, exercise instructions, which may be communicated in writing, telephonically, or electronically) together with irrevocable instructions from the participant to a broker or dealer, reasonably acceptable to ViralClear, to sell certain of the shares of common stock purchased upon exercise of the stock option or to pledge such shares as collateral for a loan and promptly deliver to ViralClear the amount of sale or loan proceeds necessary to pay such purchase price; by requesting ViralClear to withhold the number of shares otherwise deliverable upon exercise of the stock option by the number of shares of Common Stock having an aggregate fair market value equal to the aggregate option price at the time of exercise (i.e., a cashless net exercise); and/or in any other form of valid consideration that is acceptable to the Committee in its sole discretion.

Stock Appreciation Rights. The Committee may grant SARs to any participant, either as a separate award or in connection with a stock option, and impose terms and conditions on such SARs. A SAR may be exercised by the delivery (including by FAX) of written notice to the Committee setting forth the number of shares of common stock with respect to which the SAR is to be exercised and the exercise date, which shall be at least three days after giving such notice, unless an earlier time shall have been mutually agreed upon. The grant of the SAR may provide that the holder may be paid for the value of the SAR either in cash, in shares of common stock, or a combination thereof. In the event of the exercise of a SAR payable in shares of common stock, the holder of the SAR shall receive that number of whole shares of common stock having an aggregate fair market value on the date of exercise equal to the value obtained by multiplying the difference between the fair market value of a share of common stock on the date of exercise over the SAR price as set forth in such SAR (or other value specified in the agreement granting the SAR), by the number of shares of common stock as to which the SAR is being exercised, with a cash settlement to be made for any fractional shares of common stock. The SAR price for any share of common stock subject to a SAR may be equal to or greater than the fair market value of such share on the date of grant. The Committee, in its sole discretion, may place a ceiling on the amount payable upon exercise of a SAR, but any such limitation shall be specified at the time the SAR is granted.

Restricted Stock. Restricted stock consists of shares of our 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 Committee in the applicable award agreement. The Committee may, in its sole discretion, remove any or all of the restrictions on such restricted stock. The Committee will set forth in the award agreement: the number of shares of common stock awarded; the price, if any, to be paid by the participant for such restricted stock and the method of payment of the price; the time or times within which such award may be subject to forfeiture; specified performance goals of ViralClear, a subsidiary, any division thereof or any group of employees of ViralClear, or other criteria, which the Committee determines must be met in order to remove any restrictions (including vesting) on such award; and all other terms, limitations, restrictions, and conditions applicable to the restricted stock.

Restricted Stock Units. 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 Committee, which include a substantial risk of forfeiture and restrictions on their sale or other transfer by the participant. Restricted stock units shall be subject to such restrictions as the Committee determines, including, without limitation, a prohibition against sale, assignment, transfer, pledge, hypothecation, or other encumbrance for a specified period of time or a requirement that the holder forfeit (or in the case of shares of common stock or units sold to the participant, resell to ViralClear at cost) such shares or units in the event of termination of employment or service during the applicable period of restriction.

Vesting, Forfeiture, Assignment. The Committee, 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 ViralClear Plan. If the Committee imposes conditions upon vesting, then, except as otherwise provided below, subsequent to the date of grant, the Committee may, in its sole discretion, accelerate the date on which all or any portion of the award may be vested.

The Committee may impose on any award, at the time of grant or thereafter, such additional terms and conditions as the Committee determines. Except as otherwise provided in the particular award agreement, upon termination of service during the applicable restriction period, nonvested shares of restricted stock shall be forfeited by the participant.

