# **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): September 14, 2020

# **BioSig Technologies, Inc.**

(Exact name of registrant as specified in its charter)

001-38659

**Delaware** (State or other jurisdiction of incorporation)

(Commission File Number)

26-4333375 (IRS Employer Identification No.)

54 Wilton Road, 2nd Floor Westport, Connecticut (Address of principal executive offices)

06880 (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  $\Box$ 

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.

#### Item 7.01 Regulation FD Disclosure.

On September 14, 2020, BioSig Technologies, Inc. (the "Company") issued a press release, attached hereto as Exhibit 99.1, announcing that the Company will host a call and webcast to discuss the results from the first randomized, blinded signal sample analysis in the PURE EP 2.0 Clinical Study on Tuesday, September 15, 2020 at 11:00 AM Eastern Time. Also on September 14, 2020, the Company issued a press release announcing that the Company's abstract for '*Computational Reconstruction of Electrocardiogram Lead Placement*' was accepted for presentation at the 2020 Computing in Cardiology Conference (CinC). The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1 and Exhibit 99.2.

On September 15, 2020, the Company issued a press release, attached hereto as Exhibit 99.3, announcing that a scientific abstract and poster, titled 'A novel cardiac signal processing system for electrophysiology procedures: early insights from the PURE EP 2.0 study," is available electronically from August 30, 2020 at the ESC Congress 2020 – The Digital Experience. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.3.

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 Exhibits 99.1, 99.2 and 99.3, 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 September 14, 2020
99.2	Press Release, dated September 14, 2020
99.3	Press Release, dated September 15, 2020
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.

Date: September 15, 2020

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



Reminder: BioSig to Host Conference Call and Webcast on September 15, 2020 to Discuss Unblinding of PURE EP Human Data

Westport, CT, Sept. 14, 2020 (GLOBE NEWSWIRE) --

- Peer-reviewed, blinded, randomized data recently presented at ESC Congress 2020
- Commercial market update discussion
- Presentation to include webcast

Westport, CT, September 14, 2020 — BioSig Technologies, Inc. (Nasdaq: BSGM) ("BioSig" or the "Company"), a medical technology company developing a proprietary biomedical signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals, today announced it will host a call and webcast to discuss the results from the first randomized, blinded signal sample analysis in the PURE EP 2.0 Clinical Study. The data was generated during atrial fibrillation ablation procedures conducted at St. David's Medical Center, Austin, Texas.

## **Conference Call Details:**

Date: Tuesday, September 15, 2020 Time: 11:00 AM Eastern Time (ET) Dial in Number for U.S. Callers: 1-877-407-8293 Webcast link: <u>https://event.webcasts.com/starthere.jsp?ei=1369137&tp\_key=cbdbc3a4b8</u>

A replay will be available for two weeks starting on September 15, 2020, at approximately 3:00 PM ET. To access the replay, please dial 877-660-6853 in the U.S. The conference ID# is 13709732.

On August 04, 2020, <u>BioSig announced</u> that the Company installed its PURE EP(tm) System at Massachusetts General Hospital (MGH) as part of an expanding clinical study. "The PURE EP(tm) System evaluation and data collection at MGH will commence under the leadership of investigator Moussa Mansour M.D., Director of MGH's Cardiac Electrophysiology Laboratory and Atrial Fibrillation Program."

# 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 (<u>www.biosig.com</u>).

The Company's first product, PURE EP(tm) 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," "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) 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 soluting 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.

Andrew Ballou BioSig Technologies, Inc. Vice President, Investor Relations 54 Wilton Road, 2nd floor Westport, CT 06880 aballou@biosigtech.com 203-409-5444, x133



# BioSig Announces Abstract Acceptance to Computing in Cardiology 2020

# Westport, CT, Sept. 14, 2020 (GLOBE NEWSWIRE) --

- Novel algorithm can successfully reconstruct ECG lead placements
- The method may improve the automated classification of patient conditions and unlock new applications of clinical value

BioSig Technologies, Inc. (NASDAQ: BSGM) ("BioSig" or the "Company"), 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, today announced that the Company's abstract for '*Computational Reconstruction of Electrocardiogram Lead Placement*' was accepted for presentation at the 2020 Computing in Cardiology Conference (CinC).

The abstract was co-authored by Dr. Alexander D. Wissner-Gross of Reified LLC, Dr. Suraj Kapa of the Mayo Clinic, James Lee, Natasha Drapeau, and Kenneth L. Londoner of BioSig Technologies, Inc. The manuscript presents a method for computationally reconstructing the spatial placement of electrocardiogram (ECG) leads using only correlations between their recorded signals and without requiring external calibration or other prior knowledge. The work further examines the association of various cardiac abnormalities with the reconstructed geometries and reviews potential clinical applications of the method.

