# 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): April 28, 2023

# **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.)

55 Greens Farms Road, 1st Floor <u>Westport, Connecticut</u>

(Address of principal executive offices)

<u>06880</u> (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.

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 and corporate summary, which are attached hereto as Exhibits 99.1 and 99.2, respectively. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibits 99.1 and 99.2.

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 and 99.2, 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

99.1 Corporate Presentation dated April 2023 (furnished herewith pursuant to Item 7.01)	
99.2 Corporate Summary dated April 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

### **BIOSIG TECHNOLOGIES, INC.**

Date: April 28, 2023

By: /s/ Kenneth L. Londoner

Name: Kenneth L. Londoner Title: Executive Chairman



# **Corporate Presentation**



# **BioSig forward-looking statements**

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.



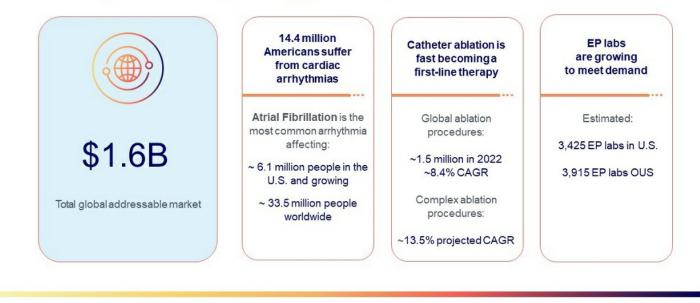


# Reimagining what's possible in cardiac care

We are 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, our technology delivers unprecedented cardiac signal clarity, ending the reliance on *mixed signals* and *reading between the lines*.

# Growing into an expanding global market



BioSig

Data source: Market/Watch Global Electrophysiology Device Market Could Exceed \$12.2 Billion By 2028. Definitive Healthcare, U.S. News & World Report, Newsweek, and BioSig estimates

# Presenting the PURE EP<sup>™</sup> Platform



BioSig

# Supporting our clinical profile with data and economic value



2 Galinghouse, G. Joseph, Natale, Andrea: Al-Akmad, Amin: Della Rosa, Domenico Giovanni: Jones, Sterling: Firmstone, Samantha: Lewen, Jason. (2022). Time of Redo Atrial Fibrillation Ablation Procedures with PURE EP Recording System for ECG/EGM Yavalization: A Randomized Study. Paper presented at APHRS 2022 Singapore: The 15th APHRS Scientific Session (197-095-2AF (55)). Identifier: <u>NCT04694440</u>.
3. Chuddik, R., Dittel, D., Stoneman, L., Thording, L. Why Hospital Laskers Should Look to Cardiology for Sustained Future Reprocessing Savings. (2018, April 25). Innovative Health. <u>https://blog.innovative-health.com/blog.</u>

# Integrating into EP labs for improved efficiency



PUREEP"

PURE EP™ delivers unprecedented clarity of the raw electrical signals of the heart, unburdening physicians from having to parse through interference of outputs from conventional technology–an on-going problem in EP labs.



# Accelerating commercialization of the PURE EP<sup>™</sup> Platform



# **Current footprint**





BioSig

# "Having high-quality, better signals makes a difference in almost every case. Since we installed the system in our lab, the efficiency in which we operate has significantly improved."

~Dhanunjaya DJ Lakkireddy, MD

Kansas City Heart Rhythm Institute, Overland Park, KS Complex AF Case Study Utilizing a New Standard in Signal Processing





# Led by strong industry experience



Kenneth L. Londoner, MBA Founder, Chairman, Chief Executive Officer, Director Endicott Management Partners; J & W Seligman & Co.; Visiting Professor, Columbia University



Gray Fleming Chief Commercial Officer St. Jude Medical; Abbott Laboratories



**Steve Buhaly** Chief Financial Officer Qorvo; Longview Fibre; Planar System



BioSig

John Sieckaus Chief Operating Officer St. Jude Medical; Abbott Laboratories



**Brenda Castrodad** VP, Human Resources TissueTech, Inc.; HeartWare Inc.

# Maintaining well-protected IP

# 59

Utility and Design Patents Granted/ Allowed in the Field of Digital Signal Processing



Worldwide Fundamental Patents Granted/Allowed



Pending Applications in the U.S.



