

# PURE EPTM System

Identifying Cardiac Ablation Targets with Confidence

#### **BioSig Technologies Profile**

### BioSig Technologies, Inc. has developed a next-generation Electrophysiology (EP) Information System - PURE EP™ System.

The PURE EP System acquires and displays high fidelity intracardiac (IC) & electrocardiogram (ECG) signals.

PURE EP assists electrophysiologists in making clinical decisions during cardiac catheter ablation in real-time by providing information that BioSig believes is not obtainable from any other equipment presently used in EP labs.

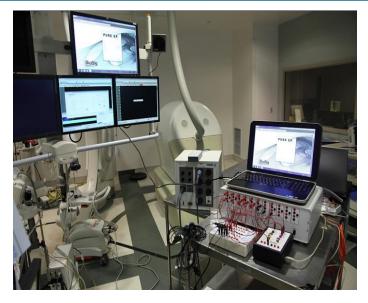


Photo: PURE EP proof of concept system during UCLA validation studies.

OTCQB: BSGM

Public Since: Oct. 10, 2014

Recent Price: \$3.00

FD Shares (9/8/14): 23.3 million

Headquarters: Los Angeles, CA



#### **BioSig Investment Highlights**

- > Proven Management Team & Board of Directors
- World-Class Medical Advisory Board
- > EP Devices: \$3B Total Addressable Market, 12.1% CAGR
- ➤ Large Cardiac Arrhythmia Patient Population; Ablations Grow 10%+
- Increasing Demand for New EP Technologies to Address:
  - Complex Ablation Treatments
  - > High Costs, with Higher Patient Throughput, Shorter Procedure Times
  - Unacceptably High Recurrence Rates (31% 46%)
- High-Growth Sector Earns Innovation Premium, Aggressive M&A



#### **Proven Management Team & Board**

Gregory D. Cash	<b>President, CEO and Director;</b> Pres: Argent International, NeuroTherm, Heartsine Tech, Vasomedical, Datascope, Eminent Tech; Mgmt: U.S. Surgical, Boston Scientific, Medtronic
Kenneth L. Londoner, MBA	<b>Co-Founder, Executive Chairman / Director;</b> Endicott Management Partners, J & W Seligman & Co; Director: Alliqua, chatAND, Freeline
Steve Chaussy, CPA	CFO; Liberski Inc, Anna & Co, Penske Automotive, Ford Hogg and Cobbe
Seth H. Z. Fischer	Board Member; Current CEO & Dir: Vivus, Inc; Former WW Chairman: J&J, Cardiovascular
Roy T. Tanaka	<b>Board Member;</b> Former Pres: J&J Dir: TomoTherapy, Volcano Corp, Advanced Cardiac Therapeutics, VytronUS, Coherex Medical
Asher Holzer, PhD	Board Member; Founder: InspireMD; Mgr: CARTO System, Biosense
Jonathan Steinhouse	Board Member; VP Sales: Oracle, Sandlot Solutions, Orange MZI Healthcare currently
Patrick J. Gallagher	<b>Board Member;</b> Mg Dir: Laidlaw & Co.; Kinex Pharmaceuticals; Director: Cingulate Therapeutics, BDR Research Group, GC Capital Partners, Kidder Peabody

























#### World Class Medical Advisory Board

Leading authorities in electrophysiology

Andrea Natale, MD, Chairman	Executive Medical Director, Texas Cardiac Arrhythmia Institute, St. David's Medical Center
Kalyanam Shivkumar, MD, PhD	Director, UCLA Cardiac Arrhythmia Center; Professor of Medicine & Radiology
Mauricio Arruda, MD	Director, Clinical Electrophysiology & Pacing, University Hospitals Case Medical Center
Vivek Reddy, MD	Director, Cardiac Arrhythmia Service and a Helmsley Trust Professor of Medicine, Mount Sinai Medical Center in New York
David E. Haines, MD	Director, Heart Rhythm Center, Electrophysiology Services, William Beaumont Hospital
Luigi Di Biase, MD PhD, FHRS	Senior Researcher at Texas Cardiac Arrhythmia Institute; Associate Professor, Albert Einstein College of Medicine, Adjunct Professor at the UT Austin













### Cardiac Arrhythmias 1 in 18 (14.4M) Americans Suffer

#### **ATRIAL FIBRILLATION (AF)**

- ➤ Increases individual's risk of

  Stroke 4- to 5-fold\* 4<sup>th</sup> Leading

  Cause of Death in the US
- ➤ Most Common Arrhythmia:
   U.S. = 2.7M 2010; 5.6M by 2050\*
   (7M 12M Worldwide)
- >≈600,000 hospitalizations/year\*
- ➤ Direct cost = \$6B annually; adding other indirect costs brings AF total cost to \$26B\*

