
**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 21, 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)

26-4333375
(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:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
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 8.01 Entry Into a Material Definitive Agreement.

On November 21, 2019, BioSig Technologies, Inc. (the “*Company*”) issued a press release announcing that the Company commenced its first clinical trial for its PURE EP™ System. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	<u>Press Release, dated November 21, 2019</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: November 21, 2019

By: /s/ Kenneth L. Londoner

Name: Kenneth L. Londoner

Title: Executive Chairman



BioSig Commences Clinical Trial Enrollment for PURE EP System

Westport, CT, November 21, 2019 /GLOBE NEWSWIRE/ — BioSig Technologies, Inc. (NASDAQ: BSGM) (“BioSig” or the “Company”), a medical technology company developing a proprietary biomedical signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals, today announced that the Company commenced its first clinical trial for its PURE EP™ System.

Texas Cardiac Arrhythmia Research Foundation (TCARF) in Austin, Texas, is the first institution to conduct patient cases under the clinical trial titled, “*Novel Cardiac Signal Processing System for Electrophysiology Procedures (PURE EP 2.0 Study)*”. Eight patient enrollments were achieved during the first week of the trial. The data collected during the trial is planned to be submitted for abstract consideration at leading industry events throughout 2020, including The Heart Rhythm Scientific Sessions in May 2020.

“Our first clinical trial is an inflection point for our Company, and we are pleased to initiate it with Texas Cardiac Arrhythmia Institute at St. David’s Hospital in Austin, Texas,” commented Kenneth L. Londoner, Chairman and CEO of BioSig Technologies, Inc.

The Shareholder Letter issued by the Company on November 14, 2019 announced several upcoming installations of the Company’s PURE EP(tm) System, including Mayo Clinic Jacksonville, FL, which is also expected to take part in the clinical trial. This allows the Company to commercialize its product in the rapidly growing \$4.6 billion electrophysiology market, and the Company believes trial data may play an important role in advancing broader commercial adoption across the universe of medical centers providing catheter ablation treatments.

About BioSig Technologies

BioSig Technologies is a medical technology company developing a proprietary biomedical signal processing platform designed to improve the electrophysiology (EP) marketplace (www.biosig.com). Led by a proven management team and a veteran Board of Directors, BioSig Technologies is preparing to commercialize its PURE EP(tm) System. The technology has been developed to address an unmet need in a large and growing market.

The Company’s first product, PURE EP(tm) System is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording and storing of electrocardiographic and intracardiac signals for patients undergoing electrophysiology (EP) procedures in an EP laboratory. The system is indicated for use under the supervision of licensed healthcare practitioners who are responsible for interpreting the data. This novel cardiac signal acquisition and display system is engineered to assist electrophysiologists in clinical decision-making during electrophysiology procedures in patients with abnormal heart rates and rhythms. BioSig’s ultimate goal is to deliver technology to improve upon catheter ablation treatments for the prevalent and potentially deadly arrhythmias, Atrial Fibrillation and Ventricular Tachycardia. BioSig has partnered with Minnetronix on technology development and received FDA 510(k) clearance for the PURE EP(tm) System in August 2018.

Forward-looking Statements

This press release contains “forward-looking statements.” Such statements may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. Forward- looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company’s control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) our inability to manufacture our products and product candidates on a commercial scale on our own, or in collaboration with third parties; (ii) difficulties in obtaining financing on commercially reasonable terms; (iii) changes in the size and nature of our competition; (iv) loss of one or more key executives or scientists; and (v) difficulties in securing regulatory approval to market our products and product candidates. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company’s filings with the Securities and Exchange Commission (SEC), including the Company’s Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC’s website at <http://www.sec.gov>. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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