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): August 22, 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 August 22, 2023, BioSig Technologies, Inc. (the "***Company***"), issued a press release, attached hereto as Exhibit 99.1, announcing the release of new software features for the PURE EP™ Platform. 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 August 22, 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: August 22, 2023

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

BioSig's PURE EP™ Platform Debuts New Automated Features in First Patient Cases

Latest Software Release Supports Electrophysiologists with Visualizing Heart Patterns Difficult to Recognize with the Naked Eye

Westport, CT, Aug. 22, 2023 (GLOBE NEWSWIRE) -- BioSig Technologies, Inc. (NASDAQ: BSGM) ("BioSig" or the "Company"), a medical technology company delivering unprecedented accuracy and precision to intracardiac signal visualization, announced today the release of new software features for the PURE EP™ Platform. The novel software features were successfully leveraged for the first time during patient cases conducted at the Kansas City Heart Rhythm Institute ("KCHRI").

Building on the FDA-cleared platform's proprietary combination of advanced hardware and software, PURE EP™'s latest software debuts two new features designed to harness the power of automation, empowering electrophysiologists to identify subtle details in cardiac arrhythmias that are difficult to observe with the naked eye. The new features include:

- **Near-Field Tracking (NFT)** automatically monitors changes in the local unipolar electrogram to provide real-time tissue feedback and characterization; helpful information for electrophysiologists as they make their final determinations between healthy and scarred tissue for lesion placement.

- **Automatic Tachycardia Characterization (ATC)** now alerts electrophysiologists in real-time to subtle changes in tachycardia conduction patterns, complementing its existing capability to monitor tachycardia rate changes that may warrant further evaluation.

"With these new features, we enhance PURE EP™'s existing capabilities, providing electrophysiologists with pure, unadulterated cardiac signals in real time," said Zachary Koch, Principal Advisor of Product Development at BioSig. "These latest features demonstrate our commitment to provide full-spectrum visibility and data analysis of intracardiac signals to enhance clinical decision-making."

The latest software upgrade builds on existing foundation of PURE EP™ proprietary features which include:

- **PURE ZONE™** visibility of intracardiac signals at high frequency and low amplitude, which provides valuable information for electrophysiologists on heart tissue characterization and localization.

- **High Frequency Algorithm (HFA)** automatically detects and eliminates radiofrequency interference (signal components >200 hertz), directing electrophysiologists' focus on what truly matters—vital intracardiac signals.

- **TRUSOURCE™** Analysis & Report for real-time detailed case insights.

Research initiated and led by Cleveland Clinic's world-class physician faculty was presented at this year's Heart Rhythm Society meeting. The findings validate PURE EP™'s ability to deliver clear, stable, trusted unipolar signals, suggesting the potential of an optimized radiofrequency technique to treat arrhythmias. The physician-initiated data revealed a 66% reduction in procedure time while maintaining accuracy, and enhancing precision.[1,2,3]

Given the mean cost of operating room time is approximately $37 per minute, PURE EP™ demonstrated potential cost savings of approximately $418.10 per procedure, per data presented at the Asia Pacific Heart Rhythm Society Scientific Session in 2022.[4] Considering electrophysiologists conduct an estimated 75,000 ablations annually in the U.S.,[5] PURE EP™, by extension, presents potential healthcare cost savings of over $30 million a year.

“PURE EP™’s capabilities have already been instrumental in improving our workflows,” said Dhanunjaya “DJ” Lakkireddy, M.D., Executive Medical Director at the KCHRI. “The incorporation of advanced features with PURE EP™ uphold our commitment to quality patient care while also introducing a higher level of automation, unlocking time efficiencies and more effective utilization of resources in laboratory procedures.”

With this latest software update, and the use of the NFT feature, additional reimbursement options are applicable when associated services are medically necessary. For more information on how PURE EP™ can enhance arrhythmia identification and laboratory workflows, visit BioSig.com.

About The PURE EP™ Platform

The PURE EP™ Platform serves physicians by enabling the real-time acquisition of raw cardiac signal data—absent of unnecessary noise or interference inherent in traditional approaches. By leveraging a first-of-its-kind combination of hardware and software, the PURE EP™ Platform is designed to deliver unprecedented intracardiac signal purity that pushes the boundaries of cardiac arrhythmia identification, diagnosis, and treatment.

In a blinded clinical study[6] recently published in the *Journal of Cardiovascular Electrophysiology*[6], electrophysiologists rated PURE EP™ as superior to conventional systems for 75.2% of signal samples, with 93.6% earning a rating of equivalent or superior. Data presented at Heart Rhythm Society 2023 demonstrated the PURE EP™ Platform’s capacity to facilitate ablations in a third of the usual time, reducing procedure time and improving workflow efficiencies, without sacrificing accuracy, precision, or efficacy.

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

About BioSig Technologies, Inc.

BioSig Technologies is a medical technology company focused on deciphering the body’s electrical signals, starting with heart rhythms. By leveraging a first of its kind combination of hardware and software, we deliver unprecedented cardiac signal clarity, ending the reliance on ‘mixed signals’ and ‘reading between the lines.’ Our platform technology is addressing some of healthcare’s biggest challenges—saving time, saving costs, and saving lives.

The Company’s product, the PURE EP™ Platform, an FDA 510(k) cleared non-invasive class II device, provides superior, real-time signal visualization allowing physicians to perform highly targeted cardiac ablation procedures with increased procedural efficiency and efficacy.

An estimated, 14.4 million Americans suffer from cardiac arrhythmias, and the global EP market is projected to reach $16B in 2028 with an 11.2% growth rate[7].

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.

References

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4. Gallinghouse, G.J., et al. (2022, November). PP-069-2-AF Reduced Time of Redo AF Ablation With PURE EP Recording System: A Randomized Study. Asia Pacific Heart Rhythm Society Scientific Session [Abstract]. Singapore. (55). https://tinyurl.com/BioSigAbstractAPHRS

5. Mansour, M., et al. (2017, February). The Impact of First Procedure Success Rate on the Economics of Atrial Fibrillation Ablation. JACC: Clinical Electrophysiology, 3(2), 129–138. doi: 10.1016/j.jacep.2016.06.002. https://pubmed.ncbi.nlm.nih.gov/29759385/

6. Al-Ahmad, A., et al (2021, September). Evaluation of a Novel Cardiac Signal Processing System for Electrophysiology Procedures: The PURE EP 2.0 Study. Journal of Cardiovascular Electrophysiology, 32(11), 2915–2922. https://doi.org/10.1111/jce.15250

7. Global Market Insights, Inc. (2022, March).

For media inquiries:
Katie Freshwater
BioSig Technologies, Inc.
Vice President, Marketing
55 Greens Farms
Westport, CT 06880
kfreshwater@biosigtech.com
203-409-5444, x162

For investor relations:
Andrew Ballou
BioSig Technologies, Inc.
Vice President, Investor Relations
55 Greens Farms
Westport, CT 06880
aballou@biosigtech.com
203-409-5444, x133