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): May 19, 2023

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.)

55 Greens Farms Road, 1st Floor **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 May 19, 2023, BioSig Technologies, Inc. (the "***Company***"), issued a press release, attached hereto as Exhibit 99.1, announcing that researchers from Cleveland Clinic will be presenting data from three abstracts at Heart Rhythm 2023. 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 May 19, 2023 (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: May 19, 2023

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

New Data at Heart Rhythm 2023 Suggests that Unipolar Signals May be Used for a More Precise, Accurate Approach to Treating Arrhythmias

Data from three abstracts highlight the potential of an optimized radiofrequency ablation technique for pulmonary vein isolation (PVI)
Preservation of raw unipolar signal using BioSig's PURE EP™ platform guidance enabled real-time tissue-specific feedback when conducting ablation

CLEVELAND, OH and WESTPORT, CT, May 19, 2023 (GLOBE NEWSWIRE) – Researchers from Cleveland Clinic will be presenting data from three abstracts at Heart Rhythm 2023 that evaluated an optimized radiofrequency ablation technique for pulmonary vein isolation (PVI)—a type of ablation procedure used to treat atrial fibrillation (AF)—compared to the existing standard, the Ablation Index™. Researchers used BioSig Technologies, Inc. (NASDAQ: BSGM) proprietary PURE EP™ Platform for real-time tissue-specific feedback to achieve equal lesion quality and dimension in a third of the time as conventional methods that rely on surrogate metrics.

Across all three studies, researchers compared the efficacy of using unipolar signals to guide procedures to the current standard of using an Ablation Index™. While there is a well-established body of pre-clinical evidence validating the use of unipolar signals to assess the efficacy of ablation, capturing the unipolar signal has been a challenge with existing processing platforms due to room and radiofrequency noise saturation, wandering baseline, and improper filtering.

"Despite past evidence suggesting validation and efficacy, unipolar signals have not been used to help guide lesion and ablation because of their susceptibility to interference from an inherently noisy lab environment," said Oussama Wazni, MD, MBA, section head, cardiac electrophysiology and pacing at Cleveland Clinic and lead researcher. "These studies suggest that the preservation of raw cardiac signal enables the use of unipolar signals to help guide ablations, while improving lesion precision and reducing procedure time."

Zachary Koch, Principal Advisor of Product Development at BioSig Technologies added, "We are thrilled to collaborate with the Cleveland Clinic on these important studies that showcase the potential of our PURE EP™ Platform to deliver unprecedented clarity of the raw electrical signal. The PURE EP™ engineering enables physicians to access the value of unipolar radiofrequency guidance, established by previous studies. These new studies not only validate previous findings, but also identify optimal duration and placement of radiofrequency therapy at the tissue level, unlocking potential time savings and improved efficacy."

Topline findings from the three abstracts are below, highlighting how this new approach improves radiofrequency ablation techniques for atrial fibrillation treatment by reducing procedure time, maintaining accuracy, and enhancing precision.

Reducing procedure time
The first abstract, entitled "Unipolar Signal Modification-Guided Radiofrequency Ablation," conducted in swine and human models, found radiofrequency ablation guided by unipolar signal modification achieved identical transmural lesion dimensions for atrial tissue thickness less than three millimeters, with ablation time being significantly shorter (8 seconds) than ablation index-guided procedures (24 seconds).

Maintaining accuracy
The second abstract, entitled "Feasibility of Unipolar Signal Guided Ablation in Creating Contiguous Lines of Conduction Block: A Proof-of-Concept Study," demonstrated that unipolar electrograms accurately placed and spaced transmural lesions to prevent gaps, creating a successful bidirectional block in four of the five swine models. A single gap was left in the linear application of the fifth model due to a misinterpretation of the unipolar EGM during pacing. In this study, physicians were blinded to the 3D mapping system traditionally used to measure lesion location and spacing and relied entirely on unipolar morphology as seen on the PURE EP™ Platform.

Enhancing precision
The third abstract, entitled "Comparison of Unipolar Electrogram Monitoring during Radiofrequency Ablation in Viable and Ablated Myocardium: Loss of the S-component" showed that unipolar electrogram monitoring can differentiate between healthy and scarred tissue in both singular isolated lesions and contiguous lesions that constitute an ablation line. This information is critical to inform lesion placement in a clinical setting where the lesion diameter can vary based on the catheter orientation.

Currently, 14.4 million Americans suffer from cardiac arrhythmias. Atrial fibrillation, of which paroxysmal atrial fibrillation is a subtype, is the most common arrhythmia affecting as many as 6.1 million people in the US now and expected 8-12 million by 2050. Atrial fibrillation increases the risk of stroke 4 to 5-fold and contributes to ~750,000 hospitalizations per year. The direct cost of atrial fibrillation is approximately $6 billion annually; adding other indirect costs brings the total cost of atrial fibrillation to $26 billion.

The PURE EP™ Platform is a non-invasive platform designed to aid electrophysiologists in acquiring high-quality cardiac signals during electrophysiology (EP) procedures. It has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) and is currently in use at several hospitals in the United States.

About The PURE EP™ Platform
The PURE EP™ Platform is a unique combination of proprietary hardware and software that enables the real-time acquisition of raw signal data—absent of unnecessary noise or interference—allowing physicians to make informed clinical decisions based on clear and precise data. With the heightened visualization of active signals, the PURE EP™ Platform is facilitating personalized patient care and innovations in the field of electrophysiology. In a blinded clinical study recently published in the Journal of Cardiovascular Electrophysiology, electrophysiologists rated PURE EP™ as equivalent or superior to conventional systems for 93.6% of signal samples, with 75.2% earning a superior rating.

The PURE EP™ Platform is currently in a national commercial launch and an integral part of well-respected healthcare systems, such as Cleveland Clinic, Mayo Clinic, Texas Cardiac Arrhythmia Institute, and Kansas City Heart Rhythm Institute.

About BioSig Technologies, Inc.
BioSig Technologies is an advanced medical 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™ 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 global EP market is projected to reach $16B in 2028 with an 11.2% growth rate.

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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