



# The Power of a 12-Lead ECG

*Always with the patient*

Second Quarter 2024

Financial Results Conference Call

NASDAQ: BEAT

August 14, 2024



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HeartBeam AIMIGo™ has not yet been evaluated by the FDA and are not approved for clinical use in the USA or other global geographies.

# Agenda

- Introduction and Company Overview
- AIMIGo Regulatory and Clinical Study Updates
- AI Program Updates
- Financial Results
- Closing Summary
- Q&A



**Branislav Vajdic, PhD**  
CEO & Founder

30 years of experience in technology development and senior management positions. At Intel, he was the designer of first Flash memory and two key inventions that enabled Flash as a product and led engineering groups responsible for Pentium 1 through Pentium 4 designs.



**Rob Eno**  
President

28 years of experience with a proven track record of developing markets and commercializing disruptive medical technologies. During his career he has created go-to-market strategies for multiple breakthrough products and held senior marketing and sales leadership roles.



**Ravi Malhotra**  
Corporate Controller

17 years of experience in finance and accounting in Life Sciences, Technology and Manufacturing industries. During his career he has held positions including Corporate Controller, Senior Director of Finance, Associate Director of Technical Accounting and Senior Manager – Assurance.



# HeartBeam's Technology is a Dramatic Breakthrough in Cardiac Monitoring



Credit-card sized, cable-free cardiac monitoring device, capable of producing a 12L ECG device, leveraging HeartBeam's core vector technology



Highest resolution 12L ECG device creates new applications for patients and physicians:

- Heart attack detection upon symptom onset
- Complex arrhythmias that existing wearables cannot detect
- Monitoring chronic conditions, prevention and screening



Implementation on a patch: bringing on-demand 12L technology to an established, reimbursed market



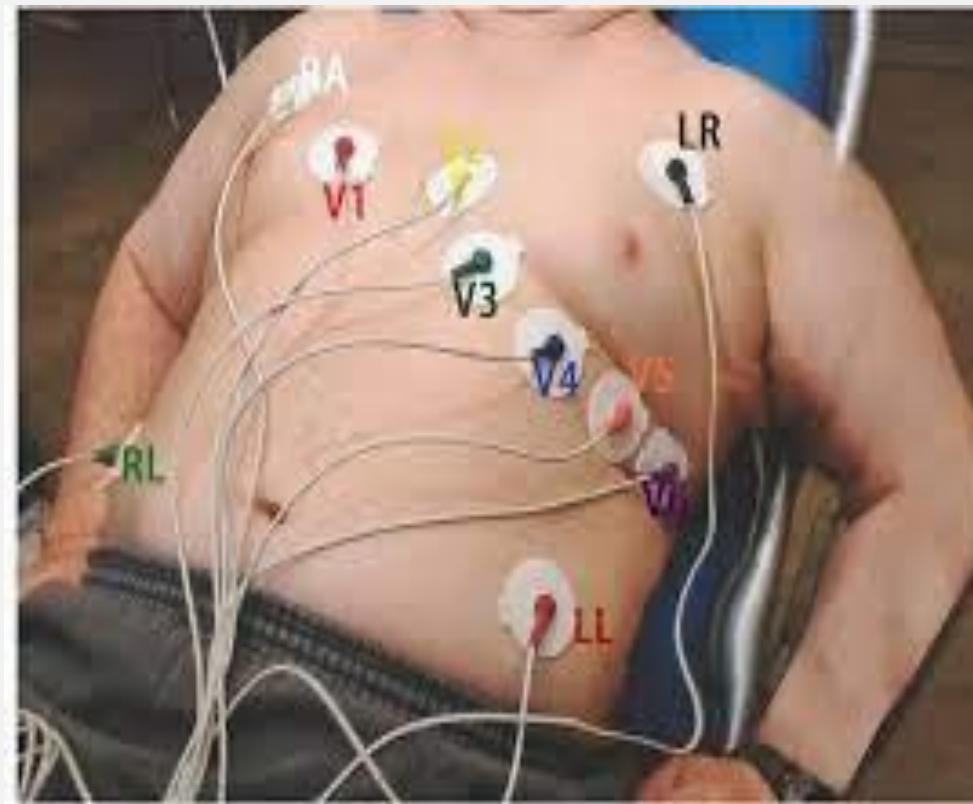
Novel watch form factor will combine a continuous monitor and a 12L



# No Heart Attack Solution Practical for Home Use on the Market

**IMPRACTICAL  
FOR HOME USE**

## TRADITIONAL 12-LEAD ECG



Standard 12-lead ECGs require a health care professional and are not practical for home use

**DO NOT DETECT  
HEART ATTACKS**

## PATIENT-FRIENDLY



**Get your Kardia device**



Start taking control of your heart health from home with Kardia. Get your device today.

