
**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): November 13, 2019

BioSig Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38659
(Commission File Number)

26-433375
(IRS Employer
Identification No.)

54 Wilton Road, 2nd Floor
Westport, Connecticut
(Address of principal executive offices)

06880
(Zip Code)

(310)-620-9320
(Registrant's telephone number, including area code)

N/A
(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))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 7.01 Regulation FD Disclosure.

On November 13, 2019, BioSig Technologies, Inc. (the “Company”) issued a letter to shareholders, which is attached hereto as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing. Furthermore, the furnishing of information under Item 7.01 of this Current Report on Form 8-K is not intended to constitute a determination by the Company that the information contained herein, including the exhibits hereto, is material or that the dissemination of such information is required by Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Shareholder Letter, November 2019 (furnished herewith pursuant to Item 7.01)

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: November 13, 2019

By: /s/ Kenneth L. Londoner

Name: Kenneth L. Londoner

Title: Executive Chairman



LETTER TO SHAREHOLDERS

November 2019

Dear BioSig Shareholder,

As 2019 rapidly comes to a close, I felt it was important to review a few compelling Company developments and accomplishments that have occurred since we published the last Shareholder Letter in June 2019. We have made significant strides toward commercialization, received additional market validation for future sales potential, and added talented team members to assist us in growing our business and creating value for our shareholders.

COMMERCIALIZATION

We continue to execute effectively to set and meet important business objectives. As we stated in our June 2019 Shareholder Letter, we are successfully bringing our PURE EP™ System to three leading centers.

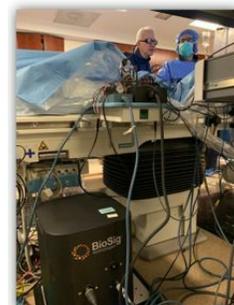
Center #1: After receiving an upgraded build of the PURE EP™ System in August, we performed a brief feasibility study in California and recently returned to the Texas Cardiac Arrhythmia Institute (TCAI) in Austin, Texas for the second phase of external evaluations. TCAI began evaluating human cases in late October and will continue doing so through the balance of the year. We expect many of the leading physicians at TCAI to gain initial user experience, as the Company collects clinical data to be used in our targeted market release phase of commercialization.

Center #2: Our next system installations are scheduled for the University of Pennsylvania in Philadelphia, PA, where we plan to commence clinical activities later in November.

Center #3: This is expected to be followed shortly by an installation at Mayo Clinic in Jacksonville, Florida.

All centers mentioned above are high-volume clinical sites that are widely regarded for their work with new technologies. The high patient count at each of these centers puts our Company right on target with our clinical plan for 2019.

In 2020, our goal is to install PURE EP™ Systems at up to nine new centers throughout the U.S., leading up to the Heart Rhythm Society's annual convention in May 2020. Our increased commercial activities will be led by Vice President of Sales John Kowalski, who spent 24 years at Johnson & Johnson's Biosense Webster division, the global leader and pioneering innovator in the electrophysiology market, and are expected to result in our first revenues in 2020. We should have ample inventory to meet planned commercial placement requirements in 2020, and, if all goes according to plan, in 2021 we will ramp domestic sales efforts even further and also stage our European commercialization efforts. Commercial activity is intended to be strongly supported by growing clinical validation and educational and training programs, including establishing training hubs at our early hospital partners' facilities. We are also currently evaluating how many of



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these partner sites may be able to potentially broadcast live patient cases, allowing us to touch more physicians and centers around the country.

BEGINNING OUR FIRST CLINICAL TRIAL

As we stated earlier in the year, the initial electrophysiology clinical cases we performed at TCAI, Greenville Memorial Hospital, and Indiana University School of Medicine in the first half of 2019 have paved the way for more fundamental clinical trials. We recently developed our very first trial program slightly ahead of schedule, and we firmly expect it to demonstrate the clinical value proposition of our technology. This blinded trial is planned to commence in November 2019, and a summary of the trial protocol can be found at the link below:

<https://clinicaltrials.gov/ct2/show/NCT04112433?term=BioSig+technologies&draw=2&rank=1>

Having persuasive clinical trial data should help us more easily penetrate the medical community and go beyond the early adopters of our technology. While we have the 510(k) approval that already allows us to commercialize the product in the rapidly growing \$4.6 billion electrophysiology market, trial data can be a key element in advancing broader commercial adoption for us across the universe of medical centers providing catheter ablation treatments.

