

August 14, 2024



# HeartBeam Reports Second Quarter 2024 Results

*Continued Clinical and Regulatory Progress on the HeartBeam AIMIGo™ System*

*Enrollment Complete in VALID-ECG Clinical Study That Will Be the Basis of the Upcoming FDA Submission on the 12-Lead Synthesis Software*

*Management to Host Webcast and Conference Call Today at 4:30 p.m. ET*

SANTA CLARA, Calif.--(BUSINESS WIRE)-- **HeartBeam, Inc.** (NASDAQ: BEAT), a medical technology company focused on transforming cardiac care through the power of personalized insights, has reported its financial and operational results for the second quarter ended June 30, 2024.

## **Second Quarter & Subsequent 2024 Operational Highlights**

The Company made steady progress toward key clinical and regulatory milestones on its HeartBeam AIMIGo™ System.

### ***AIMIGo 510(k) Submission:***

- The 510(k) submission for the HeartBeam AIMIGo System is currently being reviewed by the FDA.
- AIMIGo is a credit card-sized, cable-free cardiac monitoring device that will be capable of producing a 12-lead ECG by leveraging the Company's core vector technology, which captures 360-degree signals of the heart's electrical activity. The Company owns patents supporting the underlying technology.
- This is the cornerstone submission for HeartBeam and will be the basis of future submissions.
- The Company has successfully resolved the vast majority of the questions the FDA has asked. During the second quarter of 2024 the FDA requested additional information, which the Company is in the process of providing. The Company is working with the FDA to address the small number of remaining questions.
- The Company continues to plan for a limited launch of AIMIGo by the end of 2024.

### ***12-Lead Synthesis Software Submission:***

- HeartBeam has completed two pre-submission meetings with the FDA on the planned second 510(k) submission, which will be submitted after the initial clearance of the AIMIGo System.
- The second submission is focused on the algorithms that convert the 360-degree signals captured by the AIMIGo System into a synthesized 12-lead ECG.
- A key component of the submission will be the results of the VALID-ECG pivotal study, which is designed to demonstrate the similarity between the synthesized 12-lead ECG

and a standard 12-lead ECG.

- Patient enrollment for VALID-ECG was completed on June 20, 2024.
- The Company currently anticipates submitting the 510(k) application soon after receiving clearance for the AIMIGo System.

### ***Other Highlights:***

- New data presented at the European Heart Rhythm Association (EHRA) conference in April marked the first scientific presentation on HeartBeam AI, the Company's deep learning technology. The data validated that applying HeartBeam AI to vectorcardiography (VECG) delivered distinctly improved performance in the detection of atrial flutter over single-lead ECGs. Atrial flutter is a common arrhythmia that significantly increases a patient's risk for stroke.
- Additionally, new data presented at the Heart Rhythm Society (HRS) Conference in May demonstrated that combining HeartBeam AI with VECG outperformed an expert panel of electrophysiologists in detecting atrial flutter when reviewing 12-lead ECGs. Data showed that applying AI to VECG data provides more consistent and reliable detection of atrial flutter.
- HeartBeam AIMIGo was selected as winner of the "Best New ECG Technology Solution" award in the 8th annual MedTech Breakthrough Awards program.
- HeartBeam was added to the Russell Microcap® Index effective after the market close on June 28, 2024.
- Cash and cash equivalents totaled approximately \$9.2 million as of June 30, 2024, enabling the Company to execute on upcoming clinical and regulatory milestones.

### **Management Commentary**

"The second quarter of 2024 was highlighted by new data for the validation of HeartBeam AI, our deep learning technology, and ongoing progress with anticipated regulatory and clinical milestones for the AIMIGo vector technology platform," said Branislav Vajdic, PhD, Chief Executive Officer and Founder of HeartBeam. "We have successfully resolved the vast majority of questions the FDA has asked and are in the process of providing the additional information the FDA requested during the quarter. We are engaged in productive discussions with the FDA and believe that we are progressing toward clearance, which we anticipate later this year. We have created our initial Go-To-Market plan and will be testing this during our limited launch prior to the end of the year.

