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): December 6, 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 RD Disclosure.

On December 6, 2023, BioSig Technologies, Inc. (the "Company") issued a letter to shareholders, which is attached hereto as Exhibit 99.1, providing highlights on the Company's recent developments and updates. 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	Shareholder Letter, dated December 2023 (furnished herewith pursuant to Item 7.01)

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: December 6, 2023

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

Exhibit 99.1

BioSig Technologies, Inc.
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Westport, CT 06880

LETTER TO SHAREHOLDERS

December 2023

Dear fellow shareholders,

As we approach the end of 2023, I want to share with you BioSig's important achievements of the past 12 months, showcase our strengths and strategies, address our challenges, and offer insights about the year ahead.

This year, we completed BioSig's business transition from a traditional medtech sales model with a technology enabling superior signal visualization, to a subscription-based commercial model with a cardiac care platform poised to make game-changing improvements in how electrophysiologists treat cardiac arrhythmia, a condition affecting more than six million Americans.

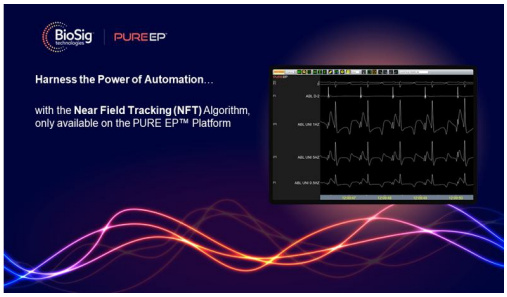
With our subscription service, we debuted new PURE EP™ software features, including unique algorithms that unlock signal data for electrophysiologists conducting even the most challenging ablation procedures. Since the launch of our version 7 (V7) software upgrade in August, two of the top three U.S. health systems in cardiology—Cleveland Clinic and Mayo Clinic—have subscribed to our technology.

Leveraging these successes, our primary goal for 2024 is to accelerate the adoption of our PURE EP™ Platform in existing and new target markets, driving multiple avenues of potential value creation.

OUR INNOVATION ENGINE

As part of V7, our new Near Field Tracking (NFT) technology alerts the physician when to ablate tissue and when to stop ablating tissue during an atrial fibrillation (AFib) procedure. To our knowledge, no other intracardiac signaling technology provider offers this level of innovation.

This functionality was developed in response to the needs communicated from leading electrophysiologists and physicians about next-level innovation for our system. This inspired our creation of V7 NFT technology, which guides a physician through an AFib procedure and prompts when to stop ablation to reduce risk for serious procedural complications. One such complication that EPs face is esophageal fistulas, a rare but lethal complication with a 70% mortality risk. We believe our technology could play a critical role in reducing and/or eliminating risk for such complications. With the highly-competitive and all-new inputs and features we have added, we expect V7 to be a significant growth lever for our PURE EP™ Platform sales and adoption strategies.



Based in part on our research findings, we believe that the NFT features can positively impact PURE EP™ Platform adoption around the country. Since the V7 launch in August, followed by subsequent improvements, we've found that the NFT features are resonating with a growing number of physicians at many leading hospitals due to the ease of use, effectiveness, time savings, and revenue-enhancing features—all designed to improve workflow during the diagnosis and catheter ablation treatment for AFib. Also, with this latest software update and the NFT features, additional reimbursement options may be applicable to hospitals when associated services are medically necessary.

DRIVING CLINICAL EXCELLENCE

Favorable clinical data helps drive product adoption. Data shows that our technology is well-positioned to drive clinical excellence.

Research initiated and led by Cleveland Clinic's world-class physician faculty was presented at this year's Heart Rhythm Society meeting. Our optimized ablation technique was tested in a pulmonary vein isolation (PVI) procedure, the most common catheter ablation treatment for AFib. The results highlighted the PURE EP™ Platform's ability to preserve raw signals that deliver real-time tissue feedback when conducting ablation, enabling physicians to perform certain aspects of the procedure in one-third of the time as conventional methods.

