UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended **December 31, 2023**

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: **001-41060**

HEARTBEAM, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-4881450**
State or Other Jurisdiction of Incorporation or Organization	I.R.S. Employer Identification No.
2118 Walsh Avenue, Suite 210 Santa Clara, CA	**95050**
Address of Principal Executive Offices	Zip Code

(408) 899-4443

Registrant's Telephone Number, Including Area Code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	BEAT	NASDAQ
Warrants	BEATW	NASDAQ

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2023, there were 25,990,516 shares of the registrant's common stock, par value $0.0001 per share, issued and outstanding, of these, 21,352,087 shares were held by non-affiliates of the registrant. The market value of securities held by non-affiliates was $51,458,385 as of June 30, 2023, based on the closing price of $2.41 for the registrant's common stock on June 30, 2023.

As of March 19, 2024, there was 26,329,032 shares of the registrant's common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

HEARTBEAM, INC.
CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In particular, statements contained in this Annual Report on Form 10-K, including but not limited to, statements regarding the sufficiency of our cash, our ability to finance our operations and business initiatives and obtain funding for such activities; our future results of operations and financial position, business strategy and plan prospects, or costs and objectives of management for future acquisitions, are forward looking statements. These forward looking statements relate to our future plans, objectives, expectations and intentions and may be identified by words such as "may," "will," "should," "expects," "plans," "anticipates," "intends," "targets," "projects," "contemplates," "believes," "seeks," "goals," "estimates," "predicts," "potential" and "continue" or similar words. Readers are cautioned that these forward-looking statements are based on our current beliefs, expectations and assumptions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified below, under Part II, Item lA. "Risk Factors" and elsewhere in this. Therefore, actual results may differ materially and adversely from those expressed, projected or implied in any forward-looking statements. We undertake no obligation to revise or update any forward looking statements for any reason.

The Company will continue to file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). Forward-looking statements speak only as of the dates specified in such filings. Except as expressly required under federal securities laws and the rules and regulations of the SEC, we do not undertake any obligation to update any forward-looking statements to reflect events or circumstances arising after any such date, whether as a result of new information or future events or otherwise. You should not place undue reliance on the forward-looking statements included in this report or that may be made elsewhere from time to time by us, or on our behalf. All forward-looking statements attributable to us are expressly qualified by these cautionary statements.

NOTE REGARDING COMPANY REFERENCES

Throughout this Annual Report on Form 10-K, "HeartBeam," the "Company," "we," "us" and "our" refer to HeartBeam, Inc.

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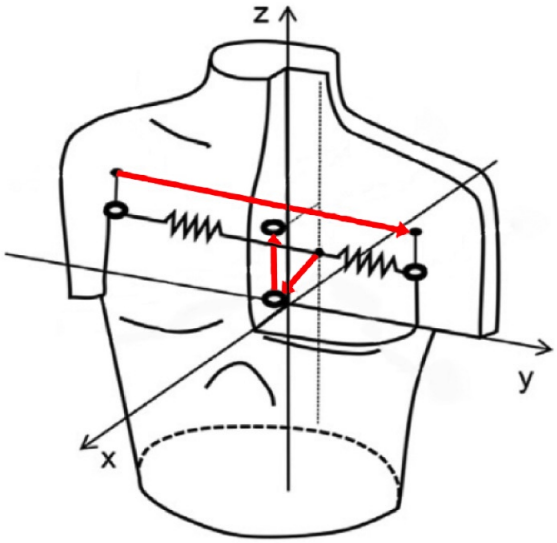
Part I

Item 1. Business

Overview

We are a medical technology company focused on transforming cardiac care through the power of personalized insights. Our aim is to deliver innovative, higher resolution ambulatory cardiac monitoring solutions that can be used by patients anywhere to enable the detection and monitoring of cardiac disease outside of a healthcare facility. Our ability to develop higher resolution Electrocardiogram ("ECG") solutions is achieved through the development of our proprietary and patented Vector Electrocardiography ("VECG") technology platform. Our VECG technology is capable of capturing three-dimensional ("3D") vector images of the heart's electrical activity and synthesizing a 12-Lead ("12L") ECG from these signals. In early studies, our approach demonstrated equal or superior diagnostic capability than traditional hospital-based 12L ECG systems.



Our products (hereinafter "Product" or "Products") require Food and Drug Administration ("FDA") clearance and have not been cleared for marketing.

We believe our Products and services will benefit many stakeholders, including patients, healthcare providers, and healthcare payors. We are developing our initial Product ("HeartBeam AIMIGo™" or "AIMIGo™"), to address the rapidly growing ambulatory cardiac monitoring market. HeartBeam AIMIGo is comprised of a credit-card sized electrocardiogram device, a patient application, a physician portal and powerful cloud-based algorithms. We intend to show that our easy-to-use device (without external electrodes) provides signals equivalent to a standard 12L device, and therefore will have a number of applications for ambulatory use. We believe that we are uniquely positioned to play a central role in ambulatory cardiac monitoring including high-risk coronary artery disease patients. Initial studies have shown that our ischemia detection system may be more accurate than existing ambulatory monitoring solutions. Coronary artery disease ("CAD") patients are at increased risk for a heart attack or Myocardial Infarction ("MI").

HeartBeam AIMIGo device in ready position (left) and the front view(right)

To date, we have developed working prototypes for HeartBeam AIMIGo and we have submitted the Product for FDA 510(k) clearance. To date, we have developed working prototypes for HeartBeam AIMIGo and we have submitted the Product for FDA 510(k) clearance. As more fully discussed in the Products and Technology section below, we have received questions from the FDA and are working through the stages of the FDA clearance process.

The custom software and hardware of our Products, we believe, are classified as Class II medical devices by the FDA, running on an FDA approved Class I registered software platform. Class II medical devices are those for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and there is sufficient information to establish special controls. Special controls can include performance standards, post-market surveillance, patient histories and FDA guidance documents. Premarket review and clearance by the FDA for these devices is generally accomplished through the 510(k) or 510(k) de-novo premarket notification process.

HeartBeam has 13 issued and allowed U.S. patents (U.S. 10,433,744, U.S. 10,117,592, U.S. 11,071,490, U.S. 11,419,538, U.S. 11,445,963, U.S. 11,701,049, U.S. 11,529,085, U.S. 10,980,433, U.S. 11,412,972, U.S. 11,234,658, U.S. 11,793,444, U.S. 11,877,853, and allowed U.S. patent application no. 18/068,481), and nine pending U.S applications. Outside of the U.S., HeartBeam has four issued patents in Germany, France, Netherlands and United Kingdom and fourteen pending applications in Canada, China, the European Union, Japan, South Korea and Australia. HeartBeam has two pending Patent Cooperation Treaty applications. The issued patents are predicted to expire between April 11, 2036 and April 21, 2042.

Market Overview

Chronic diseases are the number one burden on the healthcare system, driving up costs each year, and cardiovascular illnesses are one of the top contributors. Regulators, payors, and providers are focused on earlier diagnosis and improved management of these conditions to drive better outcomes at lower cost. One way to accomplish this is through the use of Connected Medical Devices – solutions that use technology to provide healthcare services remotely and aim to reduce healthcare expenditures while allowing patients to engage with clinicians and better self-manage their care. The Connected Medical Device Market size is estimated at $66 billion in 2024, and is expected to reach $133 billion by 2029, growing at a compounded annual growth (“CAGR”) of 15% during the forecast period (2024-2029).

Cardiovascular disease is the most expensive disease to manage and is estimated to be responsible for one in every eight healthcare dollars spent in the US, projected to cost the US healthcare system $1 trillion by 2035. As cardiovascular

disease is the leading cause of death worldwide, early detection, diagnosis, and management of chronic cardiac conditions are necessary to relieve the increasing burden on the healthcare system. Diagnostic tests such as ECGs are used to detect, diagnose, and track numerous cardiovascular conditions. The market for cardiac monitoring technologies, such as Holter monitors, patch-based cardiac monitoring technologies, and any other ECG-based technology used for clinical diagnosis is projected to reach approximately $18 billion by 2030, a CAGR of approximately 8%.

With advances in mobile communications, diagnostic monitoring of cardiac conditions is increasingly occurring outside the hospital. Global sales of Patient Monitoring Devices in 2021 were $42 billion. With a CAGR of approximately 11% from 2022 to 2032, the market is projected to reach a valuation of $125 billion by 2032. The adoption of such technology was greatly accelerated by the COVID-19 pandemic.

We believe we will be able to show that our easy-to-use device (without external electrodes) provides signals that can provide a 12L ECG representation like the gold-standard and therefore will have a number of applications for ambulatory use. Our initial Product, HeartBeam AIMIGo, will allow physicians to evaluate the full range of cardiac conditions that they currently assess with a standard 12L ECG. Currently we believe there are no products on the market that are portable, easy to use, and always with the patient to provide physicians and patients with timely and highly accurate information about all heart conditions that could be detected with a 12L ECG, including potential ischemic events. In the US, someone has a heart attack every 40 seconds. We believe a tool that is always with the patient and decreases time to intervention would have a significant effect on saving lives and healthcare dollars. We believe our technology will address this problem by providing a convenient, cost-effective cardiac monitoring solution, including software and hardware for physicians and their patients.

In the US, mobile cardiac tests are primarily conducted through outsourced Independent Diagnostic Testing Facilities ("IDTFs") or as part of an telehealth system. Reimbursement rates vary depending on the use case and generally are based on the value a technology offers to patients and healthcare providers. Actual reimbursed pricing is set by the Centers for Medicare & Medicaid Services ("CMS"). Reimbursement rates for private insurers typically provide for similar or higher reimbursement rates when compared to those set by the government for Medicare and Medicaid. Direct pay is an alternative for a product such as AIMIGo while data is being gathered.

Products and Technology

The foundation of our novel technology is the concept of VECG, a technology that has long been seen as superior to ECG in detecting MIs but is no longer used clinically because of the difficulty experienced by physicians interpreting the output. We solved the crucial problem of recording three orthogonal (x, y and z) projections of the heart vector with a device that is sized like a credit card. The thickness of our credit card-sized ECG signal collection device is about 1/8 inch (4 mm), and it weighs about 1 ounce (28 grams). The core technology consists of a series of patented inventions and associated algorithms. In addition to using VECG to get a more complete 3D characterization of cardiac activity, we use the concept of a baseline. We measure the change in cardiac parameters between an asymptomatic (baseline) recording and the symptomatic recording. It is personalized for every patient as every patient has a unique baseline. Our increase in diagnostic performance in detecting MIs, when compared to a panel of cardiologists, is attributed to a richer cardiac information set offered by VECG and the fact that our algorithms compare the patient's personalized baseline and symptomatic recordings in the 3D space of VECG.