Incentive stock options may not be transferred, assigned, pledged, hypothecated, or otherwise conveyed or encumbered other than by will or the laws of descent and distribution and may be exercised during the lifetime of the participant only by the participant or the participant's legally authorized representative, and each award agreement in respect of an incentive stock option shall so provide, except that the Committee may waive or modify such limitation that is not required for compliance with Section 422 of the Code. Other awards granted under the ViralClear Plan generally may not be transferred, assigned, pledged, hypothecated or otherwise conveyed or encumbered other than by will or the laws of descent and distribution. Notwithstanding the foregoing, the Committee may, in its discretion, authorize all or a portion of a nonqualified stock option or SAR to be granted to a participant on terms which permit transfer by such participant to the spouse (or former spouse), children, or grandchildren of the participant ("Immediate Family Members"); a trust or trusts for the exclusive benefit of such Immediate Family Members; a partnership in which the only partners are such Immediate Family Members and/or entities which are controlled by the participant and/or Immediate Family Members; an entity exempt from federal income tax pursuant to Section 501(c)(3) of the Code or any successor provision; or a split interest trust or pooled income fund described in Section 2522(c)(2) of the Code or any successor provision, provided that there shall be no consideration for any such transfer; the award agreement pursuant to which such nonqualified stock option or SAR is granted must be approved by the Committee and must expressly provide for transferability in a manner consistent with the ViralClear Plan; and subsequent transfers of transferred nonqualified stock options or SARs shall be prohibited except those by will or the laws of descent and distribution. Following any transfer, any such nonqualified stock option and SAR shall continue to be subject to the same terms and conditions as were applicable to such award immediately prior to transfer. The events of termination of service shall continue to be applied with respect to the original participant, following which the nonqualified stock options and SARs shall be exercisable or convertible by the transferee only to the extent and for the periods specified in the applicable award agreement. The Committee and ViralClear shall have no obligation to inform any transferee of a nonqualified stock option or SAR of any expiration, termination, lapse, or acceleration of such stock option or SAR. The Company shall have no obligation to register with any federal or state securities commission or agency any common stock issuable or issued under a nonqualified stock option or SAR that has been transferred by a participant under the ViralClear Plan.

Capital Adjustments. 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, rights offering, reorganization, merger, consolidation, split-up, spin-off, split-off, combination, subdivision, repurchase, or exchange of common stock or other securities of ViralClear, issuance of warrants or other rights to purchase common stock or other securities of ViralClear, or other similar corporate transaction or event affects the fair value of an award, then the Committee shall adjust any or all of the following so that the fair market value of the award immediately after the transaction or event is equal to the fair market value of the award immediately prior to the transaction or event: the number of shares and type of common stock (or the securities or property) which thereafter may be made the subject of awards; the number of shares and type of common stock (or other securities or property) subject to outstanding awards; the number of shares and type of common stock (or other securities or property) specified as the annual per-participant limitation; the option price of each outstanding award; the amount, if any, ViralClear pays for forfeited shares of common stock; and the number of or SAR price of shares of common stock then subject to outstanding SARs previously granted and unexercised under the ViralClear Plan, to the end that the same proportion of ViralClear's issued and outstanding shares of common stock in each instance shall remain subject to exercise at the same aggregate SAR price; provided, however, that the number of shares of common stock (or other securities or property) subject to any award shall always be a whole number. Notwithstanding the foregoing, no such adjustment shall be made or authorized to the extent that such adjustment would cause the ViralClear Plan or any stock option to violate Section 422 of the Code or Section 409A of the Code, and such adjustments shall be made in accordance with the rules of any securities exchange, stock market, or stock quotation system to which ViralClear is subject.

Amendment or Discontinuance of the ViralClear Plan. The ViralClear Board may at any time and from time to time, without the consent of participants, alter, amend, revise, suspend, or discontinue the ViralClear Plan in whole or in part, except that we will obtain stockholder approval of any ViralClear 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 ViralClear Plan. Any amendments made shall, to the extent deemed necessary or advisable by the Committee, be applicable to any outstanding awards theretofore granted under the ViralClear Plan, notwithstanding any contrary provisions contained in any award agreement. In the event of any such amendment to the ViralClear Plan, the holder of any award outstanding under the ViralClear Plan shall, upon request of the Committee and as a condition to the exercisability thereof, execute a conforming amendment in the form prescribed by the Committee to any award agreement relating thereto. Notwithstanding anything contained in the ViralClear Plan to the contrary, unless required by law, no action contemplated or permitted by the ViralClear Board or Committee for the alteration, amendment, revision, suspension, or termination of the ViralClear Plan shall adversely affect any rights of participants or obligations of ViralClear to participants with respect to any award theretofore granted under the ViralClear Plan without the consent of the affected participant.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Common Stock

The following table sets forth information regarding the beneficial ownership of our voting securities as of March 30, 2023 by (i) each person known to us to beneficially own five percent (5%) or more of any class of our voting securities; (ii) each of our named executive officers and directors; and (iii) all of our named directors and executive officers as a group. The percentages of voting securities beneficially owned are reported on the basis of regulations of the SEC governing the determination of beneficial ownership of securities. Under the rules of the SEC, 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, 55 Greens Farms Road, 1st Floor, Westport, Connecticut 06880. Percentage of common stock ownership is based on 66,857,687 shares of common stock issued and outstanding as of March 30, 2023. Percentage of Series C Preferred Stock ownership is based on 105 shares of Series C Preferred Stock issued and outstanding as of March 30, 2023.

