# 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): April 13, 2021

# BioSig Technologies, Inc.
(Exact name of registrant as specified in its charter)

| **Delaware** | **001-38659** | **26-4333375** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **54 Wilton Road, 2nd Floor**<br>**Westport, Connecticut** | **06880** |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

**(203) 409-5444**
(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 7.01 Regulation FD Disclosure.**

On April 13, 2021, BioSig Technologies, Inc. (the "Company") issued a press release, attached hereto as Exhibit 99.1, announcing that it completed enrollment in the PURE EP 2.0 clinical trial. 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 | Press Release, dated April 13, 2021 (furnished herewith pursuant to Item 7.01) |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL) |

**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: April 13, 2021

By: /s/ Kenneth L. Londoner
Name: Kenneth L. Londoner
Title: Executive Chairman

**Exhibit 99.1**

## BioSig Completes Enrollment in the PURE EP 2.0 Clinical Study

- **51 patients undergoing elective cardiac ablation treatments were enrolled in the trial at Mayo Clinic, Massachusetts General Hospital, and St. David's Medical Center**
- **The trial is designed to demonstrate the quality and clinical value of the PURE EP™ signals when compared to conventional sources of cardiac signals. The Company expects to announce the study results in Q3 2021**

Westport, CT, April 13, 2021 -- BioSig Technologies, Inc. (NASDAQ: BSGM) ("BioSig" or the "Company"), a medical technology company commercializing an innovative signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals, today announced it completed enrollment in the PURE EP 2.0 clinical trial.

The multi-center, prospective clinical trial was conducted at the Texas Cardiac Arrhythmia Institute at St. David's Medical Center in Austin, TX, Mayo Clinic Florida Campus in Jacksonville, FL, and Massachusetts General Hospital in Boston, MA. During the trial, the PURE EP™ System was used in all types of arrhythmia cases, including atrial fibrillation, ventricular tachycardia, and atrial flutter. Atrial fibrillation, the most common arrhythmia type affecting over 6 million people in the U.S.[1], accounted for over 40% of enrollments.

The PURE EP™ System has been awarded FDA 510(k) clearance. The Company commenced commercialization in 2020, having recently announced commercial sales to St. David's HealthCare of Austin, Texas, and HCA Healthcare-owned hospital, and Mayo Foundation for Medical Education and Research. Clinical data, collected under the terms of the PURE EP 2.0 study, will support the national rollout to medical centers across the U.S.

The study aimed to establish the safe and effective use of the PURE EP™ System and assess the quality of the PURE EP™ intracardiac signals when compared to existing recording and mapping systems. Collected clinical data underwent randomized, blinded, controlled evaluation by a panel of independent electrophysiologists to determine the clinical value of the PURE EP signals. The Company has submitted a scientific abstract for consideration by the Heart Rhythm Society. It expects to announce the study results at the Heart Rhythm 2021 convention, which is due to take place on July 28-31, 2021. The Company expects to publish the full clinical study results in leading industry publications in the second half of 2021.

In Q3 2020, the Company announced the data results recorded during 15 atrial fibrillation ablation procedures from the PURE EP™ System, the signal recording system, and the 3D mapping system. The review concluded that the PURE EP™ signals were preferred to conventional sources of intracardiac signals.

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[1] Top 10 Things You should Know About Heart Rhythm; Scripps Health.

In addition to the enrolled patient data, the Company maintains a registry of over 600 ablation procedures performed with the PURE EP™ System at eight hospitals in the United States. This dataset is being used to support new product development to complement the PURE EP™ System.

"We are pleased to complete the enrollment in our flagship clinical study. The objective of our clinical strategy is to determine the clinical and economic benefits of the PURE EP™ System which could include improved procedure efficacy, reduced procedure times, and a decrease in repeat procedures," commented Kenneth L. Londoner, Chairman and CEO of BioSig Technologies, Inc. "Strong clinical evidence is the foundation of our commercial strategy. We look forward to revealing the clinical findings from our trial in the coming months and engaging the healthcare community in our new, targeted studies to demonstrate the additional clinical value of our technology."

**About BioSig Technologies**
BioSig Technologies is a medical technology company commercializing a proprietary biomedical signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals (www.biosig.com).

The Company's first product, PURE EP™ System is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording, and storing of electrocardiographic and intracardiac signals for patients undergoing electrophysiology (EP) procedures in an EP laboratory.

**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) the geographic, social and economic impact of COVID-19 on our ability to conduct our business and raise capital in the future when needed, (ii) our inability to manufacture our products and product candidates on a commercial scale on our own, or in collaboration with third parties; (iii) difficulties in obtaining financing on commercially reasonable terms; (iv) changes in the size and nature of our competition; (v) loss of one or more key executives or scientists; and (vi) 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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