This novel technology has resulted in our initial Product, AIMIGo. Our AIMIGo ECG collection device is the size of a credit card and records cardiac signals with integrated electrodes rather than wires or self-adhesive electrodes. Unlike a standard 12L ECG machine that records signals in empirically determined locations on a human body, our approach is focused on recording three projections of the heart vector. The successful recording of the projections of the heart vector enables the synthesis, via a patented method, of a 12L signal set and internal algorithmic diagnostic work in the space of 3D heart vectors.

There are obvious ease-of-use advantages when comparing our credit card-sized device to the current 12L ECG machine. The small form factor of our device makes it portable and can be used by a patient at home or elsewhere. The device can be self-applied versus requiring a trained professional to apply. In addition, there are diagnostic performance advantages, including, based on our initial study, increased accuracy in diagnosing MIs. The collected data is sent to a physician to assess the patient's ECG in the context of the patient's baseline ECG, symptoms, and history.

Our HeartBeam AIMIGo system is initially expected to be a prescription-only cardiac monitoring system intended for individuals with known or suspected heart disease, including various arrhythmias and CAD. It helps physicians in choosing the best course of action for their patients who experience chest pain or other cardiac symptoms outside of a medical facility. HeartBeam AIMIGo will bring a medical grade ECG to patients and will enable them to receive a plan of action from a physician in a timely manner. At the time of onboarding, patients record a baseline 30-second ECG using our device. When a patient experiences symptoms, such as irregular heartbeats or chest pain, the patient simply opens the smartphone application and places the credit card sized device against the chest to collect signals. These signals are processed by cloud-based algorithms and converted to a synthesized 12L that is sent to the on-call physician, overlayed with the patient's synthesized baseline ECG recording. In addition, the patient provides input on their symptoms that is sent, along with the ECG data, to the cloud for interpretation by a physician. From start to finish, the process takes just a few minutes.

The HeartBeam AIMIGo system consists of a number of capabilities that will be introduced over time. These are:

1. A credit card sized ECG collection device. The device captures cardiac signals that represent x, y and z projections of the heart vector and transmits them via Bluetooth connection to a smartphone. It is always with the patient given its small form factor. It is easy to use as all that is required of the patient is that the device be pressed against the chest.

2. A smartphone application that receives the ECG signals from the HeartBeam signal collection device. The application has several functions: guiding the patient through the signal collection, asking about symptoms, displaying the status of the data collection including real time signal quality check, and notifying the patient of the plan of action as determined by a physician. In addition, the application will contain HIPAA-compliant video conferencing or text capabilities for the healthcare provider to communicate directly with the patient.

3. A cloud-based software system that serves four basic functions: (1) Performing a final check of the ECG signal quality, (2) Synthesizing a 12L ECG from the three measured vector leads, (3) Creating a diagnostic suggestion based on 3D VECG interpretation, risk factors and symptoms and (4) Preparing a summary report for the physician. These software functions will be introduced to the HeartBeam AIMIGo product in a sequential manner. To facilitate a more accurate physician interpretation of the data, the software overlays the patient's synthesized baseline 12L ECG waveform on the synthesized 12L ECG waveform from the current reading. To ensure high signal quality, the system checks for noise levels in the recorded signals. Those signals that can be effectively filtered are accepted and those that have a noise level above an empirically established threshold are rejected. If a recorded signal is rejected, the user is asked to repeat the recording.

4. A web-based physician portal capable of displaying the following relevant information for the physician to analyze: diagnostic suggestion, patient history, symptoms, baseline and current, synthesized 12L ECG, and recorded 3 vector leads. Our physician portal assists physicians with their diagnostic interpretation by providing both the baseline 12L synthesized ECG and the 12L synthesized ECG that is under evaluation.

5. A dedicated ECG monitoring and reading team of medical professionals to offer 24/7/365 services in order to provide a recommended course of action to patients based on the ECG signals, symptoms, and patient history. The patient will have the option of having a consult with a medical professional. This capability will be developed in-house or outsourced through a contracted third-party organization.

The market release of our Product will be in multiple versions.

The Initial Product will include a 3D VECG credit card-sized device that records the "X, Y, Z" cardiac activity as 3 leads and displays the signals for clinician review. The system also includes a patient application, a physician portal, and wireless communications among the elements. We anticipate this to be the first patient-friendly, portable VECG device to be cleared by the FDA and this will be a major milestone for the company. In addition, this clearance will provide the regulatory foundation for subsequent products in our product portfolio. An FDA 510(k) application was submitted in the 2nd quarter of 2023. The review remains active with FDA, as we have successfully passed the acceptance of the filing and have completed the initial, substantive review phase with questions and requests from FDA. As we continue to navigate the progress towards clearance, we have taken advantage of all available regulatory tools and opportunities to work interactively with FDA, gaining valuable official communication and feedback on our proposed response approach, including testing protocols. We have conducted this agreed upon testing to address FDA's open questions and are in the process of preparing our official responses. Once submitted, FDA will complete their review. We currently anticipate clearance by the end of Q2 2024.

Following the clearance of the Initial Product, we will be working to obtain a second 510(k) clearance. This clearance will be focused on the ability to offer to the physician a pair of baseline and symptomatic 12L ECGs, both synthesized from 3D VECG signals (X, Y, Z) recorded by the HeartBeam AIMIGo device. This approach leverages recently issued patents for a personalized system for synthesizing 12L ECG waveforms. The 510(k) application is planned to be submitted to FDA by Q3 2024. A key part of this submission will be a pivotal study demonstrating the similarity between the synthesized 12L output from AIMIGo and a simultaneously recorded standard 12L ECG. We have held two Pre-submission meetings with FDA on the 12L synthesis submission. These meetings have been focused primarily on the performance goals of our clinical study. Based on feedback from FDA and our clinical experts, we have designed our clinical study, "Clinical Validation of AIMIGo 12 Lead ECG Synthesis Software for Arrhythmia Detection: A Prospective Multicenter Pivotal Study," (the "VALID-ECG Study").

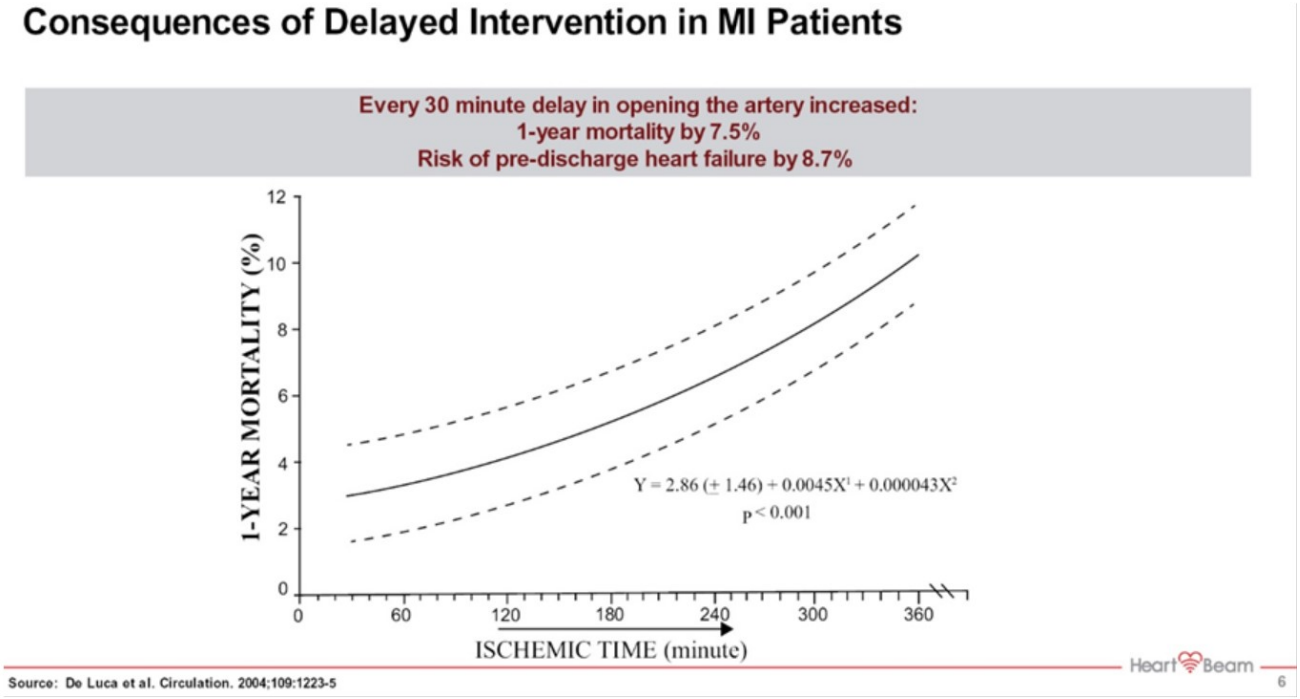
On March 13, 2024, we enrolled the first patient in the VALID-ECG study. The VALID-ECG study is a prospective single-arm multicenter trial designed with the goal to validate the AIMIGo 12L ECG Synthesis Software by comparing its results with those of a standard FDA-cleared 12L ECG using both quantitative and qualitative assessment methodologies. We plan to enroll a total of approximately 198 patients presenting to an outpatient cardiology clinic or arrhythmia center for symptoms suggestive of cardiac arrhythmia or for routine checkup of previously diagnosed arrhythmia. The study is expected to include up to 5 sites. The primary objective is to demonstrate the equivalence of ECG waveforms between AIMIGo Synthesized 12L ECG and Standard 12L ECG, recorded simultaneously in each subject, by assessing intervals and amplitudes. In addition, we have completed an 70 patient pilot study, which mirrors the pivotal study. We anticipate to complete enrollment in the VALID-ECG study in Q2 2024 and submit the second 510(k) application by Q3 2024. We continue to anticipate that our limited launch of AIMIGo will occur by the end of 2024.

Future versions of the Product may include AI algorithms that automatically classify the 3-lead VECG signals, and identify common arrhythmias as well as normal sinus rhythm. Other potential enhancements include our proprietary ECG interpretation MI algorithms and our overall MI diagnostic suggestion.

Market Opportunity

ECGs are key diagnostic tests utilized in the diagnosis and monitoring of cardiovascular disease, the number one cause of death worldwide. According to the American Heart Association, there were approximately 130 million adults living with cardiovascular disease and approximately 20 million adults with diagnosed CAD in the US. The prevalence of these cardiac conditions and thus the market size is increasing, due to an aging population and lifestyle choices.

Every 40 seconds someone in the US has a heart attack, or MI. Unfortunately, there is no way for patients at home to distinguish if the symptoms they are experiencing are due to an MI, or some other more benign condition such as indigestion. As a result, patients often ignore symptoms and delay seeking care, which leads to worse outcomes and increased mortality. Shortening that time from symptoms to the door of a medical facility would reduce complications and save lives. On the other hand, many patients who go to the ED with chest pain are not experiencing an MI. Chest pain is the second most common reason for an ED visit in patients over 45, yet fewer than 20% of chest pain ED visits result in a diagnosis of a life-threatening condition. These unnecessary ED visits lead to well over $10 billion in unnecessary healthcare expenditures.