Worldwide Design Patents Granted/Allowed

8

Pending Applications in Europe

As of April 25, 2023. This includes applications/patents exclusively licensed from May Foundation for Medical Education and Research



Pending Applications in APAC

# Why BioSig now?



### The solution

Solving the critical unmet need for better intracardiac information that may improve success rates of ablation procedures.



# Disruptive and novel technology

Our technology saves procedural time and improves workflow efficiency in an environment where the technology has not changed meaningfully in 25+ years.



# Substantial and growing global market

Global EP market is growing by 11.2% and expected to reach \$16B by 2028.



# Strong clinical data pipeline

Published/ongoing clinical studies supporting commercialization.



## First customers are industry leaders

World-renowned Medical Centers of Excellence.



### Flexible pricing model Supports recurring revenue and continuous innovation.



Fortune 500 commercial team Proven track-record of generating sales growth.



# Well-protected IP portfolio

59 Worldwide fundamental patents granted/allowed.



"Global Market Insights Inc. March 08, 2022

# **Upcoming Events**

### New Customer announcements\*

U.S. product acquisitions and expansion of footprint.

### Participation at Heart Rhythm 2023 in New Orleans May 19-21

The largest gathering of heart rhythm professionals from around the world.

### Release of Clinical Data May 2023\*

Multiple abstracts have been accepted for presentation at Heart Rhythm 2023.

### Software rollout Spring 2023, Fall 2023 and 2024\*

Commitment to continuous feature innovation.



\* Expected.

# **Key References**



Optimizing signals in the EP lab Amin Al-Ahmad, MD (Cardiac electrophysiologist - St. David's Medical Center - Texas Cardiac Arrhythmia Institute, Austin, TX – USA) – Great Debates and Updates in EP - March 2022. <u>Click here to open</u>

Complex AF case study utilizing a new standard in signal processing Dnannjay Lakkireddy. MO (Executive Medicial Director, Kansas City Heart Rhythm Institute, Overland Park, KS - USA) – January 2022 -27th Annual International AF Symposium Dhanunjay Lakkired 27th Annual Interna Click here to open

Incorporating advanced intracardiac signal information Into the clinical workflow G. Joseph Gallinghouse, MD (Texas Cardiac Arrhythmia Institute, «Austin, TX – USA) – December 2021 - <u>Click here to open</u>

PURE EP™ - from clinical data to clinical applications Viendy Tzou, MD (University of Colcieda Denver, CO.), Andres Natale, MD and Amin Al-Ahmad, MD (Cardiac electrophysiologists - St. David's Medical Center - Texas Cardiac Arrhythmia Instituta, Austin, TX – USA) – Live Roundtable Webinar – Nov. 2021. Click here to open

Evaluation of a novel cardiac signal processing system for electrophysiology procedures: The PURE EP 2.0 Study - Al-Ahmad A, Knight B, TzouW, et al. - J CardiovascElectrophysiol. 2021;32(11):2915-2922. Epub 2021 Oct 1. doi: 10.1111/joe.15250. <u>Click here to open</u>

PURE EP<sup>™</sup> - a new standard in signal processing Amin Al-Ahmad, MD (Cardiacelectrophysiologist - St. David's Medical Center - Texas Cardiac ArrhythmiaInstitute, Austin, TX – USA) – KC HRS 2021 - August 2021. Click here to open

From clinical data to clinical applications Christopher McLeod, MB, ChB (Cardiace lectrophysiologist – Mayo Clinic - Jacksonville, FL – USA) – HRS 2021 – Non-CME Satellite Symposium - July 2021 - <u>Clinic here to open</u>

The evolution of intracardiac signal acquisition and processing in today's EP lab environment - Interview with AminAl-Ahmad, MD (Cardiacelectrophysiologist - St. David's Medical Center - Texas Cardiac Arrhythmia Institute, Austin, TX – USA) – Great Debates & Updates in Electrophysiology - April 2021. - <u>Click here to open</u>

Improved intracardiac signal visualization during cryp and RF procedures Deepak Gaba, MD (Cardiac electrophysiologist – Memorial Hospital, South Bend, IN – USA) - April 2021, shares his views on how the PURE EPT<sup>®</sup> System can help be more efficient and/ow high-facility signals can improve cirrical outcome - <u>Click here to open</u>

