January 29, 2025

HeartBeam Achieves Major Milestone with FDA Submission for its Groundbreaking 12-Lead ECG Synthesis Software

SANTA CLARA, Calif.--(BUSINESS WIRE)-- **HeartBeam, Inc.** (NASDAQ: BEAT), a medical technology company focused on transforming cardiac care by providing powerful personalized insights, today announced it has submitted a 510(k) application to the U.S. Food and Drug Administration (FDA) for the Company's groundbreaking 12-lead electrocardiogram (ECG) synthesis software designed for the assessment of rhythms and arrhythmias, including sinus rhythm, atrial fibrillation, atrial flutter, bradycardia, tachycardia, and sinus with premature ventricular contraction (PVC) or premature atrial contraction (PAC).

The FDA submission is backed by robust data from the VALID-ECG pivotal study, which enrolled 198 patients across five clinical sites. The Company believes the study's findings support the clinical equivalence of HeartBeam's synthesized 12-lead ECG where the leads are similar to standard 12-lead ECGs for rhythm and arrhythmia assessment.

The submission builds on HeartBeam's recent FDA clearance for its patented technology which captures the heart's electrical signals from three distinct directions. The software synthesizes these signals into a familiar 12-lead ECG using a personalized transformation matrix.

Upon FDA clearance for the software, the Company plans to initiate commercial launch leveraging the learnings and feedback gained from its Early Access Program. Hundreds of physicians and patients have already joined the waitlist underscoring the widespread interest in a powerful and convenient cardiac monitoring option that can be used outside of a medical facility.

Robert Eno, Chief Executive Officer of HeartBeam, commented, "The FDA submission for the 12-lead synthesis software is a significant step as we work towards fulfilling HeartBeam's vision to offer patients and physicians an easy-to-use portable device and transform how cardiac conditions are monitored and detected."

Additional future planned advances include the integration of AI-based classification algorithms and detection of heart attacks to aid in reducing "symptom to door" times – an area of major focus for the American Heart Association (AHA)to shorten the time from heart attack symptom onset and treatment. HeartBeam believes its groundbreaking technology presents a transformative opportunity to bring about a paradigm shift in cardiovascular care for millions of patients globally.

Additional Details About Data Supporting FDA Submission

The FDA submission was supported by data from the VALID-ECG pivotal study, which

completed enrollment in June 2024. VALID-ECG used the same protocol as an 80-person pilot study which was presented at the AHA 2024 Scientific Sessions. The Company plans to present the results from VALID-ECG at a scientific conference in 2025.

Data from the pilot study presented at the AHA Scientific Sessions, which also supported the FDA submission, found similar performance of HeartBeam's synthesized 12-lead ECG waveforms compared to simultaneously collected standard 12-lead ECGs for arrhythmia detection. The pilot study found excellent agreement when physicians diagnosed various arrhythmias utilizing the HeartBeam synthesized 12-lead ECG compared to a standard 12-lead ECG (Sensitivity: 94%, Specificity: 100%). Arrhythmias evaluated include sinus rhythm, atrial fibrillation, atrial flutter, and sinus with premature ventricular contraction (PVC) or premature atrial contraction (PAC).

About HeartBeam, Inc.

HeartBeam, Inc. (NASDAQ: BEAT) is a medical technology company dedicated to transforming the detection and monitoring of critical cardiac conditions. The Company is creating the first ever cable-free synthesized 12-lead ECG capable of capturing the heart's electrical signals from three distinct directions. This platform technology is designed for portable devices that can be used wherever the patient is to deliver actionable heart intelligence. Physicians will be able to identify cardiac health trends and acute conditions and direct patients to the appropriate care – all outside of a medical facility, thus redefining the future of cardiac health management. The Company holds 13 US and 4 international issued patents related to technology enablement. For additional information, visit HeartBeam.com.

About the HeartBeam System

The HeartBeam System is a portable non-invasive recorder intended to record, store, and transfer a patient's 3-Lead (in three-directions) electrocardiogram (ECG) acquired from 5 electrodes. The device is intended to be used by adult patients in either a clinical setting or at home. The device does not conduct cardiac analysis and can be used with an ECG Viewer software system for manual interpretation of non-life-threatening arrhythmias by a physician or healthcare professional. For full safety information, see the full **Instructions for Use** or **Clinician Portal Manual**.

Forward-Looking Statements

All statements in this release that are not based on historical fact are "forward-looking statements." While management has based any forward-looking statements included in this release on its current expectations, the information on which such expectations were based may change. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our Forms 10-K, 10-Q and other reports filed with the SEC and available at www.sec.gov. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking

to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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