~~KardiaMobile is not tested or recommended for use with pacemakers and ICDs.~~  
KardiaMobile does not check for heart attack.

# Patients Cannot Determine if They Are Having a Heart Attack

Ignore symptoms



Go to Emergency Department

## Lost lives

- » Patients delay an average of 3 hours before seeking care
- » Delays lead to increased mortality
- » Greater incidence of heart failure among these patients

Mortality rate increases by

**40%**



for an average wait of 3-4 hours after symptoms begin

## Wasted healthcare dollars

- » Chest pain is second most common reason for an ED visit

**82%** of chest pain ED visits are unnecessary



Cost to the healthcare system each year

Am I having a heart attack?



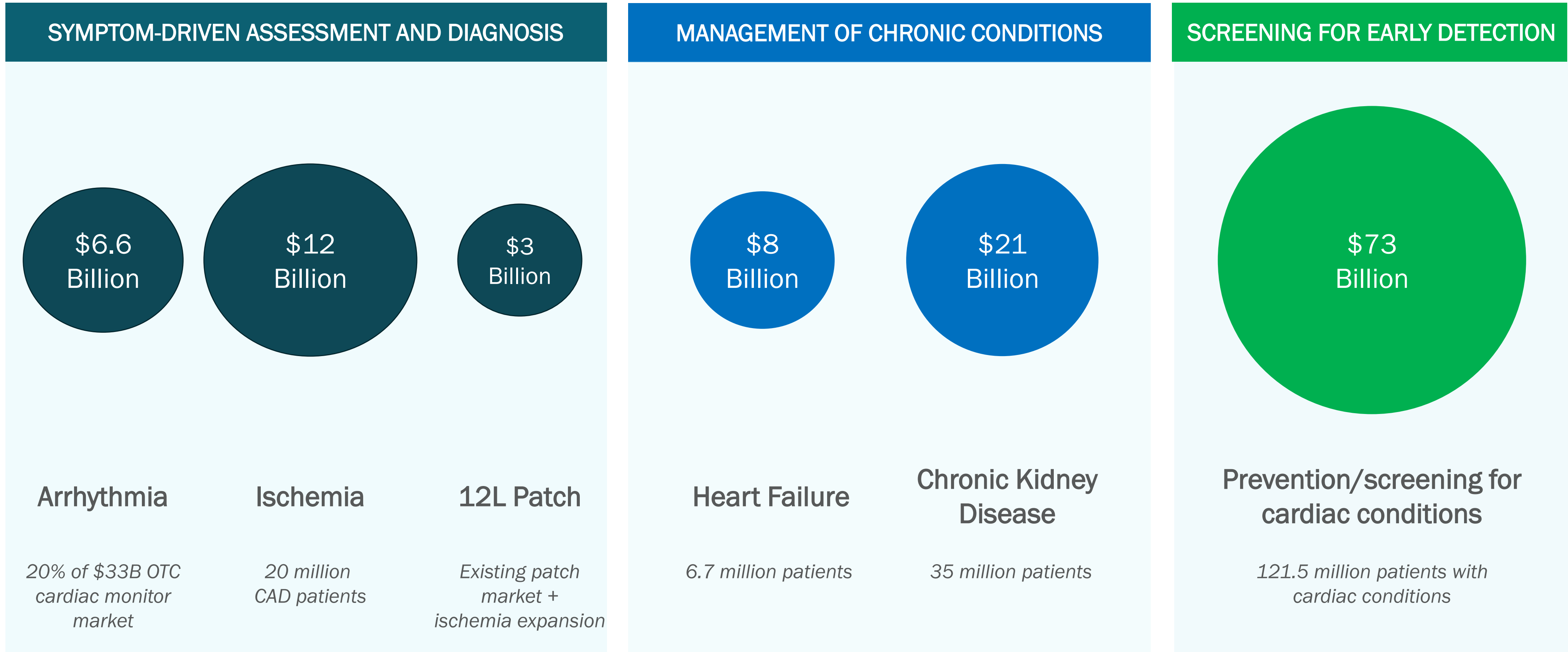
Heart  Beam



# How to use the HeartBeam AIMIGo™ System

[Video link will open in web browser](#)

# HeartBeam Market Sizes, US





# AIMIGo FDA Clearance Will be a Major Milestone

## FOUNDATION FOR FUTURE SUBMISSIONS AND PRODUCT PIPELINE

- Anticipated to be first patient-held device leveraging vector technology cleared by the FDA
- Basis for further HeartBeam FDA submissions
- Vector approach is excellent platform for AI algorithms
- AI algorithms on top of the rich 360-degree signals, particularly with the longitudinal readings, could result in unsurpassed predictive and diagnostic capabilities