Most ECGs are conducted in a healthcare facility setting using a 12L ECG machine, the gold standard. ECGs taken outside of healthcare facilities are expected to grow more quickly than in-hospital ECGs. Monitoring cardiac patients outside of a hospital is a fast-growing trend, as it is less expensive and provides a better patient experience. However, while ambulatory cardiac monitoring devices are often much easier for patients to use, they have fewer leads than the gold standard and therefore cannot offer as comprehensive a picture of cardiac health.

While a standard 12L ECG readout is of great medical value, it is simply impractical to have a standard 12L machine next to patients when they experience symptoms outside the clinical setting, since recording the event requires attaching multiple electrodes to the patient's body with professional assistance. While existing technologies use predominantly single lead ECG devices to monitor arrhythmias, these technologies do not provide information to the physician on the presence of life-threatening conditions such as acute coronary syndrome (ACS) including MIs, also known as heart attacks.

We believe our technology addresses these market needs and has several key attributes that make it a good fit for these patients. Our Product can be used anywhere when symptoms occur and offers the potential for lifelong patient usage. The device is practically always near the patient and ready to be used for recording a cardiac event. It enables real-time transmission of the 3D VECG signals and a synthesized 12L ECG. We believe physicians will typically prescribe our solution to chronic cardiovascular patients for long term monitoring, thereby enabling prolonged data collection and delivering a more complete picture for diagnosis. This will also enable the use of artificial intelligence (AI) on our future database that will have a unique set of longitudinal VECG signals and synthesized 12L ECGs.

As we believe our VECG platform demonstrates 12L equivalence and clinical & cost-effectiveness advantages, coupled with a patent protected technology, we believe this might open multiple licensing and/or partnering opportunities with players in the ECG, cardiac monitoring patch and smart watch verticals.

Market Strategy

Our goal is to establish our Products as key solutions for cardiology practices. Our efforts to enter the market involve establishing clinical evidence and demonstrating the cost-effectiveness of adopting our Products. The initial geographic market for HeartBeam AIMIGo is the US.

We believe that both HeartBeam AIMIGo Products will be subject to the US FDA's 510(k) review process. An FDA 510(k) application for the initial Product was submitted in Q2 2023.

The primary customers are cardiology practices and the cardiology departments of hospitals. Healthcare insurers are another important customer, as they will potentially benefit from the reduced costs to the healthcare system. We are working to develop new clinical studies and publish results of completed clinical studies and plan to demonstrate real world cost-effectiveness of the use of the solution.

Our initial targets for HeartBeam AIMIGo are market segments that see value in an easy-to-use device that can generate synthesized 12L ECG recordings. These will be segments in which payment for the device will be outside of the established reimbursement system. These target segments may include concierge practices, hospital-at-home segment and use in clinical trials. As we establish data on the clinical efficacy and cost-effectiveness of HeartBeam AIMIGo, we will target at-risk cardiology practices, including high-risk patients being discharged from hospitals after experiencing an MI.

Our long-term strategy is to generate sufficient evidence of clinical efficacy and cost-effectiveness to generate reimbursement coverage and payment specifically for the HeartBeam AIMIGo solution. We expect to be able to demonstrate significant clinical benefits for patients and savings to the healthcare system, justifying appropriate reimbursement levels.

Our primary marketing strategy will focus on the medical community with continued validation of clinical efficacy and cost-effectiveness and the establishment of reference sites. We will also create educational materials and provide other support to help educate our customers' patients.

We will explore other business models. For example, hospitals face CMS penalties if their 30-day readmission rates for patients who are discharged after an MI exceed certain thresholds. These CMS penalties are levied on all hospital CMS payments, so the impact can be significant. Our Product can be a tool to help hospitals manage these patients after discharge. We will explore models in which hospitals pay for the device and for the initial 30 days of service. In addition, we will explore models for value-based care, in which the use of Product reduces overall costs.

We are currently speaking with hospitals in large healthcare systems to educate them about our first two Products. These are sophisticated customers, and we plan to use technical presentations, peer-reviewed clinical data, and demonstration projects to achieve penetration of this market. We plan to continue to utilize the expertise of our medical advisory board, conduct clinical trials with leading cardiologists to increase the body of evidence, and establish reference sites among these customers.

We expect our value proposition will be progressively increased as we gradually add additional functionality to our monitoring solutions and drive down the cost by increasing scale and automation. We expect our HeartBeam AIMIGo device to incorporate internally developed algorithms with the capabilities of detecting heart conditions that can be detected via a standard 12L ECG device. Additionally, as we collect rich longitudinal data sets from our patients, we expect to train AI and ML algorithms that could potentially have predictive capabilities regarding different heart conditions. Over time and with scale we expect our costs to decrease and provide more and better services to our patients by improving our capabilities.

We plan to establish a direct sales network with relationships and experience selling to our target markets.

Clinical Data

A landmark clinical study on the HeartBeam technology was published in the August 2023 issue of the journal JACC: Advances. The publication, "Coronary Artery Occlusion Detection Using 3-Lead ECG System Suitable for Credit Card-Size Personal Device Integration" demonstrated that HeartBeam's VECG technology detects the presence of a coronary occlusion, the cause of heart attacks, with the same accuracy as a standard 12L ECG.

Both 12L ECG and VECG signals were recorded in patients undergoing percutaneous coronary intervention. Readings were taken before and after a 90 second balloon inflation that occluded the artery, a surrogate for a heart attack. Automated computer analysis of the ST segment of the 12L ECG and VECG was performed. In addition, a panel of three cardiologists analyzed the 12L ECGs.

The study showed that the automated analysis of the VECG and 12L ECG signals had similar performance in determining whether the artery was occluded. Also in the study, the human interpretation of the 12L ECGs had significant intra- and inter-observer variability, which does not occur with automated readings.

Both the 12L ECGs and the VECG readings were analyzed in two ways: a "spot" reading, when only a single recording was considered, and a "comparative" reading when a separate "normal baseline" recording was available for comparison. The presence of the "normal baseline" recording, a novel feature that is integral to HeartBeam's VECG technology, dramatically improved the accuracy of interpretation, increasing the Area Under the Curve (AUC), a standard measure of diagnostic performance, from 0.72 to 0.95. This is particularly important since physicians who are analyzing 12L ECGs often do not have access to a normal baseline, implying that the HeartBeam system could outperform this approach.

In addition, HeartBeam has had data on its deep learning algorithm accepted for presentation at two prestigious Electrophysiology conferences: the European Heart Rhythm Society, to be held in Berlin, Germany in April 2024 and the Heart Rhythm Society, to be held in Boston MA in May 2024.

Competition

The cardiac monitoring and detection market is characterized by rapid technological change and strong competition. There are numerous companies developing technologies that are competitive, in a broad sense, to our products, and many of these companies have significantly greater resources than HeartBeam.

In the category of ambulatory cardiac monitors — devices that are intended to be used outside of a health facility setting — there are two major segments: consumer devices and devices prescribed for ACS.

Consumer Devices

The consumer device segment consists of devices that are FDA cleared but are sold directly to patients, without a prescription. Generally, these devices are single lead ECG devices intended to recognize heart rhythm abnormalities, such as atrial fibrillation, but are not intended for ischemia detection or for life threatening conditions such as heart attack.

- Apple Inc, a public company located in Cupertino, CA, produces the Apple Watch, which includes ECG functionality. The Apple Watch is a single lead ECG with two electrodes that contact the wrist and the finger and is intended to detect some common cardiac arrhythmias, such as Atrial Fibrillation.

- AliveCor Inc, a private company located in Mountain View, CA, produces the KardiaMobile, KardiaMobile Card and KardiaMobile 6L devices. These devices are intended to detect some common cardiac arrhythmias, such as Atrial Fibrillation.

- Google Inc, a public company located in Mountain View, CA, produces the Pixel 2 smartwatch and ECG app. The Pixel 2 watch is a single lead ECG with two electrodes that contact the fingers and is intended to detect some common cardiac arrhythmias, such as Atrial Fibrillation.

- Samsung Electronics Co., Ltd, based in Seoul, South Korea, is publicly traded in Korea. It produces the Galaxy Watch3 and Galaxy Watch Active2 smartwatches with ECG functionality, intended to detect some common cardiac arrhythmias, such as Atrial Fibrillation.

Devices prescribed for ischemia detection
There are a small number of devices that have been cleared by FDA to be used outside of healthcare facilities that provide information for patients with potential ischemic events such as MIs.

- Angel Medical Systems, Inc. is a private company based in Eatontown, NJ. The AngelMed Guardian is an implantable cardiac monitor for patients who are deemed to be extremely high risk for an MI. Physicians implant the AngelMed Guardian in patients. We believe that the HeartBeam AIMIGo device will be a viable alternative to the AngelMed Guardian, as it does not require an implant and does not have a high up-front cost.

- SHL Telemedicine Ltd., is based in Tel Aviv, Israel and is publicly traded. It produces Smartheart, a 12L ECG indicated for patient use at home. Smartheart Pro is larger and more complex than our telehealth solution, requiring the placement of an electrode belt, two underarm electrodes and a waist electrode, and moistening the areas before use. Most patients would find this technology impractical to be carried with them at all times because of the large size and complex lead attachment procedure.

Intellectual Property

We believe our intellectual property ("IP") protects our innovations, and our goal is to become a leader in the ambulatory VECG sector. For some aspects of our proprietary technology, we rely on trade secret protection. It is our view that the combination of these two methods of IP protection maximizes our chances for success.

HeartBeam has 13 issued and allowed U.S. patents (U.S. 10,433,744, U.S. 10,117,592, U.S. 11,071,490, U.S. 11,419,538, U.S. 11,445,963, U.S. 11,701,049, U.S. 11,529,085, U.S. 10,980,433, U.S. 11,412,972, U.S. 11,234,658, U.S. 11,793,444, U.S. 11,877,853, and allowed U.S. patent application no. 18/068,481), and nine pending U.S applications. Outside of the U.S., HeartBeam has four issued patents in Germany, France, Netherlands and United Kingdom and fourteen pending applications in Canada, China, the European Union, Japan, South Korea and Australia. HeartBeam has two pending Patent Cooperation Treaty applications. The issued patents are predicted to expire between April 11, 2036 and April 21, 2042.

Our issued and pending U.S. patent applications cover compact VECG systems for remote detection and/or diagnosis of acute myocardial infarction ("AMI"). Outside of the U.S., the pending EU, Australian ("AU"), Japanese ("JP") and Chinese ("CN") patent applications correspond to the pending and issued US cases. The pending PCT applications cover methods and apparatuses for automatic cardiac diagnosis as well as compact systems including retractable electrodes.

