## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## FORM 8-K/A

(Amendment No. 1)

#### CURRENT REPORT Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 14, 2022

# **BioSig Technologies, Inc.**

(Exact name of registrant as specified in its charter)

(State or other jurisdiction

001-38659 (Commission File Number)

26-4333375 (IRS Employer Identification No.)

55 Greens Farms Road, 1st Floor Westport, Connecticut (Address of principal executive offices)

**Delaware** 

of incorporation)

<u>06880</u> (Zip Code)

(203) 409-5444

(Registrant's telephone number, including area code)

<u>N/A</u>

(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  $\Box$ 

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.  $\Box$ 

#### **Explanatory Note**

BioSig Technologies, Inc. (the "Company") filed a Current Report 8-K on December 14, 2022 (the 'Original Form 8-K").

This Amendment No. 1 on Form 8-K/A is being filed to correct a typographical error in the number of enrolled patients in the randomized study in Exhibit 99.1 of the Original Form 8-K. No other changes have been made to the Original Form 8-K.

## Item 7.01 Regulation FD Disclosure.

On December 14, 2022, the Company issued a corrected press release, attached hereto as Exhibit 99.1, announcing that its PURE EPTM System was featured in an abstract presentation during the 15th Asia Pacific Heart Rhythm Society Scientific Session in Singapore. 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 December 14, 2022 (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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

## **BIOSIG TECHNOLOGIES, INC.**

Date: December 14, 2022

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

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## Update: BioSig's PURE EP<sup>TM</sup> System Demonstrates Potential Time and Cost Savings at the 15<sup>th</sup> APHRS Scientific Session in Singapore

## • Abstract highlights promising results from PURE EPIM study at premier Asia-Pacific Heart Rhythm Society Conference

Westport, CT, December 14, 2022 (GLOBE NEWSWIRE) - BioSig Technologies, Inc. (NASDAQ: BSGM) ("BioSig" or the "Company"), an advanced digital signal processing technology company delivering unprecedented accuracy and precision to intracardiac signal visualization with its proprietary PURE EP<sup>TM</sup> System, today announced that its PURE EP<sup>TM</sup> System was featured in an abstract presentation during the 15th Asia Pacific Heart Rhythm Society (APHRS) Scientific Session in Singapore.

Results from the randomized study reveal the PURE EP<sup>TM</sup> System's potential to promote shorter procedural times and higher cost savings during catheter ablations. The study enrolled 20 patients with non-paroxysmal AF with post-ablation arrhythmia recurrence ("redo AF"). The primary objective was to determine the difference in procedural times when comparing ablations guided by PURE EP<sup>TM</sup>'s electrocardiogram (EGM) visualization to the conventional ECG recording system. Study results demonstrated that the PURE EP<sup>TM</sup> 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<sup>1</sup>, the procedural time savings demonstrated by the PURE EP<sup>TM</sup> System suggest potential cost savings of approximately \$418.10 per procedure. While this suggests that PURE EP<sup>TM</sup> might promote shorter procedural times, further studies are underway.

The abstract titled, "<u>Reduced Time of Redo Atrial Fibrillation Ablation Procedures with PURE EPTM Recording System for ECG/EGM Visualization: A Randomized Study</u>," was presented as a poster presentation by Dr. G. Joseph Gallinghouse, Cardiac Electrophysiologist at St. David's Medical Center in Austin, TX.

"With over 75,000 AF ablations performed in the US each year<sup>2</sup>, the ability to demonstrate that PURE EP<sup>TM</sup> may reduce procedure times resulting in potential healthcare cost savings is a landmark milestone for the overarching value proposition of our technology," said Gray Fleming, Chief Commercialization Officer, BioSig Technologies, Inc. "We believe a hospital can generate a meaningful return on investment in the first year of ownership of a PURE EP<sup>TM</sup> System. Additional studies demonstrating compelling clinical and economic value of the PURE EP<sup>TM</sup> System are in motion and we are looking forward to sharing these insights with the EP and healthcare community in the near future."

APHRS 2022 represents the Company's first abstract presentation at an international conference. It also marks the first physician-sponsored presentation unveiling clinical data from the Company's **REDO AF Sub Study**, initiated in July 2021. [ClinicalTrials.gov Identifier: NCT04964440]

<sup>1.</sup> Kawasaki K. Megan, Cleary J. David, Correa de Sa D. Daniel, Calame R. Susan, Dillon M. Christopher, Tsai H. Mitchell, (2019) Abstract 9552: Understanding the Costs Associated with Cardiac Ablations. Circulation, 2019;140:A9552. www.ahajournals.org/doi/10.1161/circ.140.suppl\_1.9552

<sup>2. &</sup>quot;Late-Breaking Clinical Trials II: Innovation Boulevard: Pulsed AF: First Human Experience and Acute Procedural Outcomes Using A Novel Pulsed Field Ablation System " [Friday, May 8, 2020 at 11:00 a.m. EST]

#### About APHRS

The APHRS is a leading non-profit organization that represents medical, allied health, and science professionals specializing in cardiac rhythm disorders in the Asia-Pacific region. The annual Asia Pacific Heart Rhythm Society (APHRS) is a premier event featuring industry workshops and a core scientific program delivered by international and regional speakers.

### About BioSig Technologies

BioSig Technologies is an advanced digital signal processing technology company bringing never-before-seen insights to the treatment of cardiovascular arrhythmias. Through collaboration with physicians, experts, and healthcare leaders across the field of electrophysiology (EP), BioSig is committed to addressing healthcare's biggest priorities — saving time, saving costs, and saving lives.

The Company's first product, the PURE EP<sup>TM</sup> System, an FDA 510(k) cleared non-invasive class II device, provides superior, real-time signal visualization allowing physicians to perform insight-based, highly targeted cardiac ablation procedures with increased procedural efficiency and efficacy. The PURE EP<sup>TM</sup> System is currently in a national commercial launch and an integral part of well-respected healthcare systems, such as Mayo Clinic, Texas Cardiac Arrhythmia Institute, Cleveland Clinic, and Kansas City Heart Rhythm Institute. In a blinded clinical study recently published in the Journal of Cardiovascular Electrophysiology, electrophysiologists rated PURE EP<sup>TM</sup> as equivalent or superior to conventional systems for 93.6% of signal samples, with 75.2% earning a superior rating. The global EP market is projected to reach \$16B in 2028 with a 11.2% growth rate.<sup>1</sup>

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

<sup>1</sup> Global Market Insights Inc. March 08, 2022.

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