

# HeartBeam Reports First Quarter 2025 Results

- Successfully Met Clinical Endpoints in the VALID-ECG Pivotal Study Showing 93.4%
   Overall Diagnostic Agreement for Assessment of Arrhythmia
- Productive Discussions with FDA on 510(k) Submission for Groundbreaking 12-lead Electrocardiogram (ECG) Synthesis Software
- Signed Strategic Collaboration with AccurKardia to Enhance Commercial Offering for Arrhythmia Assessment
- Added Two New US Patents to Robust IP Portfolio and Differentiated Position in Remote Cardiac Diagnostics
- Management to Host Webcast and Conference Call Today at 4:30 p.m. ET

SANTA CLARA, Calif.--(BUSINESS WIRE)-- <u>HeartBeam, Inc.</u> (NASDAQ: BEAT), a medical technology company focused on transforming cardiac care by providing powerful personalized insights, has reported its financial and operational results for the first quarter ended March 31, 2025.

#### First Quarter & Subsequent 2025 Operational Highlights

The Company continues to make significant progress towards commercial readiness with key clinical and regulatory achievements on the HeartBeam System.

#### VALID-ECG Pivotal Study:

- Successfully met the clinical endpoints in the VALID-ECG pivotal study, which enrolled 198 patients across five (5) US sites for arrhythmia assessment.
  - Data showed a 93.4% overall diagnostic agreement, indicating that the synthesized 12-lead ECG can support diagnosis of arrhythmias in a manner consistent with standard 12-lead ECGs.
  - Data was presented by Thomas Deering, M.D., of Piedmont Heart Institute, at the Heart Rhythm Society (HRS) meeting in April 2025 and showed that the study met its performance goals.
- Study formed the basis of the US Food and Drug Administration (FDA) 510(k) submission for 12-lead ECG synthesis software for arrhythmia assessment.

#### 12-Lead ECG Synthesis Software FDA Submission:

- Received foundational FDA 510(k) clearance of the HeartBeam System, which captures the heart's electrical signals in 3D (by capturing 3 non-coplanar directions), for comprehensive arrhythmia assessment in December 2024.
- Submitted FDA 510(k) application focused on the patented HeartBeam software that converts the heart's electrical signals captured in 3 non-coplanar directions into a

- synthesized 12-lead ECG in January 2025.
- Ongoing productive discussions with FDA related to the 510(k) application throughout the guarter.
- Combined with the VALID-ECG results, these interactions provide confidence that the stated timeline for FDA clearance remains intact.

#### Commercial Readiness Plans:

- Anticipate initiating commercialization upon receiving 510(k) clearance for the 12-lead ECG synthesis software.
- Commenced an Early Access Program to obtain important feedback on the end-to-end clinical workflow, ensure operational readiness and establish an early adopter funnel in anticipation of US commercialization.
- Signed contract manufacturer with ability to scale production alongside Company growth.
- Finalized strategic collaboration with AccurKardia, an innovator in ECG-based diagnostics technology, focusing on making AccurKardia's FDA-cleared ECG analysis software, AccurECG™, available on HeartBeam's devices.

#### Other Highlights:

- Closed a public offering of common stock with gross proceeds of approximately \$11.5 million in February 2025, including the exercise of the underwriter's over-allotment option, to fund key growth milestones and preparation for US commercialization.
- Received two new US patents, and now owns 20 issued US and international patents, as well as two (2) allowed patents and 32 pending patents, adding to an already robust IP portfolio that supports the company's differentiated position in remote cardiac diagnostics.
- Appointed Chief Executive Officer, Robert Eno, to the Board of Directors.
- Appointed Dr. Vivek Reddy of Mount Sinai, one of the nation's premier cardiac electrophysiologists, to the HeartBeam Scientific Advisory Board.
- Cash, cash equivalents, and short-term investments totaled \$8.2 million as of March 31, 2025, with net cash used in operating activities of \$4.5 million for the three months ended March 31, 2025.

#### **Management Commentary**

"The first quarter of 2025 demonstrated continued progress on commercial readiness plans, underscored by successful pivotal study results, a new strategic partnership, and strengthened intellectual property protection," said Robert Eno, Chief Executive Officer, HeartBeam.

"Since submitting a 510(k) application to the FDA for the 12-lead ECG synthesis software designed for the assessment of arrhythmias, we have had ongoing productive discussions with the FDA. The submission is backed by robust data demonstrating HeartBeam successfully met the clinical endpoints in the VALID-ECG pivotal study. This important milestone confirms that our technology has the ability to deliver 12-lead ECG-like insights through the convenience of a credit card-sized device that patients can use whenever arrhythmia symptoms occur.

"We recently partnered with AccurKardia, an innovator in ECG-based diagnostics technology, to add its FDA-cleared ECG analysis software, AccurECG, to our devices. We believe combining our platforms will enhance our commercial offering for arrhythmia assessment by enabling patients and physicians to get an automated rhythm assessment. This will facilitate quicker diagnosis and faster access to clinical care when needed. The strategic collaboration is expected to expedite our product development efforts, reducing both costs and timelines.

"We received two new US patents to bolster the defensive and offensive moat around our core technology. The first patent significantly advances intellectual property for our credit card-sized ECG device, and the second patent expands the use of risk-based diagnostic algorithms into our product portfolio around wearable devices. We now own 20 issued patents worldwide, cementing our leadership in cardiac monitoring innovation.

