UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 11, 2016

BioSig Technologies, Inc.

(Exact name of registrant as specified in its charter)

<u>Delaware</u>
(State or other jurisdiction
of incorporation)

<u>000-55473</u> (Commission File Number) 26-433375 (IRS Employer Identification No.)

8441 Wayzata Blvd., Suite 240
<u>Minneapolis, Minnesota</u>
(Address of principal executive offices)

<u>55426</u> (Zip Code)

Registrant's telephone number, including area code: (763) 999-7330
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:
☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))

Section 8- Other Events

Item 8.01 Other Events.

On July 11, 2016, BioSig Technologies, Inc. released a letter to its shareholders from Gregory D. Cash, its President and Chief Executive Officer, describing certain research and business updates, a copy of which is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Section 9 - Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description of Exhibit

99.1 <u>Press Release of BioSig Technologies, Inc. issued on July 11, 2016.</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOSIG TECHNOLOGIES, INC.

Date: July 15, 2016 By: <u>/s/ Kenneth Londoner</u>

By: <u>/s/ Kenneth Londoner</u> Name: Kenneth Londoner Title: Executive Chairman



July 11, 2016

Dear BioSig Shareholder:

The current year has been a period of significant growth and achievement for us here at BioSig Technologies, Inc. (OTCQB: BSGM). We have established strong partnerships in the market as we have gathered valuable data on the effectiveness of our novel PURE EPTM System.

Our proprietary technology, PURE EPTM System is aimed at the \$4 billion cardiac electrophysiology (EP) marketplace, which is growing at 12.1% CAGR and is the fastest growing segment of cardiology. EP is the science of diagnosing and treating abnormal electrical activities of the heart (arrhythmias). An arrhythmia (abnormal heart rhythm) is a change in the heart's beating pattern. There are many different types with different causes and effects. An abnormal heart rhythm is when your heart beats too fast, too slowly or irregularly. According to the Center for Disease Control, as many as 6.1 million people in the United States have Atrial Fibrillation, just one form of arrhythmia. With the aging of the U.S. population, this number is expected to increase. Our goal is to provide physicians with more accurate, relevant real-time data during diagnostic EP studies and catheter ablation treatments for mainly the complex arrhythmias, Ventricular Tachycardia (VT) and Atrial Fibrillation (AF). We believe that our technology should prove valuable to the marketplace through improved quality of care for these wide-reaching conditions.



The PURE EPTM System is a surface electrocardiogram (ECG) and intracardiac multichannel recording & analysis system developed to assist electrophysiologists in making crucial clinical decisions in real-time. PURE EPTM is designed to acquire and display high-fidelity cardiac signal recordings at previously undetectable levels and provide software tools to effectively and efficiently assist in identifying appropriate catheter ablation targets – areas of tissue to destroy that create a heart rhythm disturbance (arrhythmia). The goal here is to materially reduce the length of the procedure – a positive for both patient and health care providers – as well as improve the results, thus reducing the need for additional procedures.

With our recent achievements in preclinical trials, the Company has begun to more actively communicate our message to members of the medical and investment community. In March, at the 13th Annual International Dead Sea Symposium (IDSS) in Israel, our collaborative effort with Mayo Clinic was presented entitled, "Enhanced Electrophysiology Recording Improves Signal Acquisition & Differentiation." In May, Management attended Heart Rhythm

Society's 37th Annual Scientific Sessions in San Francisco; and, we plan on presenting at the 8th Annual International Conference of the IEEE Engineering in Medicine and Biology Society in Orlando from August 17–20. These scientific/medical conferences bring together key experts, leading doctors and scientists, as well as other health professionals in our space, and are ideal platforms for us to share our PURE EPTM System and our dedication to improving the space and patient care.

In addition to connecting with leading healthcare experts, the company also has begun to selectively communicate with the investment community. We presented at the LD Micro Invitational, the Roth Growth Conference, the Drexel Hamilton Investor Forum and others. These conferences have given us the opportunity to directly interact with investors, analysts and journalists regarding the strategic growth drivers for BioSig. The initial feedback has been positive, as the investment community begins to better understand the problem at hand and our potential to successfully address it. BioSig will continue to support the exposure of this technology as the audience develops and we achieve certain milestones.