"Following the initial FDA clearance for the AIMIGo System, we plan to submit a second 510(k) application. This submission will include results from our pivotal VALID-ECG clinical study, which compares the AIMIGo synthesized 12-lead ECG to a standard 12-lead ECG in patients presenting to an outpatient cardiology clinic or arrhythmia center for symptoms suggestive of cardiac arrhythmia or for routine checkup of previously diagnosed arrhythmia. Due to strong interest, in June, we completed patient enrollment in this important 198-patient study after only three months of enrollment, which is extremely fast for a study of this size.

"We presented positive new data for our deep learning algorithm, HeartBeam AI, at two conferences during the quarter. The data showed that HeartBeam AI combined with VECG delivered equivalent performance to a 12-lead ECG, greatly improved detection of atrial flutter over a single-lead ECG, and even outperformed an expert panel of electrophysiologists in detecting atrial flutter. We believe this presents an opportunity for a

vector-based algorithm that offers arrhythmia detection capabilities beyond what is available today.

“Looking ahead, our optimism continues for the FDA’s clearance of the AIMiGo system and we are on track for the planned second 510(k) submission. We are encouraged by our progress in using artificial intelligence with our vector technology, showcasing the potential of our artificial intelligence program to improve diagnostic accuracy when a patient is outside of a medical facility. We also see strength in our product development pipeline, notably an extended wear patch for detecting heart attacks and complex cardiac arrhythmias. This market is estimated to reach \$4.8 billion by 2030. Interest from large industry players in partnering continues on key aspects of our portfolio. Our long-term vision is to transform the monitoring and detection of cardiac conditions through our vector-based technology. Our unique approach allows us to deliver the smallest, easiest to use cable-free 12-lead ECG to patients and their physicians in a variety of form factors and unlock actionable insights on a wide range of cardiac conditions,” concluded Dr. Vajdic.

## **Second Quarter 2024 Financial Results**

Research and development expenses for the second quarter of 2024 were \$2.8 million, compared to \$1.5 million for the second quarter of 2023.

General and administrative expenses for the second quarter of 2024 were \$2.2 million compared to \$1.8 million for the second quarter of 2023.

Net loss for the second quarter of 2024 was \$5.0 million, compared to a net loss of \$3.2 million for the second quarter of 2023.

Cash and cash equivalents totaled \$9.2 million as of June 30, 2024, compared to \$16.2 million as of December 31, 2023. Net cash used in operations was \$7.0 million for the six-month period ended June 30, 2024.

## **Second Quarter 2024 Results Conference Call**

HeartBeam CEO and Founder Branislav Vajdic, PhD, President Robert Eno, and Senior Director & Corporate Controller Ravi Malhotra will host the conference call, followed by a question-and-answer period. The conference call will be accompanied by a presentation, which can be viewed during the webcast or accessed via the investor relations section of the Company’s website [here](#).

To access the call, please use the following information:

**Date:** Wednesday, August 14, 2024  
**Time:** 4:30 p.m. Eastern time (1:30 p.m. Pacific time)  
**Dial-in:** 1-844-826-3035  
**International Dial-in:** 1-412-317-5195  
**Conference Code:** 10191273  
**Webcast:** [https://viaid.webcasts.com/starthere.jsp?ei=1681274&tp\\_key=132aeeb1d7](https://viaid.webcasts.com/starthere.jsp?ei=1681274&tp_key=132aeeb1d7)

A telephone replay will be available approximately three hours after the call and will run November 14, 2024, by dialing 1-844-512-2921 from the U.S., or 1-412-317-6671 from international locations, and entering replay pin number: 10191273. The replay can also be viewed through the webcast link above and the presentation utilized during the call will be

available in the Company's investor relations section [here](#).

## **About HeartBeam, Inc.**

HeartBeam, Inc. (NASDAQ: BEAT) is a medical technology company that is dedicated to transforming cardiac care through the power of personalized insights. The Company's proprietary vectorelectrocardiography (VECG) technology collects 3D signals of the heart's electrical activity and converts them into a 12-lead ECG. This platform technology is designed to be used on portable, patient-friendly devices such as a credit-card sized monitor, watch or patch. 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 how cardiac health is managed in the future. The Company owns numerous patents related to technology enablement.

For additional information, visit [HeartBeam.com](http://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](http://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.