Benefits of the PURE EP™ System in Identifying and interpreting low amplitude signals G. Joseph Gallinghouse, MD (Texas Cardiac Arrhythmia Institute, - Austin, TX – USA) – January 2021 - 26th International Annual AF Symposium Hyperlink to access resources: <u>Click here to open</u>

Further optimizing electrogram signal quality in the EP lab Bradley P. Knight, ND, FACC, FHRS (Professor of Medicine and Director of EP - Northwestern University, Chicago, IL - USA) – January 2021 - <u>Click here to open</u>)

Advanced signal acquisition help drive procedural efficiency and efficacy Raffaele Corbitero, MD, EPS and Padram Kazamian, MD (Deborah Heat and Lung Center, Browns Milb, New Jersey – USA) EP Lab Digest - Decomber 2020: <u>Click here to coan</u>

VT in NICM by Pasquale Santangeli, MD, PhD - University of Pennsylvania Health System, Philadelphia, PA - USA - November

2020 Hyperlink to access resources: Click here to open

PURE EP case review on how high-fidelity intracardiac signals can help visualize conduction pathways faster - Andrea Natale, ND, FACC - Austin, TX – USA – September 2020 - <u>Click here to open</u>

ESC 2020: A novel cardiac signal processing system for electrophysiology procedures: early insights from the pure ep 2.0 study - <u>Click here to open</u>

Cardiac signal acquisition and clinical considerations for accurate interpretation Samuel J. Asinstham, MD (Mayo Clinic, Rochester, Minmeota, USA) and K. L. Venkatachalam, BSEE, M.D. (Mayo Clinic, Jacksonville, FL, USA). HRS Science 2020–June 12, 2020.

Click here to open

Cardiac signal acquisition and clinical implications of applying filters Samuel J. Asinvatham, MD (Mayo Clinic, Rochester, Minnecota, USA) and K. L. Vankatachatam, BSEE, M.D. (Mayo Clinic, Jacosonville, FL, USA). HRS Science 2020–July 1, 2020

Click here to open

PURE EP™ is addressing oritical unmetneeds - frequency bandwidth and linear signal acquisition Dr Veniatachalam's presentation (Mayo Clinic, Jacksonville, FL - USA) – May 2020-Stanford Biodesign New Arrhythmia Technologies Reterat\_Clinic Area to open

Shaping the future of EP through advanced signal processing and analysis Andrea Natale, MD, FACC (St David's Medical Center, Austin, TX – USA) and Matthew Dare, CEPS – April 2020 - <u>Click here to</u> open





# **Contact us**

Andy Ballou VP of Investor Relations aballou@biosigtech.com 203-409-5444, x133

BioSig Technologies, Inc. 55 Greens Farms Road Westport, CT 06880

www.biosig.com





**BioSig Technologies, Inc. (NASDAQ: BSGM)** 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, BioSig delivers unprecedented cardiac signal clarity, ending the reliance on *mixed signals* and *reading between the lines*. The Company operates within the rapidly growing electrophysiology (EP) marketplace—a market projected to reach \$16B by 2028 with an 11.2% growth rate.\*

BioSig's first product, the PURE EP™ Platform, is an FDA 510(k) cleared noninvasive class II device, that removes the unnecessary distractions, noise, and signal interruptions inherent in traditional approaches to capturing cardiac signals preserving access to the full-spectrum of raw signal data and delivering clear actionable insights that can be explored for highly-tailored, efficient procedures in the treatment of arrhythmias.

The PURE EP<sup>TM</sup> Platform is already an integral part of many well-respected healthcare systems, including Mayo Clinic, Texas Cardiac Arrhythmia Institute, Cleveland Clinic, and Kansas City Heart Rhythm Institute.

**BioSig Technologies, Inc.** 55 Greens Farms Road Westport, CT 06680 www.biosigtech.com info@biosigtech.com

#### Kenneth L. Londoner

CEO, Co-Founder, Chairman BioSig Technologies, Inc. Phone: (203) 409-5444, x133 klondoner@biosigtech.com

#### **Andrew Ballou**

Vice President, Investor Relations BioSig Technologies, Inc. Phone: (203) 409-5444, x133 aballou@biosigtech.com

\*Global Market Insights Inc. March 08, 2022.

