August 14, 2018

BioSig Technologies Announces FDA 510(k) Clearance for PURE EP System

Santa Monica, CA, Aug. 14, 2018 (GLOBE NEWSWIRE) -- BioSig Technologies, Inc. (OTCQB: BSGM), announced that the Company has received 510(k) clearance for its first product, PURE EP System, from the U.S. Food and Drug Administration (FDA).

The non-invasive PURE EP 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 system is indicated for use under the supervision of licensed healthcare practitioners who are responsible for interpreting the data. The PURE EP System aims to minimize noise and artifacts, and acquire high-fidelity cardiac signals. Improving cardiac signals may potentially increase the diagnostic value of these signals, thereby possibly improving accuracy and efficiency of the EP studies and related procedures.

To date, BioSig has performed twelve pre-clinical studies at Mayo Clinic in Rochester, MN, three at UCLA Medical Center in Los Angeles, CA, and one at Mount Sinai Hospital in New York, NY. BioSig signed a 10-year collaboration agreement with Mayo Clinic in 2017 that will enable the Company to advance the platform and expand its capabilities into other areas of clinical importance. The Journal of Innovations in Cardiac Rhythm Management published several years of pre-clinical data (https://www.biosigtech.com/technology/publications) conducted at Mayo Clinic.

Minnetronix, BioSig's manufacturing partner in St. Paul, MN, has produced initial systems that will allow the Company to enter the market in the U.S. with selected sites.

"Our PURE EP System is the culmination of many years of scientific research and business development efforts. It is our goal to provide tangible benefits to electrophysiologists and improve the current standards of EP procedures in the clinical setting. We are excited to bring the advanced platform to the U.S. market," commented Kenneth L. Londoner, Chairman and CEO of BioSig Technologies, Inc.

One of the most common reasons for an EP procedure is the diagnosis and treatment of atrial fibrillation. Atrial fibrillation is the most common arrhythmia currently affecting 33.5 million people worldwide, with 6.1 million people in the U.S. Atrial fibrillation increases the risk of stroke by 4 to 5 times and contributes to ca. 750,000 hospitalizations per year. According to the 2016 HRI Global Opportunities in Medical Devices & Diagnostics report, the current market of EP is estimated at $4.6 billion and growing at 10.5% rate annually.

On August 1, 2018 the Company announced its intention to uplist to the Nasdaq exchange. The Company expects to be trading on Nasdaq in 2018.

The Company recently filed an omnibus patent with the leading patent law firm, Sterne Kessler Goldstein & Fox in Washington, DC that thoroughly protects the Company's technology.

About BioSig Technologies
BioSig Technologies is a medical device company developing a proprietary biomedical signal processing technology designed to improve the $4.6 billion electrophysiology (EP) marketplace (www.biosigtech.com). Led by a proven management team and a veteran, independent Board of Directors, Los Angeles-based 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 FDA cleared product, PURE EP™ System, is a novel cardiac signal acquisition and display system that 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 ultimately 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 is working toward initial commercial distribution of the PURE EP™ System.

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 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 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.

Contact:
Natasha Russkina
BioSig Technologies, Inc.
VP Business Development & Corporate Finance
12600 Hill Country Blvd R-275
Austin, TX 78738

nrusskina@biosigtech.com
512-329-2643

Source: BioSig Technologies, Inc.