# Regulatory Status for AIMIGo Product

## STATUS

- HeartBeam AIMIGo 510(k) application under active FDA review
- Cornerstone submission for HeartBeam

## PRODUCT

- Clearance as cardiac monitoring device that captures 360-degree signals of the heart
- Includes credit card-sized device, patient application, physician portal and wireless communications between elements

## TIMING

- Engaged in productive discussions with the FDA, addressing small number of remaining questions
- Progressing toward clearance: limited launch anticipated by year end

# Regulatory Status for 12-Lead Synthesis Software

## STATUS

- Preparing materials for FDA 510(k) submission
- Enrollment complete in VALID-ECG study on June 20, currently analyzing data
- Results of a study that served as the pilot for VALID-ECG pivotal to be presented at American Heart Association meeting in November

## PRODUCT

- Algorithms that convert the AIMIGo 360-degree signals into a synthesized 12-lead ECG

## TIMING

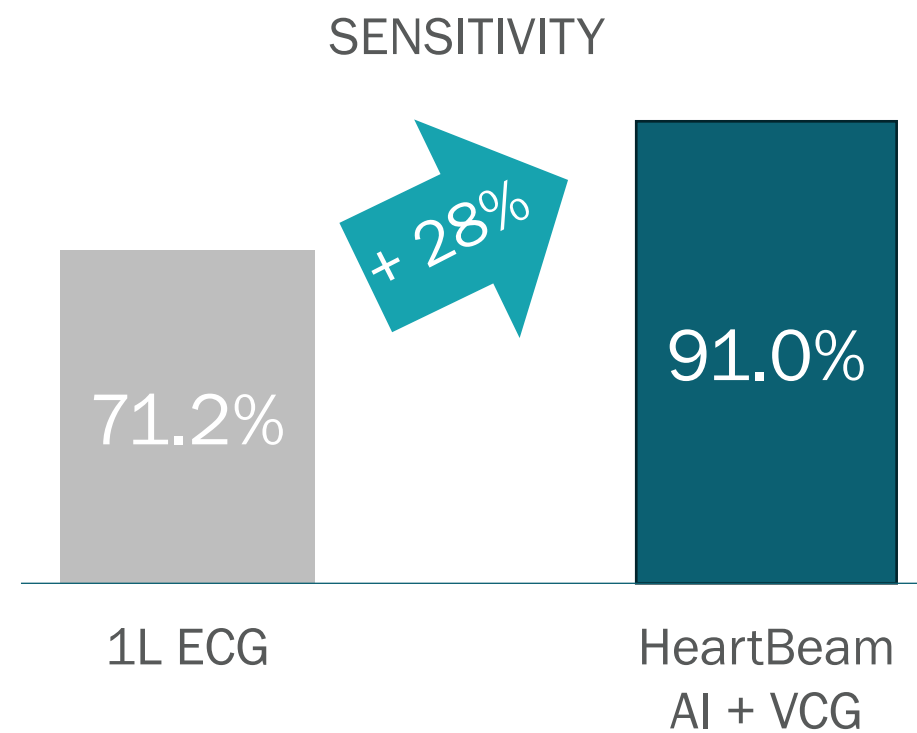
- Anticipate filing soon after we receive clearance for the AIMIGo System