The following table sets forth a brief description of issued and pending patents, including their respective titles:

Patent Type	Application No. Pat. No.	Status	Predicted Expiration	Title Summary
Utility (US)	15/096,159 US 10,433,744	Issued	Sep 15, 2036	MOBILE THREE-LEAD CARDIAC MONITORING DEVICE AND METHOD FOR AUTOMATED DIAGNOSTICS Methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction (AMI).
Utility (US)	15/632,155 US 10,117,592	Issued	Apr 11, 2036	MOBILE THREE-LEAD CARDIAC MONITORING DEVICE AND METHOD FOR AUTOMATED DIAGNOSTICS Methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction (AMI).
Utility (US)	17/092,152 US 11,877,853	Issued	Jun 2, 2037	MOBILE THREE-LEAD CARDIAC MONITORING DEVICE AND METHOD FOR AUTOMATED DIAGNOSTICS Methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction (AMI).
Utility (US)	17/202,299 US 11,071,490	Issued	Apr 11, 2036	ELECTROCARDIOGRAM PATCH DEVICES AND METHODS Methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction (AMI).
Utility (CN)	201680030550.5	Published	Apr 11, 2036	MOBILE THREE-LEAD CARDIAC MONITORING DEVICE AND METHOD FOR AUTOMATED DIAGNOSTICS Methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction (AMI).
Utility (DE)	16777474.4 DE 602016073016.2	Issued	Apr 11, 2036	MOBILE THREE-LEAD CARDIAC MONITORING DEVICE AND METHOD FOR AUTOMATED DIAGNOSTICS Methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction (AMI).
Utility (FR)	16777474.4 FR 3280326	Issued	Apr 11, 2036	MOBILE THREE-LEAD CARDIAC MONITORING DEVICE AND METHOD FOR AUTOMATED DIAGNOSTICS Methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction (AMI).
Utility (GB)	16777474.4 GB 3280326	Issued	Apr 11, 2036	MOBILE THREE-LEAD CARDIAC MONITORING DEVICE AND METHOD FOR AUTOMATED DIAGNOSTICS Methods and apparatuses for remote and detection and/or
Utility (NL)	16777474.4 NL 3280326	Issued	Apr 11, 2036	MOBILE THREE-LEAD CARDIAC MONITORING DEVICE AND METHOD FOR AUTOMATED DIAGNOSTICS Methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction (AMI).
Utility (EU)	22174820.5	Pending	Apr 11, 2036	MOBILE THREE-LEAD CARDIAC MONITORING DEVICE AND METHOD FOR AUTOMATED DIAGNOSTICS Methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction (AMI).
Utility (EU)	198948150	Pending	Nov 18, 2039	HAND HELD DEVICE FOR AUTOMATIC CARDIAC RISK AND DIAGNOSTIC ASSESSMENT Method and apparatus for performing automatic cardiac diagnosis.

Utility (US)	17/296,669 US 11,701,049	Issued	Nov 18, 2039	HAND HELD DEVICE FOR AUTOMATIC CARDIAC RISK AND DIAGNOSTIC ASSESSMENT Method and apparatus for performing automatic cardiac diagnosis.
Utility (US)	18,324,111	Pending	Nov 18, 2039	HAND HELD DEVICE FOR AUTOMATIC CARDIAC RISK AND DIAGNOSTIC ASSESSMENT Method and apparatus for performing automatic cardiac diagnosis.
Utility (US)	17/443,456 US 11,793,444	Issued	Apr 11, 2036	ELECTROCARDIOGRAM PATCH DEVICES AND METHODS Adhesive patch methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction (AMI).
Utility (US)	17/570,368 US 11,419,538	Issued	Apr 11, 2036	ELECTROCARDIOGRAM PATCH DEVICES AND METHODS Adhesive patch methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction
Utility (US)	18/363685	Issued	Apr 11, 2036	ELECTROCARDIOGRAM PATCH DEVICES AND METHODS Adhesive patch methods and apparatuses for remote and detection and/or diagnosis of acute myocardial infarction (AMI).
Utility (US)	17/609,014	Pending	May 20, 2040	COMPACT MOBILE THREE-LEAD CARDIAC MONITORING DEVICE Compact, mobile three-lead cardiac monitoring devices for remote detection and/or diagnosis of cardiac events.
Utility (AU)	2020275409	Pending	May 20, 2040	COMPACT MOBILE THREE-LEAD CARDIAC MONITORING DEVICE Compact, mobile three-lead cardiac monitoring devices for remote detection and/or diagnosis of cardiac events.
Utility (CA)	3137669	Pending	May 20, 2040	COMPACT MOBILE THREE-LEAD CARDIAC MONITORING DEVICE Compact, mobile three-lead cardiac monitoring devices for remote detection and/or diagnosis of cardiac events.
Utility (EU)	208063123	Pending	May 20, 2040	COMPACT MOBILE THREE-LEAD CARDIAC MONITORING DEVICE Compact, mobile three-lead cardiac monitoring devices for remote detection and/or diagnosis of cardiac events.
Utility (JP)	2021568329	Pending	May 20, 2040	COMPACT MOBILE THREE-LEAD CARDIAC MONITORING DEVICE Compact, mobile three-lead cardiac monitoring devices for remote detection and/or diagnosis of cardiac events.
Utility (EU)	2189294203	Pending	Nov 12, 2041	COMPACT MOBILE THREE-LEAD CARDIAC MONITORING DEVICE WITH HYBRID ELECTRODE Compact, mobile three-lead cardiac monitoring devices for remote detection and/or diagnosis of cardiac events.
Utility (EU)	18/252803	Pending	Nov 12, 2041	COMPACT MOBILE THREE-LEAD CARDIAC MONITORING DEVICE WITH HYBRID ELECTRODE Compact, mobile three-lead cardiac monitoring devices for remote detection and/or diagnosis of cardiac events.
Utility (CA)	3204059	Pending	Jan 4, 2042	AMBULATORY ELECTROCARDIOGRAM PATCH DEVICES AND METHODS Cardiac monitoring patch devices (e.g., an ECG patch for 12-lead detection) for remote detection and/or diagnosis of cardiac events (e.g., acute myocardial infarction).

Utility (CN)	2022800141214	Pending	Jan 4, 2042	AMBULATORY ELECTROCARDIOGRAM PATCH DEVICES AND METHODS Cardiac monitoring patch devices (e.g., an ECG patch for 12-lead detection) for remote detection and/or diagnosis of cardiac events (e.g., acute myocardial infarction).
Utility (EP)	227348299	Pending	Jan 4, 2042	AMBULATORY ELECTROCARDIOGRAM PATCH DEVICES AND METHODS Cardiac monitoring patch devices (e.g., an ECG patch for 12-lead detection) for remote detection and/or diagnosis of cardiac events (e.g., acute myocardial infarction).
Utility (JP)	202340687	Pending	Jan 4, 2042	AMBULATORY ELECTROCARDIOGRAM PATCH DEVICES AND METHODS Cardiac monitoring patch devices (e.g., an ECG patch for 12-lead detection) for remote detection and/or diagnosis of cardiac events (e.g., acute myocardial infarction).
Utility (US)	18260318	Pending	Jan 4, 2042	AMBULATORY ELECTROCARDIOGRAM PATCH DEVICES AND METHODS Cardiac monitoring patch devices (e.g., an ECG patch for 12-lead detection) for remote detection and/or diagnosis of cardiac events (e.g., acute myocardial infarction).
Utility (US)	17/494,806 US 11,445,963	Issued	Oct 5, 2041	METHOD AND APPARATUS FOR RECONSTRUCTING ELECTROCARDIOGRAM (ECG) DATA Synthesizing (generating) 12L ECG dataset from 3-lead ECG data.
Utility (US)	17/948099	Pending	Oct 5, 2041	METHOD AND APPARATUS FOR RECONSTRUCTING ELECTROCARDIOGRAM (ECG) DATA Synthesizing (generating) 12-lead ECG dataset from 3-lead ECG data.
Utility (PCT)	PCTUS2022 077601	Pending	May 5, 2024	METHOD AND APPARATUS FOR RECONSTRUCTING ELECTROCARDIOGRAM (ECG) DATA Synthesizing (generating) 12-lead ECG dataset from 3-lead ECG data.
Utility (US)	17/726,497 US 11,529,085	Issued	Apr 21, 2042	APPARATUS FOR GENERATING AN ELECTROCARDIOGRAM Wrist-worn device can be taken off of the wrist and held against the chest to detect three orthogonal cardiac leads, and methods of using a wrist-worn device to detect the three orthogonal cardiac leads.
Utility (US)	18/068481	Allowed	Apr 21, 2042	APPARATUS FOR GENERATING AN ELECTROCARDIOGRAM Wrist-worn device can be taken off of the wrist and held against the chest to detect three orthogonal cardiac leads, and methods of using a wrist-worn device to detect the three orthogonal cardiac leads.
Utility (PCT)	PCT/US2023 065918	Published	Oct 5, 2041	APPARATUS FOR GENERATING AN ELECTROCARDIOGRAM Wrist-worn device can be taken off of the wrist and held against the chest to detect three orthogonal cardiac leads, and methods of using a wrist-worn device to detect the three orthogonal cardiac leads.
Utility (US)	16/362,527 US 10,980,433	Issued	Oct 12, 2038	HEALTH MONITORING AND GUIDANCE Methods, systems and software for the determination of stress states utilizing PPG sensors.
Utility (US)	16/368,568 US 11,412,972	Issued	Apr 19, 2040	DETECTION OF ATRIAL FIBRILLATION Methods and software for determining atrial fibrillation utilizing PPG sensors.

Utility (US)	16/368,571 US 11,234,658	Issued	Apr 5, 2039	PHOTOPLETHYSMOGRAM DATA ANALYSIS AND PRESENTATION Methods, systems and software for the creation of ECG-type waveforms from PPG sensor data.
Utility (US)	17/887160	Published	Mar 28, 2038	DETECTION OF ATRIAL FIBRILLATION Methods and software for determining atrial fibrillation utilizing PPG sensors.
Utility (US)	18/516,793	Pending	Mar 28, 2039	HEARTBEAT DETECTION Wearable devices to detect PPG data for detection of heartrate.
Utility (EP)	EP 19724961.8	Published	Mar 28, 2039	PHOTOPLETHYSMOGRAM DATA ANALYSIS AND PRESENTATION Methods, systems and software for the creation of ECG-type waveforms from PPG sensor data.
Utility (KR)	KR 10-2020-7031103	Published	Mar 28, 2039	PHOTOPLETHYSMOGRAM DATA ANALYSIS AND PRESENTATION Methods, systems and software for the creation of ECG-type waveforms from PPG sensor data.
Utility (US)	18/595,410	Pending	Mar, 4, 2044	METHODS AND APPARATUSES FOR ELECTROMYOGRAPHY NOISE ELIMINATION FROM ELECTROCARDIOGRAM SIGNALS BY ITERATIVE REGENERATION Methods and systems, including software, for reducing or eliminating noise from ECG signals.

