

HeartBeam Announces FDA Submission of HeartBeam AIMI™ Product

Submission Seeks Approval for the Company's Proprietary ECG Technology to Aid in Diagnosis of Heart Attack in \$500 million Total Addressable Market

18+ million People in the US have Coronary Artery Disease and Heart Attacks Occur Every 40 Seconds

SANTA CLARA, Calif.--(BUSINESS WIRE)-- **HeartBeam, Inc.** (NASDAQ: BEAT), a developmental stage digital healthcare company with a proprietary ECG telemedicine technology for heart attack detection, today announced it has submitted a 510(k) application to the US Food and Drug Administration (FDA) for its HeartBeam AIMI™ platform technology for use in diagnosing heart attacks.

"The 510(k) submission of our first product, based on our platform technology, is an important milestone toward commercialization and underscores our continued progress toward making the HeartBeam AIMI platform widely available to help Emergency Department physicians correctly and expeditiously diagnose patients with chest pain or other symptoms of a heart attack," said Branislav Vajdic, PhD, HeartBeam CEO and founder. "I am proud of the HeartBeam team for their commitment to achieving this critical step in bringing the Company's technology to market. We look forward to working through the FDA review process toward our goal of clearance for the US market."

The HeartBeam AIMI platform technology is anticipated to assist health care professionals in identifying patients who present with chest pain to facilitate rapid detection of a heart attack and determine an appropriate treatment regimen. Chest pain is the second most common reason for an emergency department visit with high costs associated with these visits. The goal of HeartBeam's technology is to offer more accurate heart attack detection to triage patients and expedite treatment.

HeartBeam AIMI is software as a medical device with a 510(K) regulatory pathway. The HeartBeam algorithm used in an emergency department setting slots into existing physician workflow, leverages existing 12-lead ECG hardware and provides the attending physician with an instant comparison of the patient's baseline and symptomatic ECG for their consideration in the patient's diagnosis. This will allow physicians to quickly determine if a patient needs intervention or can be discharged which helps manage patient flow.

Jon Hunt, PhD, HeartBeam Executive Vice President and Chief Business Officer, added, "Our FDA approval process doesn't require any human or animal trials, so there is good reason to believe that we will receive FDA clearance for a limited market release by end of 2022 and full commercial roll-out in Q1 2023. While the FDA conducts its regulatory review, our team will focus on executing key components of its commercialization plan and subscription revenue model. We continue to engage in positive discussions with strategic institutions, including academic centers, regional healthcare systems and regional

community hospital systems that can utilize our products. We look forward to approval and offering our HeartBeam AIMI platform in an expected \$500 million total addressable market."

About HeartBeam, Inc.

HeartBeam, Inc. (NASDAQ: BEAT) is a development stage digital healthcare company with proprietary ECG telemedicine technology that will redefine the way high risk cardiovascular patients are diagnosed in an ambulatory setting at any time and any place. Its breakthrough solution employs a reusable, credit card sized, 3D vector ECG recording device and cloud-based software capable of assisting a physician in diagnosing a wide range of cardiovascular disease. HeartBeam is initially focusing on a huge unmet need of helping diagnose heart attacks in patients outside of a medical institution. No single lead ECG technology can offer this value to patients and their physicians. This underserved market is several times larger than the cardiac arrhythmia detection market based on the prevalence of patients with coronary artery disease at high risk of heart attack. For more information, visit 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 in 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220816005591/en/

Media and Investor Relations Contact:

Chris Tyson
Executive Vice President
MZ North America
Direct: 949-491-8235
BEAT@mzgroup.us
www.mzgroup.us

Source: HeartBeam, Inc.