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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d) of the**  
**Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): February 23, 2021

**BioSig Technologies, Inc.**

(Exact name of registrant as specified in its charter)

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

**001-38659**  
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
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. ☐

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**Item 7.01 Regulation FD Disclosure.**

BioSig Technologies, Inc. (the “*Company*”) intends, from time to time, to present, utilize, and/or distribute to the investment community and utilize at various industry and other conferences, a slide presentation, which is attached hereto as Exhibit 99.1. 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	<a href="#">Corporate Presentation, Winter 2021 (furnished herewith pursuant to Item 7.01)</a>
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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## **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: February 23, 2021

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



Corporate Presentation  
Winter 2021

NASDAQ : BSGM

# Disclaimer

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This presentation contains forward-looking statements including statements that address activities, events or developments that BioSig expects, believes or anticipates will or may occur in the future, such as predictions of financial performance, approvals and launches by BioSig of new products, market acceptance of BioSig's products, market and procedure projections, financing plans, and related documents. Forward-looking statements are based on BioSig's experience and perception of current conditions, trends, expected future developments and other factors it believes are appropriate under the circumstances and are subject to numerous risks and uncertainties, many of which are beyond BioSig's control.

These risks and uncertainties include the timing of approvals for BioSig products, rate and degree of market acceptance of products, BioSig's ability to develop and market new and enhanced products, the timing of and ability to obtain and maintain regulatory clearances and approvals for its products and the impact of failure to obtain such clearances and approvals on its ability to promote its products and train doctors and operators in the use of its products, the timing of and ability to obtain reimbursement if required of procedures utilizing BioSig's products and the potential impact of current healthcare reform initiatives thereon, competition from existing and new products and procedures or BioSig's ability to effectively react to other risks and uncertainties described from time to time in BioSig's SEC filings, such as fluctuation of financial results, reliance on third party manufacturers and suppliers, litigation or other proceedings, government regulation, negative publicity, current worldwide economic conditions and share price volatility.

BioSig does not guarantee any forward-looking statements, and actual results may differ materially from those projected. Unless required by law, BioSig undertakes no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.



## Who We Are – NASDAQ: BSGM

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- EP Tech Market 13.5% CAGR
- Global EP Market Expected to be \$12.2 Billion by 2026\*
- 31 Patents Issued
- First Customer is #1 Center by Volume in U.S.
- Razor & Blade Business Model
- FDA Approved
- Unblinding of clinical data in 2021



Data source: MarketWatch Global Electrophysiology Device Market  
Could Exceed \$12.2 Billion By 2026

SYMBOL: BSGM

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# PURE EP™ Developed Through Collaboration with Leading Centers

Relationships at leading, high-volume centers create traction for PURE EP™ in the market

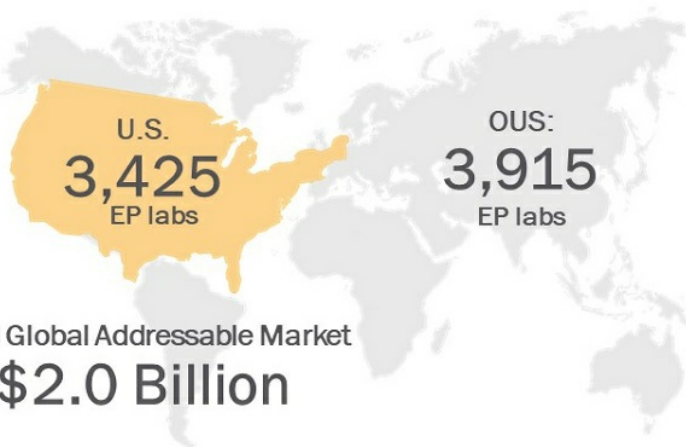




## Global EP Procedures Growing Rapidly

Cardiac Ablation Procedures Are Key Hospital Revenue Drivers

Complex Cardiac Ablation:  
**13.5% Growth Rate**



Total Global Addressable Market  
**\$2.0 Billion**



Published by Cardiovascular Rounds, Guggenheim Analyst – Chris Pasquale  
Data source: 2018 MD&D report Advisory Board and BioSig Technologies, Inc. estimates.