Beneficial ownership is determined in accordance with the rules of the SEC. For the purpose of calculating the number of shares beneficially owned by a stockholder and the percentage ownership of that stockholder, shares of common stock subject to options or warrants that are currently exercisable or exercisable within sixty (60) days of March 30, 2023 by that stockholder are deemed outstanding.

Name	Number of Shares of Common Stock Beneficially Owned (1)	Percentage Class (1) (2)	Number of Shares of Series C Preferred Stock Beneficially Owned	Percentage Class (11)	Total Voting Power
Directors and Named Executive Officers and 5% holders					
Kenneth L. Londoner	3,653,144 (3)	5.45%	—	—	5.45%
Patrick J. Gallagher	327,258 (4)	*	—	—	*
Steve Buhaly	295,382 (5)	*	—	—	*
David Weild IV	476,827 (6)	*	—	—	*
Donald E. Foley	462,455 (7)	*	—	—	*
James Barry	146,091 (8)	*	—	—	*
Frederick D. Hrkac	111,455 (9)	*	—	—	*
James L. Klein	320,091 (10)	*	—	—	*
Gray Fleming	181,868 (11)	*	—	—	*
John Sieckhaus	186,666 (12)	*	—	—	*
Donald E. Garlikov	6,425,466 (13)	9.61%	—	—	9.61%
All directors and executive officers and 5% holders as a group of eleven persons	12,586,703	18.39**%**	—	—	18.43**%**
Series C Holders					
Ray Weber	218,940 (15)	*	45	42.86%	*
INTL FCStone Financial Inc C/F Raymond E Weber IRA	170,533 (16)	*	35	33.33%	*
Martin F. Sauer	121,824 (17)		25	23.81%	*

* Less than 1%.

(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 30, 2023, 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 66,857,687 shares of common stock outstanding as of March 30, 2023.

(3) Comprised of (i) 2,296,820 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 175,000 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.

(4) Comprised of (i) 108,585 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, and (iv) options to purchase 213,873 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023.

(5) Comprised of (i) 232,882 shares of common stock and (ii) options to purchase 62,500 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023.

(6) Comprised of (i) 81,445 shares of common stock and (ii) options to purchase 395,372 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023.

(7) Comprised of (i) 188,455 shares of common stock and (ii) options to purchase 274,000 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023.

(8) Comprised of (i) 46,091 shares of common stock and (ii) options to purchase 100,000 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023.

(9) Comprised of (i) 61,455 shares of common stock and (ii) options to purchase 50,000 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023.

(10) Comprised of (i) 270,091 shares of common stock and (ii) options to purchase 50,000 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023.

(11) Comprised of (i) 36,036 shares of common stock and (ii) options to purchase 145,832 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023.

(12) Comprised of (i) 70,000 shares of common stock and (ii) options to purchase 116,666 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023.

(13) Comprised of shares of common stock.

(14) These percentages have been calculated based on 105 shares of Series C Preferred Stock outstanding as of March 30, 2023.

(15) 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 30, 2023. Ray Weber may also be deemed beneficial owner of shares held by StoneX Group Inc C/F Raymond E Weber IRA. Mr. Weber's address is 27 Zabriskie St., Jersey City, NJ 07307.

(16) 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 30, 2023. This stockholder's address is 27 Zabriskie St., Jersey City, NJ 07307.

(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 30, 2023. 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, 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 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 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 (subsequently, conditions met). The SOW has been subsequently extended through 2022 at a monthly rate of $15,000 per month. Mr. Filler is the general counsel and partner of Sherpa. During the years ended December 31, 2022 and 2021, the Company paid $165,000 and $180,000 as patent costs, consulting fees and expense reimbursements. As of December 31, 2022, and 2021, there was an unpaid balance of $75,000 and $15,000, respectively. As of June 28, 2021, Mr. Filler resigned from our Board.

On June 28, 2021, in connection with the departure of two board members, Ms. Pease and Mr. Filler, the Company extended for up to two years 125,000 and 50,000 previously granted options that would normally expire 90 days after leaving service.