We have entered, and generally plan to continue to enter into, non-disclosure, confidentiality and intellectual property assignment agreements with all new employees as a condition of employment. In addition, we intend to generally enter into confidentiality and non-disclosure agreements with consultants, manufacturers' representatives, distributors, suppliers, and others to attempt to limit access to, use and disclosure of our proprietary information. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

The ownership of all filed patents is assigned to HeartBeam, Inc.

Research and Development

In our quest to redefine the landscape of digital health through our innovative, user-friendly ambulatory VECG solutions, our primary objective remains steadfast: to deliver high medical value through products that are always with the patient, assisting physicians in monitoring and diagnosing cardiac disease in patients. We believe that our success in developing initial products, underscored by our emphasis on user-friendly solutions, will set a solid foundation for our future endeavors.

We believe that our R&D team, primarily based in the US and Belgrade, Serbia, is a testament to our commitment to excellence and innovation and is comprised of seven employees on December 31, 2023, plus consultants, with expertise in the following:

- Healthcare IT platform development, biomedical engineering, electrical engineering with expertise in machine learning, signal processing and ECG analysis from the medical device industry, as well as specialties in wireless communication,
- Of note, we have seven Physicists and Electrical Engineers (all Ph.D. E.E. or Ph.D. Physics) credited with our key inventions and patents.

In 2024, we plan to expand our team with several additional product development engineers.

Looking ahead, we anticipate further enhancing our efforts in harnessing signal processing and artificial intelligence (AI) to broaden our diagnostic solutions across a spectrum of cardiac conditions.

Our core technology, the heart vector VECG approach, is a platform technology that we believe is poised to revolutionize diagnostic solutions for cardiovascular patients. Potential applications include a VECG-based, synthesized 12L capable patch ECG monitor, offering significant diagnostic advantages through its 12L capability over existing single-lead ECG patch products. This innovation aims to provide standard of care 12L ECG capabilities in a form factor like current single-lead ECG patches, which we believe addresses a critical gap in the market.

A further potential application is a synthesized 12L ECG smartwatch-based monitor, designed for the detection of heart attacks and complex cardiac arrhythmias. The plan for this monitor is to eliminate the need for dedicated ECG devices, offering synthesized 12L ECG capabilities directly from a smartwatch, thereby enabling the detection of heart attacks and complex arrhythmias with unprecedented convenience and efficiency.

Both the patch and smartwatch-based monitor technologies are covered by patents that we believe provide us a strong position to expand beyond the current AIMIGo platform.

Our newly formed AI team, comprising industry leading experts, developed a roadmap for AI-based tool development. These tools will combine state of the art AI models and techniques applied to our unique and data rich set of VECG signals. Initial AI development results indicate potential to significantly enhance ambulatory diagnostic capabilities over what is currently available. It is expected that AI development efforts quickly become one of the major R&D efforts.

As we continue to advance our synthesized 12L VECG technology, evidenced by our recently issued and allowed patents with potentially disruptive market impacts, our initial telehealth product will leverage rule-based algorithms, including signal processing and ECG synthesis. Concurrently, we are developing AI-based arrhythmia and ischemia detection algorithms to become the cornerstone of our commercialized systems.

To further amplify the impact of our R&D efforts and ensure sustained leadership in digital health innovation, we are looking at several strategic enhancements:

1. **Expand Cross-Disciplinary Collaborations**: Forge deeper partnerships with academia, technology leaders, and healthcare institutions to access new research, diversify our expertise, and explore novel applications of our technology.
2. **Embrace Agile Development**: Integrate agile methodologies into our R&D processes, enhancing our adaptability and responsiveness to emerging technologies and market demands.
3. **Strengthen Data Analytics and AI Integration**: We plan to invest in advanced data analytics and AI to refine our diagnostic algorithms and tailor our solutions to meet specific clinical needs, driving forward personalized medicine in cardiac care.
4. **Foster Talent and Innovation Culture**: By continuing to attract and develop top-tier talent, nurturing a culture of innovation and continuous learning that aligns with the latest advancements in technology and healthcare.
5. **Prioritize Intellectual Property and Regulatory Strategy**: We believe we are able to accelerate our efforts in expanding our intellectual property portfolio, engaging with regulatory bodies early in the development process to ensure our solutions meet the highest standards of safety and efficacy.

By embracing these strategic enhancements, we are not only committed to advancing the full potential inherent in our VECG technology, but we believe we are also poised to make significant strides in transforming cardiovascular diagnostics and patient care.

Government Regulation

General

Our proposed products are subject to regulation by the FDA and various other federal and state agencies, as well as by foreign governmental agencies. These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and market surveillance of our products.

In addition to those indicated below, the only other regulations we encounter are regulations that are common to all businesses, such as employment legislation, implied warranty laws, and environmental, health and safety standards, to the extent applicable. In the future we will be subject to industry-specific government regulations that govern our products when developed for commercial use. It is possible that other regulatory approvals will be required for the design and manufacture of our products and proposed products.

U.S. Regulation

The FDA governs the following activities that HeartBeam performs, and will perform, upon the clearance or approval of its Product, or that are performed on its behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

- product design, and development
- product safety, testing, labeling and storage
- record keeping procedures; and
- product marketing.

There are numerous FDA regulatory requirements governing the approval or clearance and subsequent commercial marketing of our products. These include:

- the timely submission of product listing and establishment registration information, along with associated establishment user fees;
- continued compliance with the Quality System Regulation, or QSR, which require specification developers and manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance or approval of product modifications that could significantly affect the safety or effectiveness of the device or that would constitute a major change in intended use;
- Medical Device Reporting regulations ("MDR"), which require that manufacturers keep detailed records of investigations or complaints against their devices and to report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- adequate use of the Corrective and Preventive Actions process to identify and correct or prevent significant systemic failures of products or processes or in trends which suggest same;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary, to protect the public health or to provide additional safety and effectiveness data for the device; and
- notices of correction or removal and recall regulations.

Depending on the classification of the device, before HeartBeam can commercially distribute medical devices in the United States, it must obtain, either prior 510(k) Notification clearance, 510(k), De-Novo granting or premarket approval ("PMA"), from the FDA unless a respective exemption applies to the device under review by the FDA

The FDA classifies medical devices into one of three classes based on the degree of risk associated with each medical device and the extent of regulatory controls needed to ensure the device's safety and effectiveness:

- Class I medical devices, which are low risk and subject to only general controls (e.g., registration and listing, medical device labeling compliance, MDRs, Quality System Regulations, and prohibitions against adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements;
- Class II medical devices, which are moderate risk and generally require 510(k) Notification premarket clearance or De Novo granting before they may be commercially marketed in the United States as well as general controls and potentially special controls like performance standards or specific labeling requirements; and

- Class III medical devices, which are devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device. Class III medical devices generally require the submission and approval of a PMA supported by clinical trial data.

The custom software and hardware of our products, we believe, are classified as Class II. Class II medical devices are those for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and there is sufficient information to establish special controls. Special controls can include performance standards, post-market surveillance, patient histories and FDA guidance documents. Premarket review and clearance by the FDA for these devices is generally accomplished through the 510(k). As part of the 510(k), the FDA may have required the following

- Development of comprehensive product description and indications for use;
- Completion of extensive preclinical tests and preclinical animal studies, performed in accordance with the FDA's Good Laboratory Practice ("GLP") regulations;
- Comprehensive review of predicate devices and development of data supporting the new product's substantial equivalence to one or more predicate devices; and
- If appropriate and required, certain types of clinical trials (IDE submission and approval may be required for conducting a clinical trial in the US).

Clinical trials involve use of the medical device on human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices ("GCPs"), including the requirement that all research subjects provide informed consent for their participation in the clinical study. A written protocol with predefined end points, an appropriate sample size and pre-determined patient inclusion and exclusion criteria, is required before initiating and conducting a clinical trial. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's Investigational Device Exemption, or IDE, regulations that among other things, govern investigational device labeling, prohibit promotion of the investigational device, and specify recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," as defined by the FDA, the agency requires the device sponsor to submit an IDE application, which must become effective prior to commencing human clinical trials. The IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA denies the application or notifies the Company that the investigation is on hold and may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE that requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board ("IRB") for each clinical site. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but it must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

Given successful completion of all required testing, a detailed 510(k) premarket notification or De Novo request will be submitted to the FDA requesting clearance, or granted, to market the product. This notification will include all relevant data from pertinent preclinical and clinical trials, together with detailed information relating to the product's manufacturing controls and proposed labeling, and other relevant documentation.

A 510(k)-clearance letter from the FDA authorizes commercial marketing of the device for one or more specific indications of use.

After 510(k) clearance, HeartBeam is required to comply with several post-clearance requirements, including, but not limited to, Medical Device Reporting and complaint handling, and, if applicable, reporting of corrective actions. Also, quality control and manufacturing procedures must continue to conform to Quality System Regulations ("QSR"). The FDA periodically inspects manufacturing facilities to assess compliance with FDA's QSR, which impose extensive procedural, substantive, and record keeping requirements on medical device manufacturers. In addition, changes to the manufacturing process are strictly regulated, and, depending on the change, validation activities may need to be performed. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with QSR and other types of regulatory controls.

After a device receives 510(k) clearance from the FDA, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use or technological characteristics, requires a new 510(k) clearance or could require a PMA. The FDA requires each manufacturer to make the determination of whether a

modification requires a new 510(k) notification or PMA in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA for a particular change, the FDA may retroactively require the manufacturer to seek 510(k) clearance or PMA. The FDA can also require the manufacturer to cease U.S. marketing and/or recall the modified device until additional 510(k) clearance or PMA approval is obtained.

The FDA and the Federal Trade Commission ("FTC"), will also regulate the advertising claims of HeartBeam's products to ensure that the claims it makes are consistent with its regulatory clearances, that there is scientific data to substantiate the claims and that product advertising is neither false nor misleading.

We are applying for 510(k) clearance for the AIMIGo system. To obtain 510(k) clearance, a company must submit a notification to the FDA demonstrating that its proposed device is substantially equivalent to a predicate device (i.e., a device that was in commercial distribution before May 28, 1976, a device that has been reclassified from Class III to Class I or Class II, or a 510(k)-cleared device). The FDA's 510(k) clearance process generally takes from three to 12 months from the date the application is submitted but also can take significantly longer. If the FDA determines that the device or its intended use is not substantially equivalent to a predicate device, the device is automatically placed into Class III, requiring the submission of a PMA. Once the information is submitted, there is no guarantee that the FDA will grant a company 510(k) clearance for its pipeline products, and failure to obtain the necessary clearances for its products would adversely affect its ability to grow its business. Delays in receipt or failure to receive the necessary clearances, or the failure to comply with existing or future regulatory requirements, could reduce its business prospects.