ADVANCING INDUSTRY PRESENCE

We recently presented our first clinical observations at *Venice Arrhythmias 2019*, a distinguished industry event held every two years in Venice, Italy. The poster, titled, "*Use of a Novel Intracardiac Signal Processing System during Mapping of Complex Cardiac Arrhythmias*," was authored by Amin Al-Ahmad, M.D., Carola Gianni, M.D., Domenico G. Della Rocca, M.D., J. David Burkhardt, M.D., Rodney P. Horton, M.D., G. Joseph Gallinghouse, M.D., Patrick M. Hranitzky, M.D., Javier E. Sanchez, M.D., Luigi Di Biase, M.D. and Andrea Natale, M.D. from Texas Cardiac Arrhythmia Institute in Austin, TX. The clinical data presented in the poster was collected during two atrial fibrillation cases conducted with the PURE EP™ System in February 2019. In addition to the poster presentation, we had meetings with 14 physicians during this intense three-day event.

Later in October, we presented at the *14th Annual International Symposium on Ventricular Arrhythmias: Pathophysiology & Therapy*, which was co-hosted by the Department of Medicine Division of Cardiology, University of Pennsylvania Health System, Philadelphia, PA, and the Division of Cardiology, The Mount Sinai Hospital, New York, NY. During this event, we hosted technology presentations for 15 internationally recognized key opinion leaders.

We are happy to announce that we will begin 2020 on a very strong note, as we head to the *25th Annual International AF Symposium*, due to take place in Washington, D.C. from January 23-25, 2020. In addition to the booth presentations and technology demonstrations, our PURE EP™ System will be presented in a Spotlight Session by one of the industry's leading physicians to a large audience of potential customers.



STRONG IP PORTFOLIO FOR SUSTAINABLE INNOVATION

We have dramatically advanced our asset base in technology since June. Our patent portfolio has grown to five issued patents at the time of this writing, protecting the core aspects of the PURE EP™

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System and a new EP Simulator product. Our intellectual property work is ongoing, and shareholders should expect many more filings to come on hardware, software, tools, and other innovations. Company leadership strongly believes in the value of intellectual property and has been making substantial investments in this area. While the value of our patents may not be reflected in our stock price yet, a sophisticated investor would know that it's only a matter of time before it gets recognized and, perhaps even more importantly, translates into a larger product portfolio that should allow for significant shareholder value creation in the long term.

TAPPING INTO NEW MARKETS

On September 5, we announced that our subsidiary, NeuroClear Technologies, Inc., raised \$3.7 million in an initial seed round, valuing the advanced technology assets of BioSig at a \$40 million value, or approximately \$2 per BioSig share.



Founded in November 2018, NeuroClear Technologies, Inc. aims to address some of the biggest challenges in bioelectronic medicine, including, but not limited to, targeted nerve stimulation and a closed feedback loop system to provide appropriate stimulation. NeuroClear intends to build on the core competencies in recording and analysis of intracardiac, surface ECG, and neuronal signals, which have already been validated by BioSig. Additionally, NeuroClear intends to develop a dedicated product line to address and advance current therapies within a number of markets, such as cognitive disorders and nephrology. We plan to highlight more news on NeuroClear in 2020, as we develop, patent, test, and work to bring this important new technology platform to market.

NEW OPPORTUNITIES WITH MAYO CLINIC

In September, we also announced a new licensing agreement with Mayo Clinic, based in Rochester, MN, through Mayo Ventures. The new agreement aims to develop a new product pipeline to support some of the more advanced features of the PURE EP™ System. The development program will be run under the leadership of Samuel J. Asirvatham, M.D., Mayo Clinic's Vice-Chair of Innovation and Medical Director, Electrophysiology Laboratory. We expect to turn a recently received patent and a technology prototype, which we are advancing under the terms of this latest licensing agreement, into a commercial product over the next several years.



We are also opening a new office in Rochester, Minnesota, on November 11 to support our advancing collaboration with Mayo Clinic's outstanding physician team, including Drs. Asirvatham, Friedman, Venkatachalam, and Kapa. Our small, but highly agile, team is working on several products in parallel, and having an innovation hub in close proximity to some of our largest collaborators should allow us to accelerate our product development that is geared toward bringing clinical advances in Afib, VT, and the wider space of bioelectronic medicine.

FINANCING AND MARKETS

BioSig ended the third quarter with a cash balance of approximately \$12.3 million – the highest cash balance in our history and up 20% from the end of Q2 2019. We have increased our cash on hand 176% from the end of 2018.

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On July 1, our stock was added to the Russell 2000 and 3000 stock market indexes. Our institutional shareholder base has expanded from less than 1% at the beginning of 2019 to approximately 13.6% as of this writing. Management believes that there is a great opportunity to continue attracting healthcare-related investment funds, both domestically and internationally, that are interested in becoming shareholders in the Company.