#### **VENTRICULAR TACHYCARDIA**

- ➤ Ventricular tachycardia (VT) and ventricular fibrillation (VF) are rapidly fatal if not reversed
- ➤ Ventricular arrhythmias account for >350,000 Sudden Cardiac Deaths annually\*



<sup>\*</sup> American Heart Association data

#### Cardiac EP: Large & Growing Market

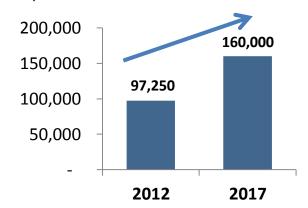
### **EP Devices: 12.1% CAGR is One of the Fastest Growing Cardio Medical Device Segments**<sup>1</sup>

Current EP Market is ~\$3B worldwide



#### U.S. AF and VT Catheter Ablations<sup>2</sup>

Forecasted to grow 10.5% annually through 2017 (VT 13.9% CAGR and AF 10.1% CAGR)



- EP Labs: Estimated 4,000 WW; 2,800 in the U.S.
- ➤ In 2012: 260,000 U.S. catheter ablation procedures; 600,000 WW
- Average ablation procedure price (USD): \$6,000 \$15,000

Sources: 1. http://www.transparencymarketresearch.com/electrophysiology-ep-devices-market.html#src=whatech 2. HRI 2013 "Global Opportunities in Medical Devices & Diagnostics" report; triangulation of multiple sources; \*AF includes left atrial tachycardia, left WPW, left atrial flutter.



#### BioSig's Technology Addresses Critical Issues

- **High ablation recurrence rates:** 31% for paroxysmal AF; 46% for persistent/permanent AF
- > Long procedure times: from 2-8 hours depending on case, clinician experience
- > Outdated technology: EP recording systems use core technology from the 1990s
  - Strong market demand as anatomical-based procedures have limited success
  - > Artifacts and noise generated by other EP lab equipment compromise signal quality; current noise reduction solutions alter acquired signal morphology
- Anti-arrhythmic drug therapies have limited **effectiveness,** driving demand for catheter ablation





#### **PURE EP System Value Proposition**



Electrograms & ECG signals – important for diagnoses and treatments



Signals are degraded by environmental noise and signal processing



Inadequate signal quality leads to poorer outcomes, clinical and economic inefficiencies

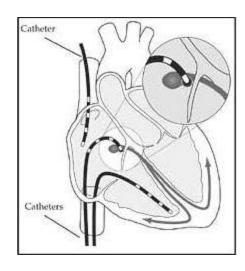


**PURE EP System** preserves morphology of ECG & IC signals and provides Confidence Indexes to ensure optimal clinical decision making

#### Why are EP Signals Critical?

### Quality Cardiac Signal Recordings ⇒ Better Clinical Decision Making

- Strong demand as anatomical-based ablation procedures have limited success
- Today's lack of reliable, real-time data and operator guidance drive high re-do rates in complex arrhythmia ablations
- Universal problem of noise in all EP labs leads to inefficient procedures
- Certain arrhythmia ablation procedures currently performed by only limited number of centers due to complexities



During EP procedures, catheters are placed on cardiac tissue to record signals and apply energy to destroy abnormal electrical pathways

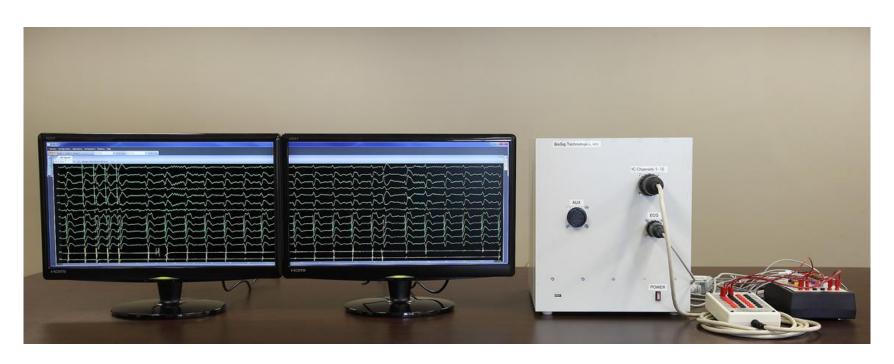


#### **PURE EP System**

Only system dedicated to improving cardiac signal recordings and providing Confidence Indexes - fundamental for improved diagnoses and treatments of cardiac arrhythmias

ACCURATE ECG & IC SIGNALS	Preserves morphology of the patient's cardiac signals
REAL-TIME ANALYSIS	Visualize crucial information in real-time
OPTIMIZE PROCEDURE TIME	Improve procedure efficiency by eliminating need for data validation using PURE EP's Confidence Indexes (CI)
CONFIDENT DECISION MAKING	Confidence Indexes provide critical information to assist in clinical decision making for improved catheter ablation outcomes