Devices that cannot be cleared through the 510(k)-process due to lack of a predicate device but would be considered low or moderate risk may be eligible for the De Novo process. In 1997, the Food and Drug Administration Modernization Act ("FDAMA") added the de novo classification pathway now codified in section 513(f)(2) of the FD&C Act. This law established an alternate pathway to classify new devices into Class I or II that had automatically been placed in Class III after receiving a Not Substantially Equivalent ("NSE"), determination in response to a 510(k) submission. Through this regulatory process, a sponsor who receives an NSE determination may, within 30 days of receipt, request FDA to make a risk-based classification of the device through what is called a "de novo request." In 2012, section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act ("FDASIA"), to provide a second option for de novo classification. Under this second pathway, a sponsor who determines that there is no legally marketed device upon which to base a determination of substantial equivalence can submit a de novo request to FDA without first submitting a 510(k).

If a company receives a Not Substantially Equivalent determination in response to a 510(k) submission, the device may still be eligible for the 510(k) de novo classification process.

Devices that cannot be cleared through the 510(k) or De Novo classification process require the submission of a PMA. The PMA process is much more time consuming and demanding than the 510(k)-notification process. A PMA must be supported by extensive data, including but not limited to data obtained from preclinical and/or clinical studies and data relating to manufacturing and labeling, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. After a PMA application is submitted, the FDA's in-depth review of the information generally takes between one and three years and may take significantly longer.

We also need to establish a suitable and effective quality management system, which establishes controlled processes for our product design, manufacturing, and distribution. We plan to do this in compliance with the internationally recognized standard ISO 13485:2013 Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes. Following the introduction of a product, the FDA and foreign agencies engage in periodic reviews of our quality systems, as well as product performance and advertising and promotional materials. These regulatory controls, as well as any changes in FDA policies, can affect the time and cost associated with the development, introduction, and continued availability of new products. Where possible, we anticipate these factors in our product development processes. These agencies possess the authority to take various administrative and legal actions against us, such as product recalls, product seizures and other civil and criminal sanctions.

Based on all available data and opinions from our well qualified external consultants who specialize in FDA submissions, we believe that both our initial products and the follow-on products qualify for the 510(k)-clearance path or De Novo granting paths.

Foreign Regulation

As we plan to market our products in the EU and other foreign markets, in addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products in foreign countries. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Preparations for Design for Manufacturing

To date, our efforts have been primarily concentrated on the research and development of our initial HeartBeam AIMIGo device. We have successfully developed fully functional versions of the product which have passed design control processes, including all necessary verification and validation testing, to ensure compliance with safety standards such as IEC 60601. Documentation for these pre-production units has been submitted as part of our 510(k) regulatory filing with the FDA, seeking market clearance. In preparation for commercial production, we have proactively designed and procured the production tooling required to facilitate the future commercialization of our product.

Our manufacturing strategy is designed to be scalable. Initially, for the HeartBeam AIMIGo devices, we are collaborating with Evolve Manufacturing Technologies, a contract medical device manufacturing firm. Evolve offers comprehensive contract manufacturing services for the medical device and life sciences sectors. As we progress towards more automated manufacturing operations, we intend to implement specialized tooling (e.g., high-integrity molds, automated tools, and processes) and establish a formal manufacturing agreement with Evolve. This partnership will capitalize on Evolve's manufacturing and packaging expertise to support the commercial launch of the HeartBeam AIMIGo device. Evolve employs Design for Excellence (DFX) methodologies, and its quality management processes are closely integrated with those of Triple Ring Technologies, Inc. (TRT), a US-based medical device and design engineering firm with which we are currently collaborating. This collaboration between Evolve and TRT should facilitate a seamless design transfer process and provide comprehensive turnkey contract manufacturing solutions, including first article builds, prototypes, and low-to-medium volume commercial units.
As we advance, we will explore partnerships with other manufacturers, both domestically and internationally, to accommodate our needs for high-volume and/or sub-assembly manufacturing.

Employees

As of December 31, 2023, we had 15 full-time employees. We have budgeted to hire additional full-time employees (including additional consultants or independent contractors) in the near future to execute our growth plans. We consider our employee relations to be good.

Corporate Information

Our principal executive offices are located at 2118 Walsh Avenue, Suite 210, Santa Clara, CA 95050. Our telephone number is (408) 899-4443 and our web address is www.heartbeam.com. Financial and other information can be accessed on the “Investors” section of our website. We make available through our website, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the Securities and Exchange Commission (the “SEC”). Also posted on our website are certain corporate governance documents, including our Code of Business Conduct and Ethics. The reference to our website is textual in reference only, and the information included or referred to on, or accessible through, our website does not constitute part of, and is not incorporated by reference into, this report or any other filing.

We also file periodic reports, proxy statements and other information with the SEC. Such reports may be obtained by visiting the Public Reference Room of the SEC at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at (800) SEC-0330. In addition, the SEC maintains an internet site at http://www.sec.gov that contains reports, proxy and information statements and other information.

Item 1A. Risk Factors.

You should consider carefully the risks, uncertainties and other factors described below, in addition to the other information set forth in this Form 10-K, before making an investment decision. Any of these risks, uncertainties and other factors could materially and adversely affect our business, financial condition, results of operations, cash flows or prospects. In that case, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock. See also "Cautionary Statement Regarding Forward-Looking Statements."

Risks Related to Our Business

We have a limited operating history upon which investors can evaluate our future prospects.
We have a limited operating history upon which an evaluation of our business plan or performance and prospects can be made. The business and prospects of the Company must be considered in the light of the potential problems, delays, uncertainties and complications encountered in connection with a newly established business and new industry. The risks include, but are not limited to, the possibility that we will not be able to develop functional and scalable products and services, or that although functional and scalable, our products and services will not be economical to market; that our competitors hold proprietary rights that preclude us from marketing such products; that our competitors market a superior or equivalent product; that we are not able to upgrade and enhance our technologies and products to accommodate new features and expanded service offerings; or the failure to receive necessary regulatory clearances for our products. To successfully introduce and market our products at a profit, we must establish brand name recognition and competitive advantages for our products. There are no assurances that we can successfully address these challenges and if unsuccessful, we and our business, financial condition and operating results could be materially and adversely affected.

The current and future expense levels of our business are based largely on estimates of planned operations and future revenues rather than experience. It is difficult to accurately forecast future revenues because our business is new and our market has not been developed. If our forecasts prove incorrect, the business, operating results and financial condition of the Company may be materially and adversely affected. Moreover, we may be unable to adjust our spending in a timely manner to compensate for any unanticipated reduction in revenues. As a result, any significant reduction in planned or actual revenues may immediately and adversely affect our business, financial condition and operating results.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

As described in Note 2 of our accompanying audited financial statements, our auditors have issued a going concern opinion on our December 31, 2023 financial statements, expressing substantial doubt that we can continue as an ongoing business for the next twelve months after issuance of their report based on our current development plans and our operating requirements and us having suffered recurring losses from operations and having a net capital deficiency. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot raise the necessary capital to continue as a viable entity, we could experience a material adverse effect on our business and our stockholders may lose some or all of their investment in us.

We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, selling and marketing and research and development activities are forward-looking statements and involve risks and uncertainties.

We have no revenues and we cannot predict when we will achieve first revenues and sustained profitability.
We have no revenues and cannot definitely predict when we will achieve revenues and profitability. We do not anticipate generating significant revenues until we successfully develop, achieve regulatory clearance, commercialize and sell our proposed products, of which we can give no assurance. We are unable to determine when we will generate significant revenues from the sale of any such products.

We cannot predict when we will achieve profitability, if ever. Our inability to become profitable may force us to curtail or temporarily discontinue our research and development programs and our day-to-day operations. Furthermore, there can be no assurance that profitability, if achieved, can be sustained on an ongoing basis.

We may never complete the development and commercialization of products that we are currently developing and future development of new generations of any of our other proposed products.
We have no assurance of success as to the completion and of the commercial launch of our products or the completion and development of any new generations of products that are currently under development or other proposed or contemplated products, for any of our target markets. We continue to seek to improve our technologies while we are developing them so that they result in commercially viable products. Failure to improve on any of our technologies could delay or prevent their successful development for our target markets. Developing any technology into a marketable product is a risky, time consuming and expensive process. You should anticipate that we will encounter setbacks, discrepancies requiring time consuming and costly redesigns and changes, and that there is the possibility of outright failure.

We may not meet our product development and commercialization milestones.
We have established milestones, based upon our expectations regarding our technologies, which we use to assess our progress toward developing our products. These milestones relate to technology development and design improvements as well as dates for achieving development goals. If our products exhibit technical defects or are unable to meet cost or performance goals, our commercialization schedule could be delayed and potential purchasers of our initial commercial products may decline to purchase such products or may opt to pursue alternative products.

We may also experience shortages of the components used in our devices. The contract manufacturing operations that we will use could be disrupted by fire, earthquake or other natural disaster, a labor-related disruption, failure in supply or other logistical channels, electrical outages or other reasons. If there were a disruption to manufacturing facilities, we would be unable to manufacture devices until these manufacturing capabilities are restored or alternative manufacturing facilities are engaged.

Generally, we have met our milestone schedules when making technological advances in our product. We can give no assurance that our development and commercialization schedule will continue to be met as we further develop products currently under development or any of our other future products.

Our business is dependent upon physicians utilizing and prescribing our solution; if we fail to engage physicians to utilize our solution, our revenues may never materialize or may not meet our projections.
The success of our cardiac diagnosis and monitoring business is dependent upon physicians prescribing and utilizing our solution. The utilization of our solution by physicians for use in the prescription of cardiac monitoring is directly influenced by a number of factors, including:

- the ability of the physicians with whom we work to obtain sufficient reimbursement and be paid in a timely manner for the professional services they provide in connection with the use of our monitoring solutions;
- establishing ourselves as a cardiac monitoring technology company by publishing peer reviewed publications showing efficacy of our solutions,
- our ability to educate physicians regarding the benefits of our cardiac monitoring solutions over alternative diagnostic monitoring solutions,
- our demonstrating that our proposed products are reliable and supported by us in the field;
- supplying and servicing sufficient quantities of products directly or through marketing alliances; and
- pricing our devices and technology service fees in a medical device industry that is becoming increasingly price sensitive.

If we are unable to drive physician utilization, our revenues may never materialize or may not meet our projections.

We are subject to extensive governmental regulations relating to the manufacturing, labeling, and marketing of our products.
Our medical technology products and operations are subject to regulation by the FDA, and other foreign and local governmental authorities. These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and post market surveillance of our medical products.