On June 30, 2021, in connection with the resignation of Mr. O'Donnell, a board member, the Company entered into a one-year consulting contract and extended for up to two years from end of contract service: 240,000 previously granted Company options, 25,000 previously granted ViralClear options and 329,000 previously issued ViralClear restricted stock units; all of which would normally expire 90 days after leaving service. In addition, the Company accelerated to fully vested previously issued restricted stock units and issued 50,000 shares of the Company's common stock in settlement.

On March 22, 2022, as an investor, but before appointment to the Board of Directors, James Klein purchased 110,000 shares of our common stock and 110,000 warrants to purchase shares of our common stock at $1.40 as part of a registered direct offering. On November 3, 2022, we offered all warrant holders of the March 22, 2022 offering a reduction in exercise price from $1.40 to $0.25. On November 14, 2022, Mr. Klein exercised his 110,000 warrants for 110,000 shares of our common stock for net proceeds of $27,500.

Independent Directors

Our board of directors has determined that each of David Weild IV, Patrick J. Gallagher, Donald E. Foley, James J. Barry, James L. Klein and Frederick D. Hrkac 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

Fees to Independent Registered Public Accounting Firms

The following is a summary of the fees billed to us by Friedman LLP and Marcum LLP for professional services rendered in the years ended December 31, 2022 and 2021:

	2022	2021
Audit Fees	$ 140,700	$ 132,350
Audit-Related Fees	86,600	25,200
Tax Fees	-	21,750
Total Fees	$ 227,300	$ 179,300

Audit Fees. This category includes the audit of our annual consolidated financial statements, reviews of our financial statements included in our Form 10-Qs and services that are normally provided by our independent registered public accounting firm in connection with its engagements for those years. This category also includes advice on audit and accounting matters that arose during, or as a result of, the audit or the review of our interim financial statements.

Audit-Related Fees. This category consists of assurance and related services by our independent registered public accounting firm that are reasonably related to the performance of the audit or review of our financial statements and are not reported above under "Audit Fees." The services for the fees disclosed under this category include consents regarding equity issuances.

Tax Fees. This category typically consists of professional services rendered by our independent registered public accounting firm for tax compliance and tax advice.

Pre-Approval Policies and Procedures

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:

Reports of Independent Registered Public Accounting Firms (PCAOB ID 711 and ID 688)
Consolidated Balance Sheets as of December 31, 2022, and 2021
Consolidated Statements of Operations for the years ended December 31, 2022, and 2021
Consolidated Statement of Changes in Equity for the Years ended December 31, 2022 and 2021
Consolidated Statements of Cash Flows for the years ended December 31, 2022, and 2021
Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

None.

(3) Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form S-1 filed on July 22, 2013)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.2 to the Form S-1 filed on July 22, 2013)
3.3	Certificate of Second Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.3 to the Form S-1 filed on July 22, 2013)
3.4	Certificate of Third Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.5 to the Form S-1/A filed on January 21, 2014)
3.5	Certificate of Fourth Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.6 to the Form S-1/A filed on March 28, 2014)
3.6	Certificate of Fifth Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on August 21, 2014)
3.7	Certificate of Sixth Amendment to the Amended and Restated Certificate of Incorporation of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on November 25, 2016)
3.8	Certificate of Seventh Amendment to the Amended and Restated Certificate of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on September 10, 2018)
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on November 9, 2017)
3.10	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on February 16, 2018)
3.11	Certificate of Designations of Series F Junior Participating Preferred Stock of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on July 17, 2020)
3.12	Amended and Restated Bylaws of BioSig Technologies, Inc. (incorporated by reference to the Exhibit 3.1 to the Form 8-K filed on September 27, 2019)
3.13	Amendment No. 1 to Amended and Restated Bylaws of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on October 22, 2019)
3.14	Amendment No. 2 to Amended and Restated Bylaws of BioSig Technologies, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on December 28, 2022)
4.1*	Description of Securities.

