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# HeartBeam Announces First Patient Enrollments in Heart Attack Detection Pilot Study

- *HeartBeam's technology uniquely capable of assessing possible heart attacks outside of traditional clinical settings*
- *ALIGN-ACS study expected to complete patient enrollment quickly*
- *Milestone signifies key step toward future FDA indication expansion for heart attack assessment*
- *Future indication expansion would unlock large market with over 20 million patients at risk of a heart attack*

SANTA CLARA, Calif.--(BUSINESS WIRE)-- [HeartBeam, Inc.](#) (NASDAQ: BEAT), a medical technology company focused on transforming cardiac care by providing powerful cardiac insights, today announced that the first patients have been enrolled in its ALIGN-ACS pilot study evaluating the HeartBeam System for heart attack detection. The first patients were enrolled by Prof. Dr. Vladan Vukcevic at the University Clinical Center of Serbia in Belgrade, Serbia. The initiation of the ALIGN-ACS pilot study represents a significant step toward collecting the data needed to support expanding the indication of the HeartBeam System beyond arrhythmia assessment to include heart attack assessment.

Heart attacks remain the leading cause of death, with more than 20 million patients in the U.S. who are at risk. Patients often delay seeking care by 3–4 hours because symptoms can be vague or subtle, driving up mortality, complications, and cost of care. While a 12-lead ECG remains the standard of care for diagnosing a heart attack, there is no reliable method for physicians to assess possible heart attacks outside of a clinical setting. HeartBeam aims to fill this gap and shorten [“symptom-to-door” times](#) by enabling patients to record a clinical-grade ECG the moment symptoms begin, wherever they are. By capturing the heart's electrical signals in 3D, from 3 non-coplanar dimensions, HeartBeam's 3D ECG technology provides physicians with a high-fidelity, reliable way to assess possible heart attacks outside of a clinical setting.

“Every minute matters during a heart attack, and early, accurate identification of a heart attack is essential to ensuring patients receive the care they need in a timely manner and improving outcomes,” said HeartBeam Scientific Advisory Board Chair C. Michael Gibson, MD, FRCP, FAHA, FSCAI, FACC, Interventional Cardiologist at Beth Israel Lahey and Professor of Medicine at Harvard Medical School. “HeartBeam's technology has the potential to meaningfully change how quickly we evaluate patients by providing timely access to clinical-grade ECG data outside the hospital, enabling clinicians to accelerate triage decisions and intervene sooner.”

The ALIGN-ACS pilot study is designed to enroll 100 patients presenting with chest pain in the emergency room (ER). Patients will be evaluated with both a standard 12-lead ECG and the HeartBeam device and both results will be compared with each patient's final diagnosis

at discharge. As the study is designed to enroll chest pain patients in the ER, enrollment is expected to progress quickly.

The pilot study builds on multiple earlier [proof of concept studies](#) demonstrating that a 3D ECG configuration similar to the HeartBeam device's ability to detect heart attacks was similar in accuracy to a standard 12-lead ECG, including a study presented at the 2025 American Heart Association Scientific Sessions on the 3D approach. Learnings from the ALIGN-ACS pilot study will inform the design of a multicenter pivotal study that would serve as the basis of a future FDA submission.

"HeartBeam was founded on the premise that since most heart attacks happen outside of a hospital, there should be a fast and easy way for patients and physicians to assess both symptoms and ECG data at home or anywhere," said Robert Eno, Chief Executive Officer for HeartBeam. "The initiation of our pilot study for heart attack detection is a defining moment for HeartBeam as this is one of the largest clinical opportunities in cardiology. Our platform is uniquely positioned to deliver clinical-grade ECG insights at the moment symptoms occur and facilitate more timely action to close the 'symptom-to-door' gap."

This milestone aligns directly with HeartBeam's key long-term growth initiatives, which also include the limited launch of the FDA-cleared HeartBeam System for arrhythmia assessment, ongoing development of the Company's working-prototype 12-lead ECG patch monitor and advancement of its AI program. These initiatives collectively position HeartBeam to advance its vision for more accessible and intelligent cardiac care.

### **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 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 received FDA clearance for arrhythmia assessment for its 3D ECG technology in December 2024 and for its 12-Lead ECG synthesis software in December 2025<sup>1</sup>. The Company holds over 20 issued patents related to technology enablement. For additional information, visit [HeartBeam.com](https://www.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](https://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.

### <sup>1</sup>**Cleared Indications for Use**

The HeartBeam System with 12-Lead ECG synthesis software for arrhythmia assessment received FDA clearance in December 2025. Refer to the Company's Cleared Indications for Use at <https://www.heartbeam.com/indications> for details on the intended use of its technology.

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