June 30, 2026

HeartBeam Completes Enrollment in Heart Attack Detection Pilot Study Ahead of Schedule

- *Accelerated enrollment completion in ALIGN-ACS study underscores HeartBeam's execution on its key strategic priority of heart attack detection*
- *Data analysis is underway, with full results anticipated for presentation at upcoming cardiology conference*
- *Findings will inform the design of the planned U.S. pivotal study and support the FDA pathway*
- *Future indication expansion could unlock a large addressable market of millions of patients at risk*

SANTA CLARA, Calif.--(BUSINESS WIRE)--

HeartBeam, Inc. (NASDAQ: BEAT), a medical technology company focused on transforming cardiac care through powerful cardiac insights, today announced completion of patient enrollment in its ALIGN-ACS pilot study evaluating the HeartBeam System for heart attack detection. Enrollment was completed ahead of the Company's previously communicated third quarter 2026 timeline.

Heart attacks remain a leading cause of death in the United States, with millions of patients at elevated risk. Patients with heart attack symptoms often delay seeking care for more than 2 hours[1] because the symptoms can be vague or subtle, which contributes to higher mortality, more complications, and greater care costs. HeartBeam's 3D ECG technology is designed to allow patients to record a clinical-grade ECG at the onset of symptoms, wherever they are, with the goal of shortening symptom-to-door times and supporting faster, more informed care decisions outside a clinical setting.

"Completing enrollment ahead of schedule reflects both the quality of the study design and the operational discipline our team has built, providing us a strong foundation as we move into pivotal study planning," said Branislav Vajdic, Ph.D., Founder and President of HeartBeam. "We believe the data from the ALIGN-ACS pilot study will be an important input into our discussions with the FDA, and we are evaluating whether this milestone supports a more accelerated path toward an expanded indication for heart attack detection. We look forward to sharing full results later this year and advancing this program with the same discipline and pace our team has demonstrated throughout this study."

The study enrolled 120 patients presenting with chest pain in the emergency department across two clinical sites in Belgrade, Serbia. Patients were evaluated with both a standard 12-lead ECG and the HeartBeam System, with physician assessment for acute coronary syndrome using both ECG modalities compared against an independently adjudicated clinical-data-based gold standard. Data analysis is underway, and the Company plans to present the results at a major cardiology conference in the coming months.

Results from the ALIGN-ACS pilot study are intended to inform the design of a planned pivotal study in the United States and support a future FDA submission seeking to expand the HeartBeam System's indication beyond arrhythmia assessment to include heart attack assessment. The Company plans to use learnings from the pilot, together with prior proof-of-concept data, including a study recently published in JACC: Advances, to inform upcoming discussions with the FDA regarding the design and scope of the pivotal program.

This milestone reinforces HeartBeam's focus on its path toward an expanded indication for heart attack detection and its broader platform strategy. The Company's long-term vision is to make its potentially life-changing system available to as many patients as possible, as quickly as possible.

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 has developed 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's 3D ECG technology received FDA clearance for arrhythmia assessment in December 2024, and the 12-Lead ECG synthesis software received FDA clearance for arrhythmia assessment in December 2025**. 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.

References:

1. De Luca G. Circulation. 2004 Mar 16;109(10):1223-5, Heidenreich PA, J Card Fail. 2022 Mar;28(3):453-466

****Cleared Indications for Use:**
The HeartBeam System with 12-Lead ECG synthesis software is FDA cleared for arrhythmia assessment only. The heart attack detection indication is not FDA cleared and not available in the US or any other geography at this time. 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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