#### **Current PURE EP System Prototype**



PURE EP System Prototype connected to an ECG/IC Simulator

#### **Validation of PURE EP System**



- ➤ Testing of the PURE EP System is underway FP & Animal labs at UCLA
- ➤ BioSig is collaborating with the leading Cardiac Centers:
  - > Texas Cardiac Arrhythmia Institute
  - UCLA Cardiac Arrhythmia Center
  - U.H. Case Medical Center in Cleveland
  - William Beaumont Hospital in Michigan
  - Mount Sinai Medical Center in NY
  - Mayo Clinic in Minnesota
- ➤ BioSig has developed ECG/IC simulator to objectively measure/compare PURE EP's performance vs. existing EP systems

#### **EP Competitive Landscape**

#### **EP Market: Intense Competition & Rapid Technological Advances**

- 4 large companies share the majority of EP recording market share
- They produce the following EP recording systems @~\$250,000/unit:
  - Bard's LabSystem PRO EP Recording System, originally designed in the late 1980s; acquired by Boston Scientific in 2013
  - > Siemens developed the Axiom Sensis XP in 2002
  - GE's CardioLab Recording System developed early '90s by Prucka Engineering; acquired by GE 1999
  - St. Jude Medical's EP-WorkMate Recording System was acquired from EP MedSystems in 2008, received FDA approval in 2003



#### **EP Sector M&A Activity**

Company	Proof of Concept	Prototype	Clinical Data	CE Mark	FDA	Sales	Acquirer/ Investor	Valuation
Abbott/Topera (Closing Q4-14)	•	•	•	•	•		Abbott	\$250M+ milestone \$\$ Q4-14 Deal
Bard EP Division of CR Bard	•	•	•	•	•	•	Boston Scientific	\$275M 2013 Deal
Rhythmia Medical Formed 2004	•	•	•				Boston Scientific	\$265M 2012 Deal
Ablation Frontiers Formed 2004	•	•	•	•			Medtronic	\$225M+ 2009 Deal
EP Medsystems Formed 1993	•	•	•		•	•	St. Jude	\$92.1M 2008 Deal
Cryocath Formed 1995	•	•		•	•	•	Medtronic	\$380M 2008 Deal
Endocardial Solutions Formed 1992	•	•	•				St. Jude	\$272M 2005 Deal
Prucka Engineering Formed 1988	•	•	•		•	•	GE	Undisclosed 1999
BioSig Technologies Formed 2011	•	•	•					



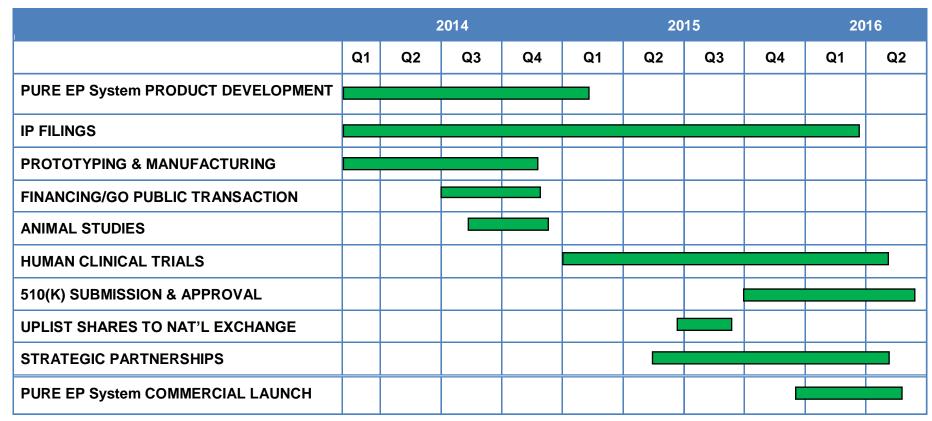
#### BioSig's Key 12-Month Milestones

- Continue Animal Studies at UCLA's Cardiac Arrhythmia Center
- Commence In-Human Clinical Studies
- ➤ Submit FDA 510(k) Application Q4-15: Typical Approval is ~5-9 Months
- > Continue to Build Intellectual Property Portfolio
- Raise Growth Capital
- Uplist to National Exchange in 2015
- Prepare for Commercialization, transition to Sales & Marketing Org



#### **Milestones & Timelines**

#### **PURE EP System Milestones & Timelines**



#### **Financing History**

Founders: 2009-2010

Friends & Family:	Mar 2011	\$150K	\$7M PMV*
Series A Preferred:	June 2011	\$1M	\$15M PMV
Series B Preferred:	April 2012	\$1M	\$17.5M PMV
Series C Preferred:	July 2013	\$2.78M	\$20M PMV
Common:	April 2014	\$1.37M	\$36 - \$38M PMV
Common:	Sept 2014	\$1M	\$51M PMV

- > No Debt
- > 27% Fully Diluted D&O Ownership
- Consistent Management & Board Participation in Financings

\*PMV = Pre-Money Valuation



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