4.2	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on February 24, 2020)
4.3	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on July 2, 2021)
4.4	Form of Common Stock Purchase Warrant dated March 22, 2022 (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on March 24, 2022)
4.5	Form of Common Stock Purchase Warrant dated December 27, 2022 (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on December 28, 2022)
4.6	Form of Common Stock Purchase Warrant dated January 24, 2023 (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on January 24, 2023)
4.7	Form of Common Stock Purchase Warrant dated January 13, 2023 (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on January 17, 2023)
4.8	Form of Common Stock Purchase Warrant dated January 26, 2023 (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on January 26, 2023)
4.9	Form of Laidlaw Warrant dated January 24, 2023 (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on February 7, 2023)
4.10	Form of Common Stock Purchase Warrant dated February 8, 2023 (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on February 8, 2023)
4.11	Form of Laidlaw Warrant dated January 13, 2023 (incorporated by reference to Exhibit 4.2 to the Form 8-K filed on February 8, 2023)
4.12	Form of Laidlaw Warrant dated February 8, 2023 (incorporated by reference to Exhibit 4.3 to the Form 8-K filed on February 8, 2023)
4.13	Form of Common Stock Purchase Warrant dated February 13, 2023 (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on February 13, 2023)
4.14	Form of Laidlaw Warrant dated March 16, 2023 (incorporated by reference to Exhibit 4.2 to the Form 8-K filed on March 15, 2023)
4.15	Form of Common Stock Purchase Warrant dated March 16, 2023 (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on March 15, 2023)
4.16	Form of Laidlaw Warrant dated March 29, 2023 (incorporated by reference to Exhibit 4.2 to the Form 8-K filed on March 29, 2023)
4.17	Form of Common Stock Purchase Warrant dated March 29, 2023 (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on March 29, 2023)
10.1+	BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form S-1 filed on July 22, 2013)
10.2+	Form of Stock Option Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Form S-1 filed on July 22, 2013)
10.3+	Amendment No. 1 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.27 to the Form S-1/A filed on March 28, 2014)
10.4+	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)
10.5+	Amendment No. 2 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 99.3 to the Form S-8 filed on April 17, 2015)
10.6+	Amendment No. 3 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.41 to the Form S-1 filed on May 20, 2015)
10.7+	Amendment No. 4 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to the Form 8-K filed on May 29, 2015)
10.8+	Amendment No. 5 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on November 25, 2016)
10.9	Form of Warrant used in connection with the April 30, 2018 private placement (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on May 1, 2018).
10.10+	Amendment No. 6 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on July 30, 2018)
10.11	Form of Series B Common Stock Purchase Warrant in connection with the July 30, 2018 private placement (incorporated by reference to Exhibit 10.3 to the Form 8-K filed on August 16, 2018)
10.12	Securities Purchase Agreement dated as of March 12, 2019, by and between BioSig Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on March 14, 2019)
10.13	Form of Securities Purchase Agreement dated as of August 5, 2019, by and between NeuroClear Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 5, 2019)
10.14	Form of Securities Purchase Agreement dated as of September 5, 2019, by and between NeuroClear Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on September 5, 2019)
10.15	Patent License Agreement, dated September 12, 2019, by and between Mayo Foundation for Medical Education and Research and BioSig Technologies, Inc. (incorporated by reference to Exhibit 10.3 to the Form 10-Q filed on October 23, 2019)