"We are encouraged by the early successes that Alex and his team have demonstrated in developing machine learning solutions for PURE EP(tm). From early disease detection to more accurate diagnosis to improved decision making during treatment, the transformative potential of artificial intelligence and machine learning in healthcare is vast. We are excited to report on our progress during the CinC 2020 and look forward to exploring further clinical applications through novel AI-powered algorithms," commented Kenneth L. Londoner, Chairman and CEO of BioSig Technologies, Inc.

"We found that electrophysiological waveforms could encode a surprising amount of spatial information about the context in which they were recorded and look forward to translating this and other advanced biomedical signal analytics into clinical usage," added Dr. Wissner- Gross.

CinC 2020 takes place on September 13-16, 2020, in a hybrid of live and <u>online sessions</u>, in Rimini, Italy. The Company's abstract will be presented virtually by Dr. Alexander D. Wissner-Gross, on Tuesday, September 15, from 15:45-17:45 Central European Time (09:45 - 11:45 Eastern Time).

Please view the CinC 2020 program usingthis link.

In December 2019, the Company announced that it<u>partnered</u> with Cambridge, Massachusetts-based Reified LLC, a provider of advanced artificial intelligence-focused technical advisory services to the private sector. Initial machine learning and AI solutions developed under the terms of this collaboration are focused on BioSig's core competencies in electrophysiology.

# About Computing in Cardiology

CinC provides a forum for scientists and professionals from the fields of medicine, physics, engineering, and computer science to discuss their current research on topics about computing in cardiology and cardiovascular physiology.

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# BioSig Releases PURE EP Study Abstract with Data Presented at European Society of Cardiology's 'ESC Congress 2020'

Positive responses confirm that the PURE EP signals are preferred to conventional sources of intracardiac signals in a blinded, independent analysis. Abstract concludes PURE EP<sup>TM</sup> System is able to produce reliable and high-quality signals when compared to the available standard of care systems.

Westport, CT, Sept. 15, 2020 (GLOBE NEWSWIRE) -- BioSig Technologies, Inc. (NASDAQ: BSGM) ("BioSig" or the "Company"), a medical technology company developing a proprietary biomedical signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals, today announced a scientific abstract and poster entitled, "A novel cardiac signal processing system for electrophysiology procedures: early insights from the PURE EP 2.0 study" is available electronically from August 30th at the ESC Congress 2020 – The Digital Experience.

The abstract is co-authored by Carola Gianni, M.D., Amin Al-Ahmad, M.D., Shane M. Bailey, M.D., G. Joseph Gallinghouse, M.D., Rodney P. Horton, M.D. and Andrea Natale, M.D. of the Texas Cardiac Arrhythmia Institute (TCAI) at St. David's Medical Center in Austin, TX. The independent, blinded reviewers were Bradley P. Knight, M.D. (Northwestern University), Wendy Tzou, M.D. (University of Colorado), and Pasquale Santangeli, M.D. (University of Pennsylvania).

Identical electrocardiographic and intracardiac signal data were recorded during 15 atrial fibrillation ablation procedures from the PURE EP<sup>TM</sup> System, the signal recording system, and the 3D mapping system. The collected signals underwent blinded, controlled evaluation by three independent electrophysiologists to determine whether the PURE EP<sup>TM</sup> signals are a viable alternative to conventional sources and if it provides additional or clearer diagnostic information. Reviewers were asked to record the quality of each signal sample on a scale of 1-10 and select a rationale for their rating in a dropdown menu.

Based on the ratings for each pair of signals, a cumulative total of 29 PURE EP<sup>TM</sup> signals out of 34 (85.3%) were rated as statistically equivalent or better for this dataset. In 35.5% of samples, the reviewers selected PURE EP<sup>TM</sup> data because "more signal components were visible." The abstract concludes that the PURE EP<sup>TM</sup> System is able to produce reliable and high-quality signals when compared to the available standard of care systems.

"BioSig Technologies is very pleased to see some of the early results from the PURE EP<sup>™</sup> study shared during ESC 2020. We greatly appreciate the scientific collaboration with the team at TCAI and the independent EP reviewers. The PURE EP<sup>™</sup> study is on-going, and we look forward to sharing multi-center data with the EP community in the coming months," commented Julie Stephenson, VP of Clinical Affairs at BioSig Technologies, Inc.

Exceptionally, this year, the online event is available at no charge, but pre-registration is required: <u>Register for the ESC Congress</u> 2020 – The Digital Experience

# About ESC Congress 2020

The European Society of Cardiology (ESC) is an independent, non-profit organization. Its members and decision-makers are busy healthcare professionals who volunteer their time and expertise. The ESC represents more than 95,000 men and women in the field of cardiology from Europe, the Mediterranean Basin, and far beyond. Due to the COVID-19 pandemic, the government in the Netherlands has banned all meetings until September 1. As Amsterdam was to be the host city, it is no longer possible for ESC Congress to take place as planned. However, the ESC remains committed to delivering practice-changing science to the cardiology community and looks forward to bringing you 'ESC Congress 2020 - The Digital Experience'.

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