A Costly Problem a nd t he PURE EPTM Solution

The CDC estimates that AF costs the United States about \$6 billion each year, with indirect costs of \$26 billion. Medical costs for people who have AF are about \$8,705 higher per year than for people who do not suffer with the condition. Additionally, it leads to more than 750,000 hospitalizations every year, while contributing to an estimated 130,000 deaths.

Ventricular tachycardia prevalence continues to increase as more and more people are surviving heart attacks. Scar tissue in the lower chambers of the heart often results from a heart attack – this scarring can lead to rapid abnormal rhythms that interfere with the heart pumping blood, causing fainting and even sudden cardiac arrest. Approximately 450,000 sudden cardiac arrests occur in the US each year.

As the awareness of complex arrhythmias increases, patients invariably seek options for treatment. Drug therapies and implantable devices have often proved ineffective or resulted in debilitating side effects. Catheter ablation, the form of treatment that the PURE EPTM system is designed to support, has become an increasingly more popular and effective treatment. Ablation procedures for AF and VT are oftentimes empirical and 2-8 hours in length; and, many patients need repeated procedures to treat their disorder. The PURE EPTM System is designed to retain true cardiac signal data and display vital information that is currently undetectable with today's technology. Supplying physicians with these signals in a usable format provided by PURE EPTM may lead to more effective procedures and better patient outcomes.

Strategic Focus

There is an increasing demand in the field for new technologies to treat these complex arrhythmias. Additionally, there is a drastic shortage of innovators who are able to address the problem. This imbalance of supply/demand creates a unique value proposition for our shareholders. Additionally, the medical technology industry continues to show indicators of

bullish activity. There have been significant valuation premiums placed on similar companies, due to the significant merger and acquisition activity in the sector. There have been several major acquisitions made in the past 18 months of innovators by strategic medical device companies: Abbott (NYSE: ABT) bought Topera for \$350 million, Medtronic (NYSE: MDT) bought CardioInsight for \$272 million and AtriCure (NASDAQ: ATRC) bought nContact for \$149 million. In February of this year, Medical device company Stryker Corp. (NYSE: SYK) announced that it would acquire defibrillator maker Physio-Control International for \$1.28 billion in cash. Most notably, Abbott also announced a \$25 billion definitive agreement with St. Jude Medical, Inc. to enter the atrial fibrillation, structural heart, heart failure and neuromodulation markets. These buyouts are proof that elite technologies operating in this booming industry can demand premium valuations.

Management and Board

BioSig has an experienced management team with a world-class Board of Directors and scientific advisory board. The Board boasts a veritable who's who within the medical and financial industries. I myself have been involved within the medical device space for nearly 40 years. I've been engaged at world-class companies such as Medtronic, Boston Scientific and Sorin Group. I can honestly say that BioSig Technologies' C-Suite execs and Board of Directors are on par with that of a Fortune 500 healthcare company. It has been a pleasure to work with people of such impressive stature, including Dr. Jerome B. Zeldis, MD, PhD, CEO of Celgene Global Health and Chief Medical Officer of Celgene Corporation; Mr. Jeffrey F. O'Donnell, Sr., CEO, Chairperson of Trice Medical, Chairperson of Mela Sciences and Founder of Embrella Cardiovascular; and Mr. Seth H. Z. Fischer, current Chief Executive Officer & Director of Vivus Inc. and former Worldwide Chairman of Johnson & Johnson, Cardiovascular. In addition to our healthcare expertise, BioSig is also well versed in capital markets expertise. Mr. Ken Londoner, Founder, Executive Chairman and Director of BioSig, has a wealth of knowledge and experience in the financial industry in general and, more specifically, as an investor in companies that are focused in the medical space. Mr. Londoner began his career with J. & W. Seligman & Co. Inc., a leading institutional money management firm, where he rose from research analyst to managing \$3.5 billion in mutual funds, pension funds and international assets. Mr. David Weild IV joins Ken in this capacity. David has served as the Founder & CEO of Weild & Co., Vice Chairman of NASDAQ and the Head of Corporate Finance at Prudential. This is only a small sample of our team, as I should mention our collaborations with several other leading executives, doctors and scientists who come from prominent hospitals, healthcare programs, Fortune 500 companies and elite educational institutions - including Texas Cardiac Arrhythmia Institute, Mayo Clinic, Mount Sinai, UCLA, Boston Scientific, Medtronic, St. Jude Medical, J.P. Morgan and GE Healthcare.

