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HeartBeam Provides Update on Regulatory Path Following FDA Decision on 12-Lead ECG Synthesis Software Application

- *Company engaging in multiple options for a constructive resolution*
- *Strategy is underpinned by a clinical study that achieved the agreed upon endpoints*
- *Company believes that labeling modifications can address any outstanding concerns*

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 its regulatory strategy following receipt of a Not Substantially Equivalent (NSE) decision on the Company's 510(k) submission for its 12-lead Electrocardiogram (ECG) Synthesis Software.

Immediately following the receipt of the NSE letter and through today, HeartBeam has been engaging with the Food and Drug Administration (FDA) review staff to better understand the concerns and determine the best path forward.

- The FDA has signaled a willingness to work with the Company towards a constructive resolution.
- The Company stands behind the clinical study (VALID-ECG) submitted in support of the application. The study met its clinical endpoints and the Company believes it has a viable argument to address outstanding concerns of the agency.
- The Company believes these concerns can be addressed through modifications to the proposed labeling of the device.

HeartBeam has determined that the best course of action to reach a favorable resolution with the FDA is to pursue multiple parallel paths, which are designed for this type of situation.

- The range of options include, but are not limited to, an appeal process or a resubmission of a 510(k) application.
- Based on the recent discussions with the FDA and the information available at present, the Company believes there is a path forward under an appeal process.
- The official appeal process has a timeline of approximately 60 days from submission of an appeal to resolution.

The Company looks forward to working with the agency to resolve the unexpected NSE letter. While this regulatory process moves forward, the Company will continue to provide shareholders with updates on the commercial launch and funding plans.

"HeartBeam appreciates the extensive interactions with the FDA on the HeartBeam 12-lead Synthesis Software," said Robert Eno, Chief Executive Officer of HeartBeam. "We have engaged in good faith with the agency over a period of two years and have had extremely

positive interactions. Together with the agency, we resolved the vast majority of open questions.

“After assessing our options, we believe that the best way to resolve the open questions and to get this technology into the hands of patients is to engage in the multiple paths available for constructive resolution. Since the remaining concerns from the FDA are well defined and can be readily addressed by our team, we believe these paths can lead to a favorable resolution.”

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 three non-coplanar dimensions, 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 over 20 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.

Cleared Indications for Use

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**.

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