CORPORATE SUMMARY

### **KEY GROWTH DRIVERS**

#### **Advanced Technology**

• While the field of cardiology has advanced in innumerable ways, platforms for capturing cardiac signaling have not kept pace. BioSig is solving the critical unmet need for delivering better cardiac signaling information that can potentially help improve success rates of ablation procedures, which are fast becoming first-line procedures to treat arrhythmias.

#### **Market Opportunity**

• The global electrophysiology market is expected to exceed US \$16B by 2028 and is growing at a compound annual growth rate (CAGR) of 11.2%.

#### **KOL Support**

- The PURE EP™ Platform is in use by many of the nation's leading medical centers and physicians, including Dr. Andrea Natale and Dr. G. Joseph Gallinghouse of Texas Cardiac Arrhythmia Institute; Dr. Dhanunjaya "DJ" Lakkireddy of Kansas City Heart Rhythm Institute, and Oussama Wazni, MD of Cleveland Clinic
- The Company achieved proof of concept validation through UCLA and has performed numerous
  preclinical and clinical studies at leading Medical Centers of Excellence. In 2017, the Company
  inked a 10-year strategic collaboration with Mayo Clinic. More recently, the Company signed a
  Master Research Agreement with Cleveland Clinic to explore expanded applications for the PURE
  EPTM Platform.



The PURE EPTM Platform combines noise-dampening physical hardware

with one-of-a-kind algorithms and customizable software features to

eliminate distortion and provide vital data analysis and pure cardiac

signals that allow for enhanced evaluation and confidence in the

### **RECENT HIGHLIGHTS**

Signed Purchase Agreement with Bellin Health in Green Bay, Wisconsin

Signed Purchase Agreement with San Antonio Methodist Hospital

Signed Purchase Agreement with Kansas City Rhythm Institute at Overland Park Medical Center

PURE EP<sup>TM</sup> highlighted in a peer-reviewed case report (JAFIB- EP)

Signed Master Agreement with Hospital Corporation of America (HCA)

Announced Multi-System Evaluation Agreement with Cleveland Clinic

treatment of arrhythmias.

Surpassed 3,000 procedures

59 allowed/issued design and utility patents

Clinical data acquired by PURE EP™ published in the Journal of Cardiovascular Electrophysiology

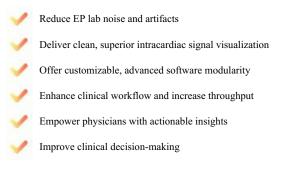
Selected Plexus Corp. as its manufacturing partner

CORPORATE SUMMARY

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### **THE PURE EP™ PLATFORM**

A unique combination of proprietary hardware and software, The PURE EP<sup>TM</sup> Platform removes unnecessary distractions to preserve the value of cardiac signals and delivers clear, actionable insights for today's electrophysiologist. PURE EP<sup>TM</sup> is demonstrating impact on hospital profitability through innovative feature designs not found in any other platform.





The company's subscription model supports operational expenditure goals by optimizing case-by-case and day-to-day department expenses, removing the burden of ownership and maintenance. With a comprehensive suite of tools and software upgrades, the PURE EPTM Platform can deliver the latest developments in electrophysiology to physicians as they emerge, with the flexibility to add enhancements as desired.

#### INVESTMENT HIGHLIGHTS A GROWING GLOBAL MARKET Proven management team and independent Board of Directors The Cardiac Arrhythmia Epidemic: 14.4M Americans suffer from cardiac arrhythmias. Substantial and growing market Two of the most prevalent, complex and potentially deadly types of arrhythmias today are Atrial Fibrillation (AF) and Ventricular Tachycardia (VT). Strong clinical data supports commercialization • AF is the most common arrhythmia affecting 33.5 million people Technology solves a critical unmet need, saves procedural time, and **9**] worldwide, with as many as 6.1 million people in the U.S. now and improves workflow efficiency expected 8-12 million by 2050. AF increases the risk of stroke 4x to 5x and contributes to $\sim 750,000$ hospitalizations per year. The direct 2 Flexible pricing model supports recurring revenue and continuous innovation cost of AF is approximately \$6B annually; adding other indirect costs brings AF total cost to \$26B. First customers are industry leaders • Ventricular arrhythmias account for approximately 300,000 sudden deaths per year in the United States alone. IP Strategy led by Sherpa Technology and Sterne Kessler Goldstein & Fox-59 allowed/issues patents Catheter ablation is fast becoming a first-line therapy, driving demand for improved technologies. Significant Insider Ownership Global Ablation Procedure Growth: 8.4% growth rate, from 973,220 in 2017 to 1.45 projected million in 2022. National purchasing agreement with HCA, Inc. • Complex Ablation Procedures: 440,629 in 2017 to 830,390 in 2022; 13.5% projected growth rate. • Estimated 3,425 EP labs in US 10-year strategic collaboration with Mayo Clinic • Estimated 3,915 EP labs OUS

