

February 20, 2019



BioSig Announces Successful First-In-Human Use of PURE EP System

Early Results Suggest Improved Cardiac Signal Detection and Fidelity

Santa Monica, CA, Feb. 20, 2019 (GLOBE NEWSWIRE) -- BioSig Technologies, Inc. (NASDAQ: BSGM), a medical device company developing a proprietary biomedical signal processing platform designed to address an unmet technology need for the electrophysiology (EP) marketplace, today announced that the Company successfully conducted first patient cases using PURE EP(tm) System, its FDA approved proprietary signal acquisition and processing technology. The first commercial use of the System was completed at the Texas Cardiac Arrhythmia Institute ("TCAI") in Austin, TX.



BioSig's PURE EP System is a novel cardiac signal acquisition and display system which aims to improve accuracy and efficiency of EP studies and catheter ablation for arrhythmias.

The patient studies were conducted by Andrea Natale, M.D., F.A.C.C., F.H.R.S., F.E.S.C., Executive Medical Director, Texas Cardiac Arrhythmia Institute at St. David's Medical Center.

"With the use of the PURE EP(tm) System I was able to identify cardiac signals which were previously undetectable to me. I believe that the PURE EP(tm) System could change diagnostic and treatment strategies of arrhythmias, leading to more successful outcomes,"

commented Dr. Natale.

The PURE EP(tm) System was used during the standard studies on patients with persistent atrial fibrillation and conducted in parallel with Abbott's EnSite Precision(tm) and Biosense Webster's (Johnson & Johnson) CARTO(tm) cardiac mapping systems. The goal of the first commercial use of the technology was aimed at validating the System's key value proposition elements and report on the overall user experience during the procedure.

"We are highly encouraged by the first results reported by Dr. Natale and his team at this world-leading facility. A positive First-in-Human experience is a major inflection point for our Company and lays a strong foundation for our early commercialization efforts," commented Kenneth L. Londoner, Chairman and CEO of BioSig Technologies. "We are well positioned to deliver on our strategic goals for 2019 and look forward to the expansion of our evaluation efforts in the coming months."

The Company released its [Shareholder Letter](#) earlier in February 2019, where it stated its intentions to present the results from the First-in-Human studies and the early feedback from the use of the PURE EP(tm) System to a larger community of physicians during the Heart Rhythm Society event in May 2019.

The 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. The PURE EP(tm) System aims to minimize noise and artifacts and acquire high-fidelity cardiac signals. Improving fidelity of acquired cardiac signals may potentially increase the diagnostic value of these signals, thereby possibly improving accuracy and efficiency of the EP studies and related procedures. The results of pre-clinical studies have been [published](#) in a number of journals, including [The Journal of Innovations in Cardiac Rhythm Management](#).

[PURE EP System](#)

About Texas Cardiac Arrhythmia Institute

Located at St. David's Medical Center in Austin, Texas, the Texas Cardiac Arrhythmia Institute is a recognized training, research and treatment facility dedicated solely to heart rhythm disorders.

St. David's is a state-of-the-science medical center with a well-qualified medical support staff. Its robotics, magnetics and other advanced technologies complement the expertise of TCAI's physicians. The Institute brings TCAI's respected physicians and researchers together with St. David's superior facilities to address even the most challenging arrhythmias.

About BioSig Technologies

BioSig Technologies is a medical technology company developing a proprietary biomedical signal processing platform designed to improve the electrophysiology (EP) marketplace (www.biosig.com). Led by a proven management team and a veteran Board of Directors, BioSig Technologies is preparing to commercialize its PURE EP™ System. The technology has been developed to address an unmet need in a large and growing market.

The Company's first product, PURE EP™ System, is a novel cardiac signal acquisition and display system which is engineered to assist electrophysiologists in clinical decision-making during procedures to diagnose and treat patients with abnormal heart rates and rhythms. BioSig's main goal is to deliver technology to improve upon catheter ablation treatments for the prevalent and potentially deadly arrhythmias, Atrial Fibrillation and Ventricular Tachycardia. BioSig has partnered with Minnetronix on technology development and has received FDA 510(k) clearance for the PURE EP™ System in August 2018.

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," "aims," "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) our inability to manufacture our products and product candidates on a commercial scale on our own, or in collaboration with third parties; (ii) difficulties in obtaining financing on commercially reasonable terms; (iii) changes in the size and nature of our competition; (iv) loss of one or more key executives or scientists; and (v) 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.

Attachment

- [PURE EP System](#)

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Source: BioSig Technologies, Inc.