SYMBOL: BSGM

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# EP During COVID-19

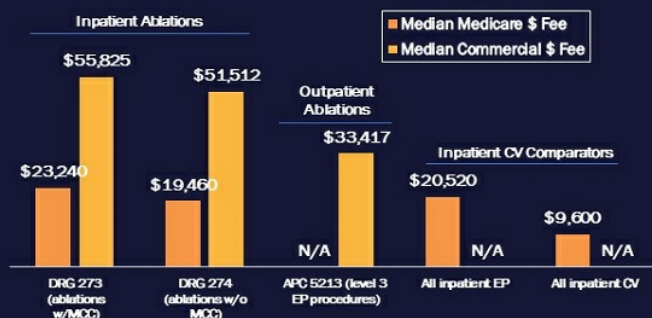
## EP procedures are clinically urgent

- Delaying procedure increases stroke risk and worsens outcomes

## EP procedures are revenue generating

- CV surgery and invasive cardiology have the highest net annual revenue compared to all other service lines

Median Revenues Per Case For Ablation and Select EP Procedures



## Reimbursement rates continue to increase

- From 2019 to 2020 ablations and LAAO (DRG 274) had a reimbursement rate increase of 8.8%

CMS Reimbursement Changes From FY 2019 to FY 2020

Procedure	Reimbursement Rate Change
<b>Inpatient</b>	
All inpatient services	2.5%
<b>Ablations and LAAO (DRG 274)</b>	<b>8.8%</b>
Pacemaker implant (DRG 244)	0.9%
ICD implant (DRG 227)	0.9%
<b>Outpatient</b>	
All outpatient services	2.6%
Ablations (APC 5213)	6.3%
Pacemaker implant (APC 5223)	3.8%
ICD implant (APC 5232)	5.3%



\*Data Source: Advisory Board, Published by Cardiovascular Rounds

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# PURE EP™ System – Customer Installations



Hospital of the  
University of Pennsylvania



Texas Cardiac Arrhythmia Institute



SYMBOL: BSGM

# Challenges in EP For All Procedures

*Physicians Can't Fix What They Can't See*

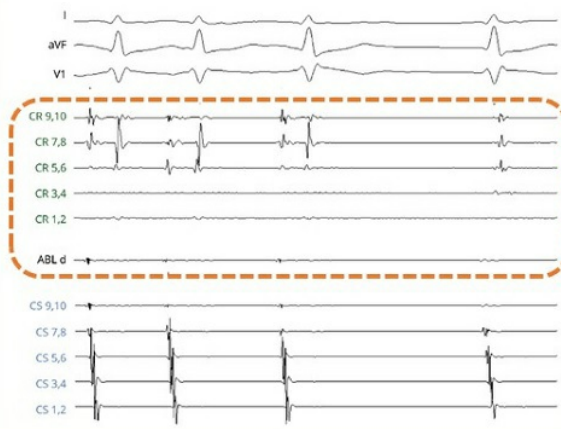
**Signal Quality**  
81% of physicians rated  
signal quality as "Critical"

**Success Rate**  
20 - 40% of ablations are  
unsuccessful

## PURE EP



## Control



Data source: PUBMED 11/2017 and Healthwise and the University of Michigan, 12/15/2019.

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# Expanded Product Adoption, Experience, and a Growing Database

# PURE EP Procedures by Account	
TCAI (TX)	266
Mayo JAX (FL)	103
Penn (PA)	70
MGH (MA)	13
Deborah (NJ)	54
Overland Park (KS)	31
Memorial (IN)	13
EE 1 cases (4 ctrs)	20
<b>TOTAL</b>	<b>570</b>

\*Data as of Feb. 19, 2021 w a lag in some reporting  
 \*COVID shutdown Mar 12 - May 3  
 \*Diagnosis was not logged for all procedures

# Physician Users	
TCAI	10
Mayo	3
Penn	12
MGH	1
Deborah	2
Overland Park	4
Memorial	2
Other EE Ctrs	4
<b>TOTAL</b>	<b>38</b>