Year to date, the Company's stock has increased by 56.4% through Friday, November 1. This compares favorably to the major markets through the same period, such as the Nasdaq (up 26.4%) and the Russell 2000 (up 17.9%). However, while we are pleased to be outperforming the markets, we still believe that our shareholders can expect more upside in the months and years ahead.

TALENT FOR GROWTH

We value excellence and team dynamics at BioSig, and we are confident that engaged employees help us establish excellent relationships with our customers. It is for that reason that we tirelessly search for the best talent and fit for our management and Board of Directors. We strongly believe the quality of human resources is a major determining factor in the ultimate success or failure of a company. Since the publication of our June letter, we have had great success in attracting and hiring top-level professionals.

Program Office: In late June, we established our Program Office, which is led by Ms. Manasi Patwardhan, Director of Strategic Planning. With approximately 20 years of experience in our field and a successful track record in driving complex engineering projects at Verily Life Sciences, Medtronic, and Boston Scientific, she has demonstrated her excellence in advancing our manufacturing relationship, vendor management, systems engineering, cross-functional team performance, and operating process improvement.

Product Marketing: Shortly thereafter, Mr. Olivier Chaudoir joined us as Director of Marketing, having recently left a 20+ year career at Johnson & Johnson, 17 years of which were spent at its BioSense Webster division. Mr. Chaudoir now leads all of our marketing efforts, including defining the product positioning for our PURE EP[™] System and developing a set of tools and materials that are vital for commercialization.

Clinical Affairs and Physician Engagement: In July, we established a strong customer-facing team that is led by Ms. Julie Stephenson, MBA. Ms. Stephenson joined us from Medtronic and brings nearly 30 years of experience in physician engagement, medical education, including development of nationwide peer-to-peer education programs, and close collaboration with internationally recognized physician leaders.

Engineering and Product Development: We recently brought in two more talented senior engineers to complement our technology team. Mr. Sina Farahmand, Ph.D., brings to us a wealth of experience in neuromodulation. His work on noise-assisted connectivity analysis for personalized deep brain stimulation has recently been presented at the prestigious *Society for Neuroscience 2019* conference in Chicago, IL. His peer, Mr. Prasanth Ganesan, Ph.D., has recently joined us from the Institute for Sensing and Embedded Network Systems Engineering at Florida Atlantic University. Mr. Ganesan is an experienced developer of novel signal processing algorithms and is an invaluable addition to our PURE EP[™] development team. Our Engineering team keeps growing, and we are actively interviewing for a number of additional roles.



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Institutional Investor Relations: We recently appointed Mr. Andrew Ballou to head up our internal investor relations team and grow the institutional investor base. Mr. Ballou brings to BioSig over 25 years of experience in capital markets, including institutional equity sales and research analysis, having managed large institutional accounts at Janney Montgomery Scott, LLC and RBC Capital along the way. Mr. Ballou becomes our fourth full-time IR employee, and his knowledge, experience, and relationships should bring value in 2020 and beyond.

Board of Directors: We were pleased that Ms. Martha Pease agreed to join our Independent Board of Directors, as she fully rounds out our Board at nine members. Ms. Pease brings to the Company over 30 years of experience in developing customer-centric growth strategies and creating digital leverage, powered by data analytics, to increase shareholder value. The highlights of Ms. Pease's career in advertising include managing the IBM Personal Computer account at Lord, Geller, Federico, Einstein and the Apple account at BBDO. An on-air and online commentator for CNN, she analyzes the impact of breaking news on perceptions and leadership. Ms. Pease's history in bringing new technologies to market and her brand-building expertise will be immensely helpful to the Company.

SUMMARY

Thus far, 2019 has been an excellent year of progress for the Company, and we are well-positioned for 2020 to be the best year in our 11-year corporate history.

Next year, in 2020, we expect to see our first commercial revenues, European CE Mark approval, engineering, clinical and operational team expansion, and rapid development of our subsidiary, NeuroClear.

Our Board of Directors has been strengthened with the addition of three new members, all of whom bring considerable direct industry experience to an already impressive group.

We hope that all of the activities outlined in this corporate update will serve as confirmation that the Company is on track strategically and has the right technology, people, and partners to ultimately deliver for our shareholders.

The Board and management team are, collectively, the largest shareholders, owning 19.8% of the Company. Moreover, over the last 12 months, management has purchased nearly 100,000 shares, at a total purchase price of approximately \$578,000 in the open market. Our commitment to the Company, our mission, and our direction has never been stronger. We sincerely appreciate your continued support and encouragement, as we continue to develop innovative medical products. We hope to see as many of you as possible at our next scheduled Shareholder Meeting on November 18, 2019.

With best wishes,

/s/ Kenneth L. Londoner

Kenneth L. Londoner, Chairman & CEO

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