10.16	Form of Securities Purchase Agreement dated as of October 21, 2019, by and between NeuroClear Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on October 24, 2019)
10.17+	Amendment No. 7 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on November 20, 2019)
10.18	Form of Securities Purchase Agreement dated as of December 31, 2019, by and between BioSig Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on December 31, 2019)
10.19	Common Stock Purchase Warrant of BioSig Technologies, Inc., dated November 20, 2019, issued to Mayo Foundation for Medical Education and Research (EP Software Warrant)
10.20	Common Stock Purchase Warrant of BioSig Technologies, Inc., dated November 20, 2019, issued to Mayo Foundation for Medical Education and Research (Tools Warrant)
10.21	Common Stock Purchase Warrant of NeuroClear Technologies, Inc., dated November 20, 2019, issued to Mayo Clinic Ventures
10.22+	Amendment No. 8 to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on June 30, 2020)
10.23	Form of Securities Purchase Agreement dated June 24, 2020 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 June 26, 2020)
10.24+	Ninth Amendment to the BioSig Technologies, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on June 29, 2021).
10.25	Form of Securities Purchase Agreement dated as of March 21, 2022 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 24, 2022)
10.26	ATM Sales Agreement by and between Virtu Americas LLC and BioSig Technologies, Inc. (incorporated by reference to Exhibit 1.1 to the Form 8-K filed on May 17, 2022)
10.27	Form of Securities Purchase Agreement dated as of November 18, 2022 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 November 21, 2022)
10.28	Form of Securities Purchase Agreement dated as of December 21, 2022 by and between BioSig Technologies, Inc. and certain purchasers set forth therein (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on December 28, 2022)
10.29	Form of Securities Purchase Agreement dated as of January 10, 2023 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 January 17, 2023)
10.30	Form of Securities Purchase Agreement dated as of January 23, 2023 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 January 24, 2023)
10.31	Form of Securities Purchase Agreement dated as of January 25, 2023 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 January 26, 2023)
10.33	General Release and Severance Agreement dated January 29, 2023 by and between Steve Chaussy and BioSig Technologies, Inc. (incorporated by reference to Exhibit 10.1 to the amended Form 8-K filed on February 7, 2023)
10.34	Form of Securities Purchase Agreement dated as of February 3, 2023 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 February 8, 2023)
10.35	BioSig Technologies, Inc. 2023 Long-Term Incentive Plan dated February 7, 2023 (incorporated by reference to Exhibit 10.1 to Form 8-K filed on February 9, 2023)
10.36	Form of Securities Purchase Agreement dated as of February 8, 2023 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 February 13, 2023)
10.37	Form of Securities Purchase Agreement dated as of March 14, 2023 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 15, 2023)
10.38	Form of Securities Purchase Agreement dated as of March 24, 2023 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 29, 2023)
21.1	Subsidiary List of BioSig Technologies, Inc. (incorporated by reference to Exhibit 21.1 to the Form 10-K filed on March 15, 2021).
23.1*	Consent of Marcum LLP
23.2*	Consent of Friedman LLP

31.01*	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.02*	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.01**	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101 INS*	Inline XBRL Instance Document
101 SCH*	Inline XBRL Taxonomy Extension Schema Document
101 CAL*	Inline XBRL Taxonomy Calculation Linkbase Document
101 LAB*	Inline XBRL Taxonomy Labels Linkbase Document
101 PRE*	Inline XBRL Taxonomy Presentation Linkbase Document
101 DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

+ Indicates a management contract or compensatory plan.

ITEM 16 – FORM 10-K SUMMARY

None.

SIGNATURES

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

BIOSIG TECHNOLOGIES, INC.

Date: March 31, 2023

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

Date: March 31, 2023

By: /s/ STEVEN J. BUHALY
Steven J. Buhaly
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

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

Name	Position	Date
/s/ DONALD E. FOLEY Donald E. Foley	Director	March 31, 2023
/s/ PATRICK J. GALLAGHER Patrick J. Gallagher	Director	March 31, 2023
/s/ JAMES J. BARRY PhD James J. Barry, PhD	Director	March 31, 2023
/s/ FREDERICK D. HRKAC Frederick D. Hrkac	Director	March 31, 2023
/s/ DAVID WEILD IV David Weild IV	Director	March 31, 2023
/s/ JAMES L. KLEIN James L. Klein	Director	March 31, 2023

CORPORATE INFORMATION

DIRECTORS AND EXECUTIVE OFFICERS

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

Steven Buhaly
Chief Financial Officer

John Sieckhaus
Chief Operating Officer

Michael Graydon Fleming, Jr.
Chief Commercial Officer

Patrick J. Gallagher
Director

Donald E. Foley
Director

James J. Barry, PhD
Director

Frederick D. Hrkac
Director

James L. Klein
Director

David Weild IV
Director

CORPORATE HEADQUARTERS

55 Greens Farms Road, 1st Floor
Westport, CT 06880

STOCK LISTING

Nasdaq Capital Market: BSGM

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Marcum LLP
730 3rd Avenue, 11th Floor
New York, NY 10017

TRANSFER AGENT AND REGISTRAR

Securities Transfer Corporation
2901 N Dallas Parkway, Suite 380
Plano, TX 75093
Telephone: (469) 633-0101

ANNUAL GENERAL MEETING OF STOCKHOLDERS

The 2023 Annual General Meeting of Stockholders will be held at 55 Greens Farms Road, 1st Floor, Westport, CT at 10:00 a.m. Eastern Time on December 18, 2023. Stockholders of record on October 31, 2023, are entitled to notice of and to vote at the Annual General Meeting.

COMPANY WEBSITE

www.biosig.com