**HEARTBEAM, INC.**  
**Condensed Balance Sheets (Unaudited)**  
(In thousands, except share data)

	<u>June 30, 2024</u>	<u>December 31, 2023</u>
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 9,157	\$ 16,189
Prepaid expenses and other current assets	544	636
<b>Total Current Assets</b>	<u>9,701</u>	<u>16,825</u>
Property and equipment, net	370	256
Other assets	55	50
<b>Total Assets</b>	<u>\$ 10,126</u>	<u>\$ 17,131</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities:</b>		
Accounts payable and accrued expenses (includes related party \$- and \$2, respectively)	\$ 1,420	\$ 1,194
<b>Total Current Liabilities</b>	<u>1,420</u>	<u>1,194</u>
<b>Total Liabilities</b>	<u>1,420</u>	<u>1,194</u>
Commitments (Note 7)		
<b>Stockholders' Equity</b>		
Preferred stock - \$0.0001 par value; 10,000,000 authorized; 0 shares outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock - \$0.0001 par value 100,000,000 shares authorized; 26,562,111 and 26,329,032 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	3	3
Additional paid in capital	55,090	52,759
Accumulated deficit	(46,387)	(36,825)
<b>Total Stockholders' Equity</b>	<u>8,706</u>	<u>15,937</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 10,126</u>	<u>\$ 17,131</u>

**HEARTBEAM, INC.**  
**Condensed Statements of Operations (Unaudited)**  
(In thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
<b>Operating Expenses:</b>				
General and administrative	\$ 2,246	\$ 1,828	\$ 4,602	\$ 4,303
Research and development	2,844	1,484	5,272	3,165
Total operating expenses	5,090	3,312	9,874	7,468
Loss from operations	(5,090)	(3,312)	(9,874)	(7,468)
<b>Other Income</b>				
Interest income	134	158	312	178
Total other income	134	158	312	178
Loss before provision for income taxes	(4,956)	(3,154)	(9,562)	(7,290)
Income tax provision	—	—	—	—
<b>Net Loss</b>	\$ (4,956)	\$ (3,154)	\$ (9,562)	\$ (7,290)
Net loss per share, basic and diluted	\$ (0.19)	\$ (0.16)	\$ (0.36)	\$ (0.52)
Weighted average common shares outstanding, basic and diluted	26,566,832	19,690,251	26,538,863	13,910,365

**HEARTBEAM, INC.**  
**Condensed Statements of Cash Flows (Unaudited)**  
(In thousands)

	<b>Six months ended June 30,</b>	
	<b>2024</b>	<b>2023</b>
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (9,562)	\$ (7,290)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock based compensation expense	2,247	1,095
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	92	152
Accounts payable and accrued expenses	210	(1,094)
	<b>(7,013)</b>	<b>(7,137)</b>
<b>Net cash used in operating activities</b>		
<b>Cash Flows From Investing Activities</b>		
Purchase of property and equipment	(98)	—
Purchase of short-term investments	—	(3,939)
<b>Net cash used in investing activities</b>	<b>(98)</b>	<b>(3,939)</b>
<b>Cash Flows From Financing Activities</b>		
Proceeds from sale of equity, net of issuance costs	76	24,764
Proceeds from exercise of stock options	8	103
Proceeds from exercise of warrants	—	16
<b>Net cash provided by financing activities</b>	<b>84</b>	<b>24,883</b>
	<b>(7,027)</b>	<b>13,807</b>
<b>Net increase (decrease) in cash and restricted cash</b>		
<b>Cash, cash equivalents and restricted cash – Beginning of period</b>	<b>16,239</b>	<b>3,594</b>
<b>Cash, cash equivalents and restricted cash – Ending of period</b>	<b>\$ 9,212</b>	<b>\$ 17,401</b>
<b>Reconciliation of cash, cash equivalents and restricted cash:</b>		
Cash and cash equivalents	\$ 9,157	\$ 17,401
Restricted cash (included in other assets)	55	—
<b>Total cash, cash equivalents and restricted cash</b>	<b>\$ 9,212</b>	<b>\$ 17,401</b>
<b>Supplemental Disclosures of Cash Flow Information:</b>		
Purchase of property and equipment in accounts payable	\$ 16	\$ —
Taxes paid	\$ —	\$ —

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