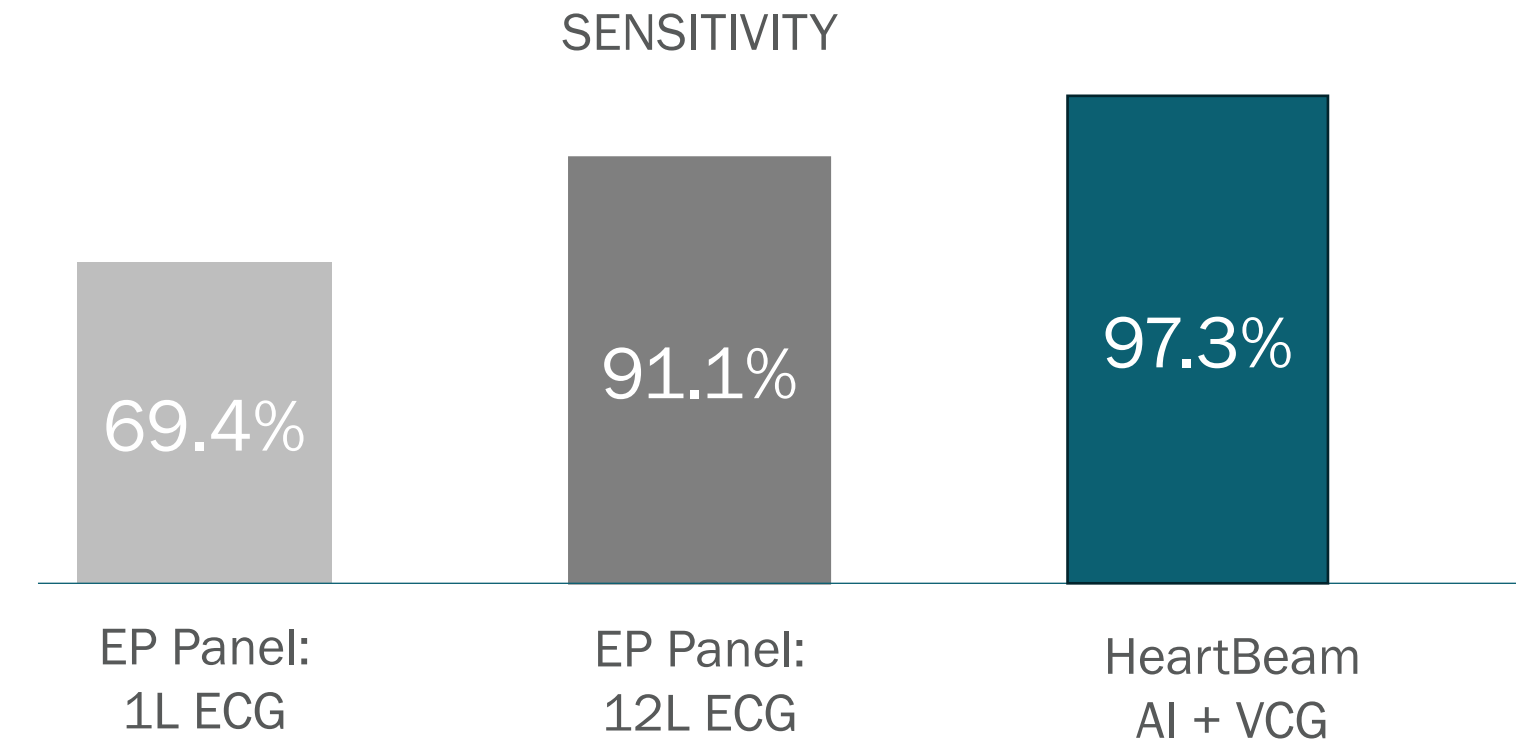
# Recent Scientific Presentations Demonstrate HeartBeam AI's Ability to Improve Arrhythmia Detection

- Atrial flutter is a common arrhythmia and typically requires a 12-lead ECG to be taken in a medical setting which is challenging
- Common smartwatches /wearables only offer Single-lead ECG, limiting ability to detect broad range of arrhythmias

**IMPROVED DETECTION OF ATRIAL FLUTTER VS. SINGLE-LEAD ECG**



**IMPROVED DETECTION OF ATRIAL FLUTTER VS. PANEL OF ELECTROPHYSIOLOGISTS**



**Opportunity to provide benefits of Vector 360-degree signals and 12-lead ECG with the patient outside of a medical facility**

Reddy, V., Presentation at EHRA, April 2024. Lampert, J., Presentation at HRS, May 2024.

