April 29, 2025

HeartBeam Successfully Meets Clinical Endpoints in Pivotal Study for its Groundbreaking 12-Lead ECG Synthesis Technology

Milestone results formed the basis of HeartBeam's 12-lead ECG synthesis software application submitted to FDA in January 2025

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 that its groundbreaking synthesized 12-lead electrocardiogram (ECG) successfully met the clinical endpoints in the VALID-ECG pivotal study. Thomas Deering, M.D., of Piedmont Heart Institute, presented the data during the just concluded Heart Rhythm Society's annual conference in San Diego.

The study evaluated the mean difference in ECG intervals and amplitudes between HeartBeam's synthesized 12-lead ECG and simultaneously collected standard 12-lead ECG that are important in assessing non-life-threatening arrhythmias. Data showed a **93.4% overall diagnostic agreement**, indicating that HeartBeam's synthesized 12-lead ECG can support diagnosis of arrhythmias in a manner consistent with standard 12-lead ECGs.

"This important milestone successfully confirms that our novel technology can deliver diagnostic insights similar to a standard 12-lead ECGs for arrhythmia assessment," said Robert Eno, Chief Executive Officer, HeartBeam. "The ability to deliver 12-lead ECG-like data through a credit card-sized device that patients can use whenever and wherever arrhythmia symptoms occur underscores our long-term vision of bringing advanced cardiac health insights beyond medical facilities to improve patient outcomes."

HeartBeam's patented 3D ECG technology captures the heart's electrical signals in 3 non-coplanar directions and then synthesizes these signals into a 12-lead ECG using a personalized transformation matrix. Data from the VALID-ECG study formed the basis of the FDA application for the 12-lead ECG synthesis softwaresubmitted by HeartBeam in January 2025.

The Company plans to initiate commercialization upon receiving FDA clearance for the 12-lead ECG synthesis software. In advance of that, the Company recently commenced an Early Access Program to obtain important feedback on the end-to-end clinical workflow, ensure operational readiness and establish an early adopter funnel in anticipation of US commercialization.

The VALID-ECG pivotal study was a multicenter trial that enrolled 198 patients across five clinical sites in the US, including Allegheny Health Network, Atlanta Heart Specialists, Mount Sinai Hospital, Northwell Health and Piedmont Heart Institute.

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 device capable of collecting ECG signals in 3D, from 3 non-co-planar directions, and synthesizing the signals into a 12-lead ECG. 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. HeartBeam's 3D ECG technology received FDA clearance for arrhythmia assessment in December 2024. The Company holds 14 U.S. and 4 international issued patents related to technology enablement. For additional information, visit HeartBeam.com.

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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