Under the United States Federal Food, Drug, and Cosmetic Act, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. We believe that our products currently under development and planned products will be Class II medical devices. Class II medical devices are subject to additional controls, including full applicability of the Quality System Regulations, and requirements for 510(k) pre-market notification.

The FDA may disagree with the classification of a new Class II medical device and require the manufacturer of that device to apply for approval as a Class III medical device. If the FDA determines that our Class II medical Products should be classified as Class III medical devices, we could be precluded from marketing the devices for clinical use within the United States for a period of time, the length of which depends on the specific change in the classification. Reclassification of our Class II medical Products as Class III medical devices could significantly increase our regulatory costs, including the timing and expense associated with required clinical trials and other costs.

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products in foreign countries. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

The policies of the FDA and foreign regulatory authorities may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our products and could also increase the cost of regulatory compliance. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

The FDA and non-U.S. regulatory authorities require that our products be manufactured according to rigorous standards. These regulatory requirements may significantly increase our production costs and may even prevent us from making our products in quantities sufficient to meet market demand. If we change our approved manufacturing process, the FDA may need to review the process before it may be used. Failure to comply with applicable regulatory requirements discussed could subject us to enforcement actions, including warning letters, fines, injunctions, and civil penalties, product recall or seizure of our products, operating restrictions, partial suspension or total shutdown of our production, and even criminal prosecution.

Federal, state, and non-U.S. regulations regarding the manufacture and sale of medical devices are subject to future changes. The complexity, timeframes and costs associated with obtaining marketing clearances are unknown. Although we cannot predict the impact, if any, these changes might have on our business, the impact could be material.

Following the introduction of a product, these agencies will also periodically review our design and manufacturing processes and product performance. The process of complying with the applicable good manufacturing practices, adverse event reporting, clinical trial and other requirements can be costly and time consuming, and could delay or prevent the production, manufacturing, or sale of our products. In addition, if we fail to comply with applicable regulatory requirements, it could result in fines, delays or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation. Recent changes in enforcement practice by the FDA and other agencies have resulted in increased enforcement activity, which increases the compliance risk for the Company and other companies in our industry. In addition, governmental agencies may impose new requirements regarding registration, labeling or prohibited materials that may require us to modify or re-register products already on the market or otherwise impact our ability to market our products in those countries. Once clearance or approval has been obtained for a product, there is an obligation to ensure that all applicable FDA, and other regulatory requirements continue to be met.

Additionally, injuries caused by the malfunction or misuse of cardiac devices, even where such malfunction or misuse occurs with respect to one of our competitor's products, could cause regulatory agencies to implement more conservative regulations on the medical cardiac monitoring industry, which could significantly increase our operating costs.

If we are not able to both obtain and maintain adequate levels of third-party reimbursement for our products, it would have a material adverse effect on our business.

Healthcare providers and related facilities are generally reimbursed for their services through payment systems managed by various governmental agencies worldwide, private insurance companies, and managed care organizations. The manner and level of reimbursement in any given case may depend on the site of care, the procedure(s) performed, the final patient diagnosis, the device(s) utilized, available budget, the efficacy, safety, performance and cost-effectiveness of our planned products and services, or a combination of these or other factors, and coverage and payment levels are determined at each payer's discretion. The coverage policies and reimbursement levels of these third-party payers may impact the decisions of healthcare providers and facilities regarding which medical products they purchase and the prices they are willing to pay for those products. Thus, changes in reimbursement levels or methods may impact sales of our products.

We have no direct control over payer decision-making with respect to coverage and payment levels for our medical device products and services. Additionally, we expect many payers to continue to explore cost-containment strategies (e.g., comparative, and cost- effectiveness studies, so-called "pay-for-performance" programs implemented by various public and private payers, and expansion of payment bundling schemes such as Accountable Care Organizations, and other such methods that shift medical cost risk to providers) that may potentially impact coverage and/or payment levels for our products and services.

The ability of physicians and other providers to successfully utilize our cardiac diagnostic and monitoring solutions and successfully allow payors to reimburse for the physicians' technical and professional fees is critical to our business because physicians and their patients will select solutions other than ours in the event that payors refuse to adequately reimburse our technical fees and physicians' professional fees.

Changes in reimbursement practices of third-party payers could affect the demand for our products and services and our revenue levels.

The sales of our proposed products and services could depend, in part, on the extent to which healthcare providers and facilities or individual users are reimbursed by government authorities, private insurers and other third-party payers for the costs of our products, or the services performed with our products. The coverage policies and reimbursement levels of third-party payers, which can vary among public and private sources and by country, may affect which products customers purchase and the prices they are willing to pay for those products and services in a particular jurisdiction. Reimbursement rates can also affect the acceptance rate of new technologies. Legislative or administrative reforms to reimbursement systems in the United States or abroad, or changes in reimbursement rates by private payers, could significantly reduce reimbursement for medical actions using the Company's products or result in denial of reimbursement for those products, which would adversely affect customer demand, or the price customers may be willing to pay for such products and services.

We may experience difficulty in obtaining reimbursement for our services from commercial payors that consider our technology to be experimental and investigational, which would adversely affect our revenue and operating results.

Many commercial payors refuse to enter into contracts to reimburse the fees associated with medical devices or services that such payors determine to be "experimental and investigational." Commercial payors typically label medical devices or services as "experimental and investigational" until such devices or services have demonstrated product superiority evidenced by a randomized clinical trial.

For example, clinical trials have been performed on some mobile cardiac telemetry devices, proving higher diagnostic yield than monitoring devices and services that are already being reimbursed. Certain remaining commercial payors, however, have stated that they do not believe the data from the clinical trials justifies the removal of the experimental designation for mobile cardiac telemetry solutions. As a result, certain commercial payors may refuse to reimburse the technical and professional fees associated with cardiac monitoring solutions such as the one expected to be offered by the Company.

If commercial payors decide not to reimburse physicians or providers for their services during the utilization of our cardiac monitoring solutions, our revenue could fail to materialize or meet our projections.

Reimbursement by Medicare is highly regulated and subject to change; our failure to comply with applicable regulations could decrease our expected revenue and may subject us to penalties or have an adverse impact on our business.

The Medicare program is administered by CMS, which imposes extensive and detailed requirements on medical services providers, including, but not limited to, rules that govern how we structure our relationships with physicians, and how and where we provide our cardiac solutions. Our failure to comply with applicable Medicare rules could result in the inability

of physicians to receive reimbursement as they will likely utilize our cardiac monitoring solution under the Medicare payment program.

Consolidation of commercial payors could result in payors eliminating coverage of mobile cardiac monitoring solutions or reducing reimbursement rates.

When payors combine their operations, the combined company may elect to reimburse physicians for cardiac monitoring services at the lowest rate paid by any of the participants in the consolidation. If one of the payors participating in the consolidation does not reimburse for these services at all, the combined company may elect not to reimburse at any rate. Reimbursement rates tend to be lower for larger payors. As a result, as payors consolidate, our expected average reimbursement rate may decline.

Product defects could adversely affect the results of our operations.

The design, manufacture and marketing of our hardware and software products involve certain inherent risks. Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of our products can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by the FDA, or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. A recall could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Personal injuries or deaths relating to the use of our products could also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

Interruptions or delays in telecommunications systems or in the data services provided to us by cellular communication providers or the loss of our wireless or data services could impair the delivery of our cardiac monitoring services.

The success of our cardiac monitoring services will be dependent upon our ability to transmit, store, retrieve, process and manage data and to maintain and upgrade our data processing and communication capabilities. Our monitoring solution relies on a third-party wireless carrier to transmit data over its data network. All data sent by our monitors via this wireless data network is expected to be routed directly to healthcare providers and data centers or third-party ECG monitoring centers. We are therefore dependent upon a third party wireless carrier to provide data transmission services to us.

As we expand our commercial activities, an increased burden is expected to be placed upon our data processing systems and the equipment upon which they rely. Interruptions of our data networks, or the data networks of our wireless carrier, for any extended length of time, loss of stored data or other computer problems could have a material adverse effect on our business and operating results. Frequent or persistent interruptions in our cardiac monitoring services could cause permanent harm to our reputation and could cause current or potential users or prescribing physicians to believe that our systems are unreliable, leading them to switch to our competitors. Such interruptions could result in liability, claims and litigation against us for damages or injuries resulting from the disruption in service.

Our systems are also expected to be vulnerable to damage to or interruption of telecommunication services from earthquakes, floods, fires, power loss, telecommunication failures, terrorist attacks, computer viruses, break-ins, sabotage, and acts of vandalism. Despite any precautions that we may take, the occurrence of a natural disaster or other unanticipated problems could result in lengthy interruptions in these services. We do not carry business interruption insurance to protect against losses that may result from interruptions in service as a result of system failures. Moreover, the communications and information technology industries are subject to rapid and significant changes, and our ability to operate and compete is dependent on our ability to update and enhance the communication technologies used in our systems and services.

Interruptions in computing and data management cloud systems could impair the delivery of our cardiac monitoring services.

The success of our cardiac monitoring services will be dependent upon our ability to perform computing functions associated with our cardiac signal processing algorithms and data management. The diagnostic and monitoring functions rely on the uninterrupted availability of third-party cloud based computational and data management services. Availability of the cloud-based infrastructure is a critical link in our ability to deliver our services and could have a material adverse effect on our business and operating results. Furthermore, loss of data due to catastrophic events at the sites for these cloud based computer systems could cause permanent harm to our customers. These adverse events associated with unavailability of our cloud based computational infrastructure could result in liability, claims and litigation against us for damages or injuries resulting from the disruption in service.

Our systems are also expected to be vulnerable to damage or interruption in cloud computational services from earthquakes, floods, fires, power loss, technical failures, terrorist attacks, computer viruses, break-ins, sabotage, and acts of vandalism. Despite any precautions that we may take, the occurrence of a natural disaster or other unanticipated problems could result in lengthy interruptions in these services.

We could be exposed to significant liability claims if we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims.

The testing, manufacture, marketing and sale of medical devices entail the inherent risk of liability claims or product recalls. Product liability insurance is expensive and, if available, may not be available on acceptable terms at all periods of time. A successful product liability claim or product recall could inhibit or prevent the successful commercialization of our products, cause a significant financial burden on the Company, or both, which in either case could have a material adverse effect on our business and financial condition.

We require additional capital to support our present business plan and our anticipated business growth, and such capital may not be available on acceptable terms, or at all, which would adversely affect our ability to operate.

We will require additional funds to further develop our business plan. We may choose to raise additional capital in order to expedite and propel growth more rapidly. We can give no assurance that we will be successful in raising any additional funds. We may need to raise additional funds, doing so through debt and equity offerings, in order to meet our expected future liquidity and capital requirements, including capital required for the development completion and introduction of our future products and technologies. Any such financing that we undertake will likely be dilutive to current stockholders.