Healthcare Relationships and Testing

BioSig has been collaborating with the UCLA Cardiac Arrhythmia Center since 2013. Together, we've worked on the PURE EPTM System proof of concept testing and prototype testing – we successfully compared PURE EPTM to the conventional recording system, in that the electrocardiogram and intracardiac signals displayed on our system showed less baseline wander, noise and artifacts compared to signals displayed on the other recording

systems. In December 2014, we began our research program with Dr. Samuel Asirvatham at the Mayo Clinic in Rochester, Minnesota. Based upon the success of our preclinical trials at Mayo Clinic throughout 2015, we announced in January a new Advanced Research Initiative, which triples our investment to fully characterize and develop novel features for generation II of our PURE EPTM System. The first of these nine studies has been successfully completed with the next planned for later this month. We also completed our first study at Mount Sinai Hospital in New York with Drs. Vivek Reddy and Jacob Koruth.

The objective of our preclinical studies is to demonstrate the clinical potential of PURE EPTM, and yield results not obtainable with present recording systems. Once the studies have been completed, we plan to publish the results at industry conferences and peer-reviewed journals in 2016.

In February, BioSig initiated a development deal for its PURE EPTM System with Minnetronix, an award-winning medical technology development and manufacturing firm. Minnetronix is widely considered to be a market leader in design, development, manufacturing, commercialization and service of medical electronic and electromechanical products. This deal is important as we move through testing towards commercialization of our technology and into production. Management is currently developing a Quality Management System (QMS) and beginning to formulate our 510(k) submission to the Food and Drug Administration. The FDA 510(k) premarket notification submission is based on a comparison of your device to another medical device that has already been cleared by the FDA (called the Predicate Device). The submission is scheduled for early 2017. Finally, we have also identified a notified body to help us obtain a CE Mark, required for commercial release in Europe.

Financial Achievements and Goals

On May 3, 2016, we announced the completion of a \$4.5 million private placement. BioSig issued 3,003,016 common shares at a price of \$1.50 per share and a half warrant with a three-year expiration at a cash exercise price of \$1.95. Board members and insiders purchased \$630,000 of the \$4.5M, or approximately 12.5% of the deal – and this is not the first time we have seen insider participation in our financing activities. The continued investment from insiders represents the strong confidence we have in our technology and our ability to commercialize our platform. The proceeds of this deal will be used to drive our clinical, technology and commercialization efforts forward. In addition to providing us with a strong foundation of working capital, the deal provided us with access to a strategic network of committed investors with a proven track record of assisting emerging-growth medtech companies to reach critical mass. Having secured a significant capital infusion, it is a priority of BioSig to see its shares up-list to a national exchange, NASDAQ or the New York Stock Exchange. This "up-listing" will provide us access to a broader range of investors while enhancing our status throughout the med tech industry. We will strive to complete this move during the current calendar year.

It is evident that we have made significant strides toward market adoption and commercialization. In fact, we are already strategizing for a potential commercial launch in

2017. Additionally, the Company expects to file at least two additional patents within the year. Management believes that significant potential exists within the intellectual property aspects of the medical device arena and will continue to drive value for us in the long term. With an influx of capital, an enhanced IP portfolio and a widespread foundation of investors, we are strongly positioned to establish ourselves as a market innovator within this rapidly growing industry.

On behalf of our management team and our Board of Directors, we want to thank you again for your continued support. We are looking forward to a busy and exciting year as we work to leverage the opportunities ahead in order to establish BioSig Technologies as a market leader within the medical technology industry.

Sincerely,

/s/ Gregory D. Cash

Mr. Gregory D. Cash President and Chief Executive Officer BioSig Technologies, Inc. (BSGM) www.biosigtech.com