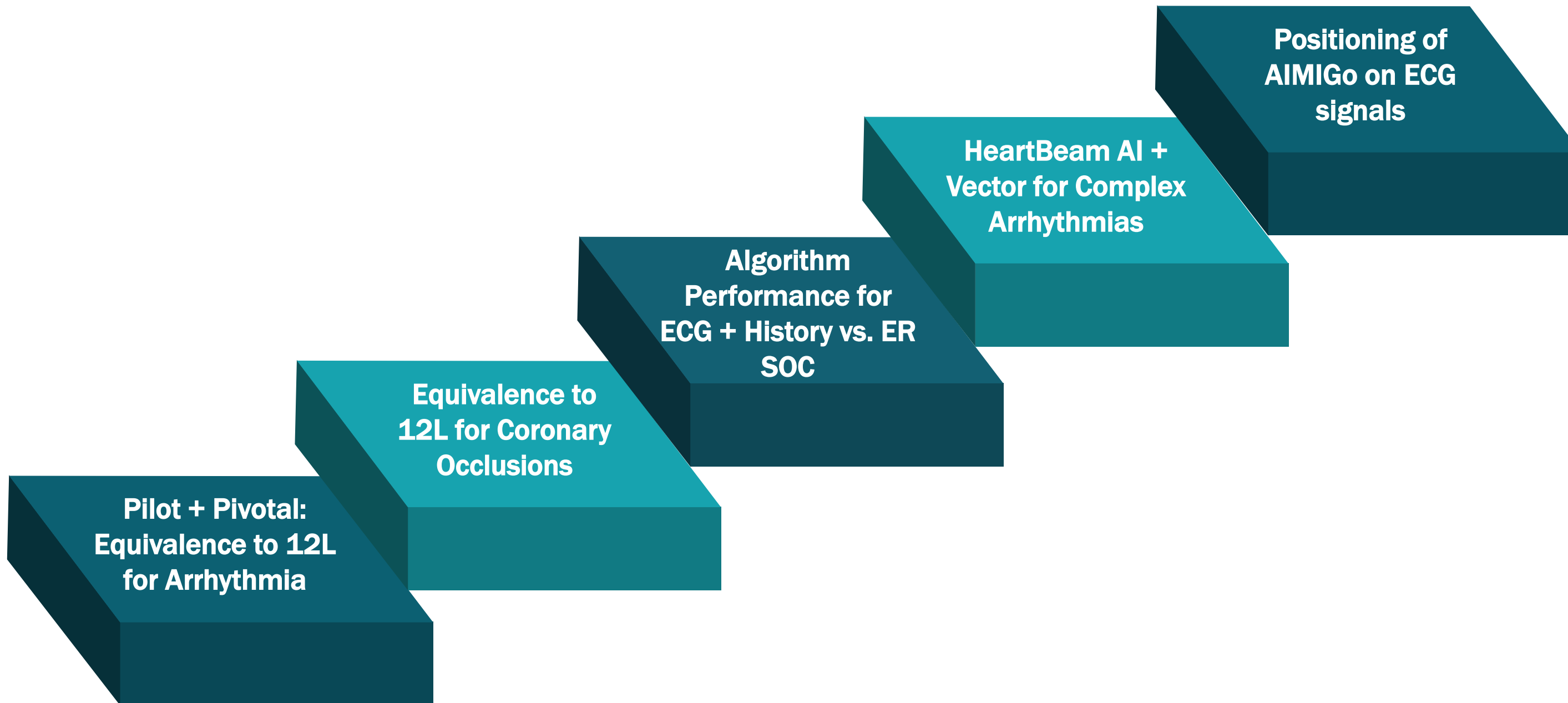
# AI Program Update

## HeartBeam AI algorithms for arrhythmia classification

- Close to freezing our multiple AI models
- Once cleared by FDA, will provide a comprehensive set of diagnostic suggestions
- AI classification + 12L ECG output provided to cardiologist create an offering beyond anything that is available in a patient-obtained ECG

# Significant Body of Evidence on HeartBeam's Groundbreaking Technology

**500**  
PATIENTS IN  
CLINICAL STUDIES



**250+**  
REAL-WORLD  
PATIENTS

**>7500**  
RECORDINGS



# Q2 2024 Financial Highlights

\$ in Thousands	Quarter Ended June 30,	
	2024	2023
Operating Expenses:		
General & Administrative	\$2,246	\$1,828
Research & Development	2,844	1,484
Total Operating Expenses	5,090	3,312
Loss from Operations	(5,090)	(3,312)
Interest and Other Income	134	158
<b>Net loss</b>	<b>\$(4,956)</b>	<b>\$(3,154)</b>
\$ in Thousands	June 30, 2024	December 31, 2023
Cash & Cash Equivalents	\$9,157	\$16,189

# Closing Summary

## BREAKTHROUGH IN CARDIAC TECHNOLOGY

- Smallest, easiest-to-use and first cable-free 12-lead ECG device
- Enabled by HeartBeam's unique and IP-protected vector technology
- Potential to disrupt numerous large markets and clinical applications

## SIGNIFICANT CLINICAL AND REGULATORY PROGRESS

- AIMIGo 510(k) under active review. Engaged in productive discussions with the FDA, answering small number of remaining questions.
- Progressing toward clearance; limited launch anticipated by year end
- Preparing materials for second 510(k) submission, on 12L synthesis software. Anticipate submission soon after initial AIMIGo clearance.
- Completed enrollment in VALID-ECG study

## AI PROGRAM PROGRESSING

- Positive clinical data on deep learning algorithm, HeartBeam AI
- Excellent performance in detecting atrial flutter; outperformed panel of EPs reading 12L
- Working to freeze algorithms in preparation for clinical study and subsequent 510(k) submission

# Q&A

## Company

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