"Looking ahead, we are focused on commercial readiness activities and key growth milestones, leveraging gross proceeds of approximately \$11.5 million from the recent fundraising we completed during the quarter. With productive discussions with the FDA on our 12-lead ECG synthesis software submission, we believe our timeline for clearance remains intact. We also commenced initial FDA interactions on expanding our indication to include ischemia and acute coronary events such as heart attacks. We expect to start enrollment in a Pilot Study on this indication in the second half of 2025. Taken together, we are advancing steadily on our milestones and look forward to additional updates in the months to come," concluded Eno.

#### First Quarter 2025 Financial Results

Research and development expenses for the first quarter of 2025 were \$3.5 million, compared to \$2.4 million for the first quarter of 2024.

General and administrative expenses for the first quarter of 2025 were \$2.0 million compared to \$2.4 million for the first quarter of 2024.

Net loss for the first quarter of 2025 was \$5.5 million, compared to a net loss of \$4.6 million for the first quarter of 2024.

Net cash used in operating activities was \$4.5 million for the three months ended March 31, 2025, as compared to \$3.5 million for the first quarter of 2024.

Cash, cash equivalents, and short-term investments totaled \$8.2 million as of March 31, 2025, compared to \$2.4 million as of December 31, 2024. On February 25, 2025, the Company closed a public offering of common stock with gross proceeds of \$11.5 million in February 2025, including the exercise of the underwriter's over-allotment option.

#### First Quarter 2025 Results Conference Call

HeartBeam CEO Robert Eno and CFO Tim Cruickshank 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 <a href="here">here</a>.

To access the call, please use the following information:

Date: Tuesday, May 13, 2025

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:
 10199007

Webcast: HeartBeam First Quarter 2025 Earnings Conference Call

A telephone replay will be available approximately three hours after the call and will run through August 13, 2025, by dialing 1-844-512-2921 from the U.S., or 1-412-317-6671 from international locations, and entering replay pin number: 10199007. 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 <a href="heterogeneering-neeri

#### 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 3 non-co-planar 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. The Company holds 20 issued patents related to technology enablement. For additional information, visit <a href="HeartBeam.com">HeartBeam.com</a>.

#### **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 <a href="https://www.sec.gov">www.sec.gov</a>. 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)

A	N	larch 31, 2025	D	ecember 31, 2024
Assets				
Current Assets:				
Cash and cash equivalents	\$	4,390	\$	2,377
Short-term investments		3,760		_
Prepaid expenses and other current assets		458		393
Total Current Assets		8,608	_	2,770
Property and equipment, net		443		450
Other assets		56		56
Total Assets	\$	9,107	\$	3,276
Liabilities and Stockholders' Equity				
Current Liabilities:	Φ	500	Φ	504
Accounts payable (includes related party \$5 and \$5, respectively)	\$	523 1,055	\$	531 1,091
Accrued expenses				
Total Current Liabilities		1,578		1,622
Total Liabilities		1,578		1,622
Commitments				
Stockholders' Equity				
Preferred stock - \$0.0001 par value; 10,000,000 authorized; 0 shares outstanding at March 31, 2025 at December 31, 2024	nd	_		_
Common stock - \$0.0001 par value 100,000,000 shares authorized; 33,734,548 and 26,960,901 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively		3		3
Additional paid in capital		69,283		57,924
Accumulated deficit		(61,757)		(56,273)
Total Stockholders' Equity		7,529	_	1,654
	\$	9,107	\$	3,276
Total Liabilities and Stockholders' Equity	<b>—</b>		<u> </u>	

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

	Thre	Three months ended March 31,			
		2025	:	2024	
Operating Expenses:					
General and administrative	\$	2,012	\$	2,356	
Research and development		3,492		2,428	
Total operating expenses		5,504		4,784	
Loss from operations		(5,504)		(4,784)	
Other Income and (Expense)					
Interest income		20		178	
Total other income		20		178	
Lange before any delay for income toward		(F. 404)		(4.000)	
Loss before provision for income taxes		(5,484)		(4,606)	
Income tax provision		_		_	
Net Loss	\$	(5,484)	\$	(4,606)	
	Φ.	(0.40)	Φ.	(0.47)	
Net loss per share, basic and diluted	<u> </u>	(0.18)	<b>&gt;</b>	(0.17)	
	20	270 751	26.1	E11 201	
Weighted average common shares outstanding, basic and diluted	3(	30,378,751		26,511,201	

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

		Three months e		
	2025		2024	
Cash Flows From Operating Activities				
Net loss	\$ (5,484	) \$	(4,606)	
Adjustments to reconcile net loss to net cash used in operating activities	_			
Depreciation	7			
Stock based compensation expense	1,109		1,207	
Changes in operating assets and liabilities:	(0.5	`	00	
Prepaid expenses and other current assets	(65	)	33	
Accounts payable and accrued expenses	(44	)	(97)	
Net cash used in operating activities	(4,477	)	(3,463)	
Cash Flows From Investing Activities				
Purchase of property and equipment			(88)	
Purchase of short-term investments	(3,760	)	_	
Net cash used in investing activities	(3,760	)	(88)	
Cash Flows From Financing Activities				
Proceeds from sale of equity, net of issuance costs	10,250		_	
Net cash provided by financing activities	10,250			
	2,013		(3,551)	
Net increase (decrease) in cash and restricted cash	·			
Cash, cash equivalents and restricted cash – Beginning of period	2,433		16,239	
Cash, cash equivalents and restricted cash – Ending of period	\$ 4,446 	\$	12,688	
Reconciliation of cash, cash equivalents and restricted cash:				
Cash and cash equivalents	\$ 4,390	\$	12,638	
Restricted cash (included in other assets)	56		50	
Total cash, cash equivalents and restricted cash	\$ 4,446	\$	12,688	
Supplemental Disclosures of Cash Flow Information:				
Purchase of property and equipment in accounts payable	\$ 2	\$	_	

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