CORPORATE SUMMARY

### **PROVEN TEAM**

BioSig is led by a proven management team with significant inside ownership. BioSig has brought together leading physicians, executives and engineering experts from leading medical centers of excellence, healthcare programs, Fortune 500 Companies and elite educational institutions for its Advisory Board, including Mayo Clinic, Mount Sinai Medical Center, UCLA, Johnson & Johnson, Nasdaq and Prudential Securities.

	Kenneth L. Londoner, MBA Founder, Chairman, Chief Executive Officer, Director Endicott Management Partners; J & W Seligman & Co., Visiting Professor, Columbia University	Steve Buhaly Chief Financial Officer Qorvo; Longview Fibre; Planar Systems
MANAGEMENT AND PAST EXPERIENCE	Gray Fleming Chief Commercial Officer St. Jude Medical; Abbott Laboratories	John Sieckhaus <i>Chief Operating Officer</i> St. Jude Medical; Abbott Laboratories
	Andrew Ballou VP, Investor Relations Janney Montgomery Scott LLC., RBC Capital Markets	Brenda Castrodad VP, Human Resources TisueTech, Inc., HeartWare Inc.
	Katie Freshwater VP, Marketing Cardinal Health, Medtronic, Kimberly-Clark Healthcare	Zachary Koch CCDS, CEPS, Clinical Director Abbott, St. Jude Medical
	Donald E. Foley	Patrick J. Gallagher, MBA
DIRECTORS	Director Former CEO & Chair: Wilmington Trust; Sr VP, Treas & Dir: ITT Corp; Asst Treas: International Paper Co	<i>Director</i> Mg Dir: Laidlaw & Co.; Kinex Pharmaceuticals; Director: Cingulate Therapeutics, BDR Research Group, GC Capital Partners, Kidder Peabody
	David Weild IV, MBA Director Current Chairman & CEO; Weild & Co.; Former Vice Chairman: NASDAQ; Former Head of Corporate Finance & Equity Markets:	Frederick D. Hrkac Director 30+ years of industry experience including Europe, Middle East & Africa President of Boston Scientific; Executive: Johnson & Johnson, Biosense Webster
	Markets: Prudential Securities	
	James Klein Director Former President of Infrastructure and Defense Products, Qorvo, where he was focused on bringing innovative RF technology to the medical testing market	James J. Barry Director Principal Owner; Convergent Biomedical Group LLC; former President and CEO; InspireMD, Inc.; former SVP of Corporate Technology at Boston Scientific

## ANALYST COVERAGE Laidlaw & Co (UK) Ltd., Taglich Brothers, Ascendiant Capital Markets, Trickle Research

BioSig Forward-Looking Statements: Statements contained in this release that are not historical facts may be deemed to be forward-looking statements. Investors are cautioned that forward-looking statements are inherently uncertain. Actual performance and results may differ materially from that projected or suggested herein due to certain risks and uncertainties including, without limitation, ability to obtain financing, regulatory approvals, competition and marketplace demand. More information, and BioSig risk factors, are set forth in its filings with the SEC. BioSig assumes no obligation to publicly update or revise its forward-looking statements. Data Sources: 2018 MD&D report, Worldwide Epidemiology of Atrial Fibrillation in the journal Circulation, 2013; CDC Fact Sheet on Atrial Fibrillation; American Heart Association; Ventricular Tachycardia in Medscape, December 2017; "Healthcare Costs Drop Sharply after Successful Ablation," Marlene Busko, Medscape, May 4, 2016, and Biolelectronic Medicine 2019-2029. IDTechEx Research. \*As reported in the 09/30/21 form 10Q filed on November 15th, 2021.

CORPORATE SUMMARY