Researchers are expanding abstracts from this study into manuscripts for potential inclusion in leading scientific peer-reviewed publications. In addition, several investigator-initiated studies are in progress at other institutions that will be presented in the second half of 2024. We believe that the communication of this data, plus additional data from a pipeline of physician-initiated studies next year, will illuminate the unique benefits of the PURE EP™ Platform by way of high-profile conference presentations, peer-to-peer networking, and, most importantly, direct engagement with electrophysiologists and health centers.

A.I. COLLABORATION

This year, we advanced research and development for an artificial intelligence (A.I.) medical device platform through a majority-owned subsidiary, BioSig AI Sciences, Inc. (BioSig AI) which initially began in 2019 and was later paused during the pandemic. In July 2023, we closed a $2.2 million seed funding round for the subsidiary to support the development of this platform with certain collaborators.

The integration of A.I. and machine learning in electrophysiology (EP) devices is powering substantial expected growth for this market, and we intend to be a leader in developing applications of these technologies. BioSig AI's foundational machine learning model is based on integrated healthcare datasets, beginning with ECG and iECG data acquired by the PURE EP™ Platform. Electrophysiology-focused technological solutions developed under the terms of the collaboration may be integrated into our PURE EP™ technology for potential commercial application.

The market opportunity is significant. According to Data Bridge Market Research, the market for artificial intelligence in healthcare, estimated at $9.6 billion in 2022, is expected to reach nearly $273 billion by 2030, at a CAGR of 52% during the forecast period.[1]

ROBUST IP & MANUFACTURING

Our intellectual property is well protected. This year, we added five new patent awards, bringing our total number of patents to over 100. These include utility patents, worldwide design patents, and U.S. and foreign utility patent applications covering various aspects of the PURE EP™ Platform.

We also have licenses to 11 patents and nine worldwide utility patent applications pending from the Mayo Foundation for Medical Education and Research.

Additionally, we have one allowed and one pending patent for BioSig AI.

During the current quarter, we completed a manufacturing transition to Plexus, a world-class manufacturer that generates nearly half of its over $3 billion of revenues from well-known healthcare and life sciences customers. We're confident that Plexus will be able to support future demands for the PURE EP™ Platform.

FINANCING AND CAPITAL ALLOCATION

As an early–stage commercial company, we rely on the capital markets to fund our operations. With broad market instability and economic uncertainty over the past two years, the constrained funding environment has been incredibly challenging for early commercial-stage companies like BioSig.

Medtech equity financing declined 27% last year, its lowest point in seven years according to Ernst & Young, and a recent JPMorgan analyst research report states that medtech trading this year is at the lowest levels of sentiment since the Great Recession in 2008 and 2009.[2] The challenges for BioSig are real.

Despite these headwinds, over the past 12 months, BioSig has raised over $20 million, primarily through private placements of our securities and a recent registered direct offering.

We are working hard to prioritize fundraising and capital allocation for commercial expansion and innovation in order to deliver durable returns. We are committed to the conscientious use of capital to ensure funding for expanded commercialization, and we are strategic about cost savings, especially in this current economy.

COMMITMENT AND VISION

While we are disappointed in the market valuation of our Company and performance of our stock this year, we remain deeply committed to improving shareholder value through operational success. BioSig's senior management and employees are all shareholders like you and share the interest in durable returns.

2023 brought multiple new business leaders to our management team and our board who have delivered substantive contributions to our business operations and strategies. We believe our software belongs in every EP lab, and we are making every effort to realize our belief.

BioSig's capacity for innovation is stronger than ever, and we believe our opportunities for sustainable growth are achievable. With sound execution around our ramp-up of commercial placements and a sharp focus on building relationships and brand awareness, we expect to deliver significant progress in the year ahead.

As always, we greatly appreciate your interest and valued support of our mission to disrupt and uplift the industry's standard for cardiac care.

Sincerely,

Kenneth L. Londoner, Chairman & CEO

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[1] Data Bridge Market Research. Global Artificial Intelligence in Healthcare Market – Industry Trends and Forecast to 2030. January 2023.

[2] Ernst & Young (EY), *Pulse of the Industry* medical technology report 2023

SAFE HARBOR DISCLOSURE

This shareholder letter 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. Such statements include, but are not limited to, the intended use of proceeds from the registered direct offering. 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; (vi) difficulties in securing regulatory approval to market our products and product candidates; and (vii) market and other conditions. 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 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.