Diagnosis		Diagnosis	
Persistent AF	150	Atypical Flutter	11
Paroxysmal AF	176	Atrial Tachycardia	7
PVC	70	AVNRT	10
Ischemic VT	18	Typical Flutter	8
Nonischemic VT	14	AVRT/WPW	5



# Our Clinical Path

PURE EP™

## PRE-CLINICAL STUDIES

- 23 studies
- Mayo Clinic, Mount Sinai, University of Pennsylvania
- Published peer reviews in leading journals

## FIRST-IN-HUMAN CASES

- 21 patients
- TCAI, Greenville Memorial Hospital, University of Indiana
- Results shown improved signal fidelity



## CLINICAL TRIAL

- >500 patients cases conducted to date with >60 patients enrolled in the trial
- TCAI, Mayo Clinic FL, and Mass General
- Independent signal review is randomized and blinded
- Data expected to be presented in leading peer-reviewed publications



# Clinical Data PURE EP™ 2.0 Studies

- *The Primary Aim: to further establish the safety and effectiveness of the PURE EP™ System.*
- *The Secondary Aim: to assess the quality and clinical relevance of the PURE EP™ System's signals when compared to other sources of intracardiac signals.*

## Stage 1: COMPLETE

- 32 samples, single center
- Only Afib Ablations
- A blinded, independent analysis confirmed that the PURE EP™ system's signals are preferred to conventional sources
- Key Finding - 36% of the time PURE EP™ provides important additional signal components

## Stage 2: UNDERWAY

- 138 samples, multi-centered
- All Ablation Types
- Currently undergoing blinded, independent analysis
- Q1/21 - Submission of abstract and manuscript (expected)
- Q3/21 - Expected unblinding and dissemination of the results

# Physician Testimonies



"The PURE EP System does provide innovative design with greater resolution and greater bandwidth, which should allow for safer and more efficacious ablations in the future."

- K. Venkatachalam, M.D., *Cardiac Electrophysiologist, Mayo Clinic*



"The quality of the recording that we can get in the lab can make a big difference [during the procedure]. . . The PURE EP System clearly gave us better quality of intracardiac recording [compared to conventional systems.]"

- Andrea Natale, M.D., *Texas Cardiac Arrhythmia Institute*



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# Commercialization – Regions and Centers of Excellence



**Florida**  
120 EP Programs  
240 Labs

**Texas**  
220 EP Programs  
440 Labs

**Northeast**  
175 EP Programs  
400 Labs

**Revenue Potential**  
**\$286 Million**

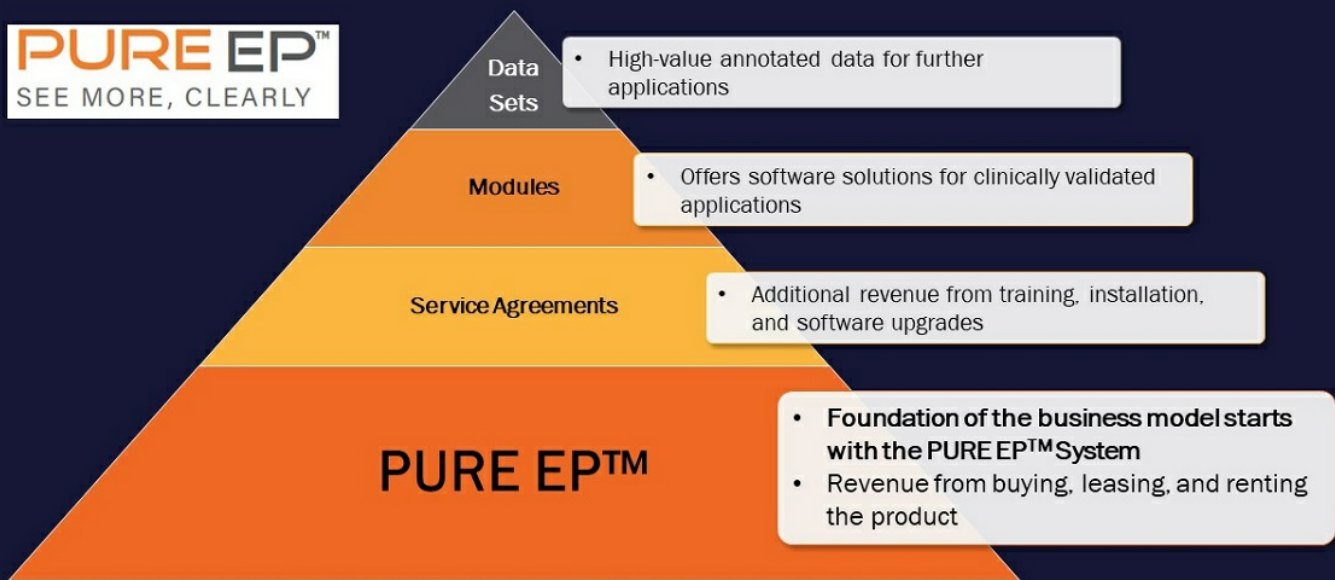


Source: Industry data and BioSig Technologies, Inc. estimates.

SYMBOL: BSGM

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# Business Model



# Unique Collaboration with Mayo Clinic

- 10-year strategic agreement
  - Collaboration on technology development
  - Joint IP filings
  - Licensing opportunities
  - Mayo Clinic has invested capital in the development of the PURE EP™ System
  - New R&D program to develop transformative AI and machine learning for PURE EP™
- First PURE EP™ System installed at Mayo Clinic in Florida in January 2020



# Strong IP Portfolio

31 allowed/issued worldwide design and utility patents, which cover various features of the PURE EP™ System's display screens and graphical user interface for enhanced visualization of biomedical signals



Differentiated combination of hardware and software is supported by strong IP and serves as the main competitive advantage over competing systems

Sherpa Technology Group and Sterne Kessler Goldstein & Fox are effectively developing patent and IP strategy

Conducted a thorough Landscape Review to understand ability to successfully file patents

BioSig is an exclusive licensee of Mayo Clinic to several patents and applications covering software features of PURE EP™ and additional complementary technologies

All patents and applications are assigned or exclusively licensed to the company

## Value Drivers

- Raised \$41 million in 2020
- \$32 million in cash on the balance sheet and no debt
- Achieved first commercial contract 4Q20
- Expect to triple the customer base in 2021
- Expect sequential revenue growth in 2021
- Expect CE mark approval / EU entry 2022



 **Nasdaq: BSGM**



# Management Team



**Kenneth L. Londoner, MBA**  
 Founder, chairman, CEO, Director  
 Neuroclear Technologies; Endicott Management Partners;  
 J & W Seligman & Co.



**Natasha Drapeau**  
 Executive Vice President  
 Neuroclear Technologies; Alliance for Advancing Bioelectronic Medicine;  
 Institute of Directors, UK; IG Group Plc, UK



**Barry Keenan, Ph.D., MBA, PMP**  
 Vice President, Engineering  
 Medtronic; Nexon MedSystems; Alfred Mann Institute for Biomedical Engineering;  
 Alfred Mann Foundation for Scientific Research



**Todd Wiltshire**  
 Senior Vice President, Corporate Development  
 Fidelity Investments; Credit Agricole; UBS; Morgan Stanley



**John Kowalski**  
 Vice President, Sales  
 Biosense Webster (Johnson & Johnson)



**Olivier Chadoir**  
 Senior Director, Marketing  
 Biosense Webster; DePuy Synthes



**Steve Chaussy, CPA**  
 CFO  
 Neuroclear Technologies; Libeski Inc; Anna & Co; Penske Automotive;  
 Ford Hogg and Cobbe



**Brenda Castrodad**  
 Director of Human Resources  
 TissueTech, Inc.; HeartWare, Inc.; Schering-Plough Corp



**Andy Ballou**  
 Vice President, Investor Relations  
 Janney Montgomery Scott; RBC Capital Markets



**Julie Stephenson, BSN, MBA**  
 Vice President, Clinical Affairs  
 Medtronic; Boston Scientific; Guidant Corporation



**Manasi Patwardhan**  
 Director of Strategic Planning; Verily Life Sciences; Boston  
 Scientific- Neuromodulation; Medtronic