We intend to continue to make investments to support our business growth, including patent or other intellectual property asset creation. In addition, we may also need additional funds to respond to business opportunities and challenges, including our ongoing operating expenses, protecting our intellectual property, satisfying debt payment obligations, developing new lines of business and enhancing our operating infrastructure. While we may need to seek additional funding for such purposes, we may not be able to obtain financing on acceptable terms, or at all. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our Common Stock. We may also seek to raise additional funds through arrangements with collaborators or other third parties. We may not be able to negotiate any such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all our business plans.

We cannot predict our future capital needs and we may not be able to secure additional financing.

We will need to raise additional funds in the future to fund our working capital needs and to fund further expansion of our business. We may require additional equity or debt financings, collaborative arrangements with corporate partners or funds from other sources for these purposes. No assurance can be given that necessary funds will be available for us to finance our development on acceptable terms, if at all. Furthermore, such additional financings may involve substantial dilution of our stockholders or may require that we relinquish rights to certain of our technologies or products. In addition, we may experience operational difficulties and delays due to working capital restrictions. If adequate funds are not available from operations or additional sources of financing, we may have to delay or scale back our growth plans.

The results of our research and development efforts are uncertain and there can be no assurance of the commercial success of our products.

We believe that we will need to incur additional research and development expenditures to continue development of our existing proposed products as well as research and development expenditures to develop new products and services. The products and services we are developing and may develop in the future may not be technologically successful. In addition, the length of our product and service development cycle may be greater than we originally expected, and we may experience delays in product development. If our resulting products and services are not technologically successful, they may not achieve market acceptance or compete effectively with our competitors' products and services.

If we fail to retain certain of our key personnel and attract and retain additional qualified personnel, we might not be able to pursue our growth strategy.

Our future success will depend upon the continued service of Dr. Branislav Vajdic and other members of our key management team and our technical contributors. Though no individual is indispensable, the loss of the services of these individuals could have a material adverse effect on our business, operations, revenues or prospects. We do not currently maintain key man life insurance on the lives of these individuals.

We will not be profitable unless we can demonstrate that our products can be manufactured at low prices.

To date, we have focused primarily on research and development of the first versions of our software and hardware products, as well as other technologies we plan to introduce in our eco-system, and their proposed marketing and distribution. Consequently, we have little experience in manufacturing these products on a commercial basis. We plan to manufacture our products through third-party manufacturers. We can offer no assurance that either we or our manufacturing partners will develop efficient, automated, low-cost manufacturing capabilities and processes to meet the quality, price, engineering, design and production standards or production volumes required to successfully mass market our products, especially at the low-cost levels we require to absorb the cost of near free distribution of our products pursuant to our proposed business plan. Even if we or our manufacturing partners are successful in developing such manufacturing capability and processes, we do not know whether we or they will be timely in meeting our product commercialization schedule or the production and delivery requirements of potential customers. A failure to develop such manufacturing processes and capabilities could have a material adverse effect on our business and financial results. If we or our suppliers fail to achieve or maintain regulatory approval of manufacturing facilities, our growth could be limited and our business could be harmed.

In order to maintain compliance with FDA and other regulatory requirements, our development and manufacturing facilities must be periodically re-evaluated and qualified under a quality system to ensure they meet production and quality standards. Suppliers of components and products used to manufacture our devices must also comply with FDA regulatory requirements, which often require significant resources and subject us and our suppliers to potential regulatory inspections and stoppages. If we or our suppliers do not maintain regulatory approval for our manufacturing operations, our business could be adversely affected.

Our dependence on a limited number of suppliers may prevent us from delivering our devices on a timely basis.
We currently rely on a limited number of suppliers of components for our prototype devices. If these suppliers became unable to provide components in the volumes needed or at an acceptable price, we would have to identify and qualify acceptable replacements from alternative sources of supply. The process of qualifying suppliers is lengthy. Delays or interruptions in the supply of our requirements could limit or stop our ability to provide sufficient quantities of devices on a timely basis or meet demand for our devices or services, which could have a material adverse effect on our business, financial condition and results of operations.

We rely significantly on information technology and any failure, inadequacy, or security lapse of that technology, including any cybersecurity incidents, could harm us.
We believe that companies have been increasingly subject to a wide variety of security incidents, cyberattacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber threats may be generic, or they may be custom-crafted against our information systems. Over the past few years, cyber-attacks have become more prevalent and much harder to detect and defend against. Several key areas of our business depend on the use of information technologies, including production, manufacturing, marketing, and logistics, as well as clinical and regulatory matters. We also utilize systems that allow for the secure storage and transmission of proprietary or confidential information regarding our customers, employees, and others, including personal information. Despite our efforts to prevent such behavior, third parties may nonetheless attempt to hack into our systems and obtain data relating to our pre-clinical studies, clinical trials, patients using our VCG technology and our telehealth ECG collection device or other information relating to us or our business. If we fail to maintain or protect our information systems and data integrity effectively, we could have problems in determining product cost estimates and establishing appropriate pricing, have difficulty preventing, detecting, and controlling fraud, have disputes with physicians, and other health care professionals, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach, or suffer other adverse consequences and reputational damages. While we have invested in the protection of data and information technology, there can be no assurance that our efforts or those of our third-party collaborators, if any, or manufacturers, to implement adequate security and quality measures for data processing would be sufficient to protect against data deterioration or loss in the event of a system malfunction, or to prevent data from being stolen or corrupted in the event of a security breach. Any such loss or breach could harm our business, operating results, and financial condition. For a discussion of our management of cybersecurity risks, see **Item 1C, "Cybersecurity-Risk Management" and "-Governance."**

We have identified weaknesses in our internal controls, and we cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future.
As a public company, we are subject to the reporting requirements of the Exchange Act, and the Sarbanes-Oxley Act. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly, and place significant strain on our personnel, systems and resources.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures, and internal controls over financial reporting.

We do not yet have effective disclosure controls and procedures, or internal controls over all aspects of our financial reporting. We are continuing to develop and refine our internal controls over financial reporting. Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. We will be required to expend time and resources to further improve our internal controls over financial reporting, including by expanding our staff. However, we cannot assure you that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

We have identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses identified to date include (i) lack of formal risk assessment under COSO framework (ii) policies and procedures which are not adequately documented, (iii) lack of proper approval processes, review processes and documentation for such reviews, (iv) insufficient GAAP experience regarding complex transactions and reporting and (v) insufficient number of staff to maintain optimal segregation of duties and levels of oversight.

Starting in third quarter of 2023, we have undertaken specific remediation actions to address the material weaknesses in our financial reporting. We are establishing more robust processes related to the review of complex accounting transactions, the preparation of account reconciliations and the review of journal entries. These remediation actions included hiring a Controller in July 2023, who we believe has extensive experience in developing and implementing internal controls and executing plans to remediate control deficiencies. We will be required to expend time and resources to further improve our internal controls over financial reporting. However, we cannot assure you that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock.

Our independent registered public accounting firm is not required to audit the effectiveness of our internal control over financial reporting until after we are no longer an "emerging growth company" as defined in the JOBS Act and meet other requirements. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating. Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business and operating results, and cause a decline in the market price of our common stock.

Risks Related to Economic Conditions

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.
Our cash is held in accounts at U.S. banking institutions that we believe are of high quality. Cash held in non-interest-bearing and interest-bearing operating accounts may exceed the Federal Deposit Insurance Corporation (“FDIC”) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations.

Changes in tax laws or regulations may increase tax uncertainty and adversely affect results of our operations and our effective tax rate.

We are subject to taxes in the United States and in the future expect to be subject to certain foreign jurisdictions. Due to economic and political conditions, tax rates in various jurisdictions, including the United States, may be subject to change. Our future effective tax rates could be affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in tax laws or their interpretation. In addition, we may be subject to income tax audits by various tax jurisdictions. Although we believe our income tax liabilities are reasonably estimated and accounted for in accordance with applicable laws and principles, an adverse resolution by one or more taxing authorities could have a material impact on the results of our operations.

Escalating global trade tensions, the Russia and Ukraine war, the Israel-Hamas war, the adoption or expansion of tariffs and trade restrictions and economic disruption and uncertainty resulting therefrom could negatively impact us.

The Russia and Ukraine war and Israel-Hamas war could lead to disruption, instability and volatility in global markets and industries that could negatively impact our operations and could adversely affect our business and/or our supply chain, business partners or customers in other countries beyond Russia and Ukraine. The U.S. government and other governments in jurisdictions in which we operate have imposed severe sanctions and export controls against Russia and Russian interests and threatened additional sanctions and controls. It is not possible to predict the broader consequences of this conflict, which could include sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, currency exchange rates and financial markets. The impact of these measures, as well as potential responses to them by Russia, is currently unknown and they could adversely affect our business, supply chain, partners or customers. More specifically, while it is difficult to anticipate the impact the sanctions announced to date may have on our Research and Development team is largely based in Belgrade, Serbia any further sanctions imposed or actions taken by the U.S. or other countries, and any retaliatory measures by Russia in response, such as restrictions on energy supplies from Russia to countries in the region, could increase our costs, reduce our sales and earnings or otherwise have an adverse effect on our operations.

Natural disasters and other events beyond our control could materially adversely affect us.

Natural disasters or other catastrophic events may cause damage or disruption to our operations, international commerce and the global economy, and thus could have a strong negative effect on us. Our business operations are subject to interruption by natural disasters, fire, power shortages, pandemics and other events beyond our control. Such events could make it difficult or impossible for us to deliver our products and services to our customers and could decrease demand for our products and services.

Our business and operations, and the operations of our suppliers and customers, have been, and may in the future be adversely affected by epidemics, pandemics or other public health crises such as the COVID-19 pandemic outbreak.

We may face risks related to health epidemics and pandemics or other outbreaks of communicable diseases. The COVID-19 pandemic and governments' measures taken in response had a significant adverse impact, both direct and indirect, on our business and on the broader economy. We may in the future experience, weakened demand from certain customers as a result of a public health crisis, which could adversely affect our revenues. For example, healthcare providers have, at times, deferred elective medical procedures in order to focus on combating the COVID-19 pandemic, which significantly reduced demand for certain of our medical products.

We also faced difficulty sourcing some materials and components necessary to fulfill our developmental requirements due to suppliers' capacity constraints and shipping and transportation disruptions during the COVID-19 pandemic. These disruptions adversely affected our ability to meet our schedules. If we are not able to mitigate similar disruptions effectively in future epidemics, pandemics or other public health crisis, our ability to manufacture our products or meet our customers' schedules would be adversely affected, possibly materially, and our business could be harmed. In addition, efforts to find alternate sources of supply may increase our costs or lower the quality of our product, which could negatively affect our profitability, financial condition and business.

Risks Related to Our Industry

The industry in which we operate is highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products that are safer, more effective, less costly, easier to use, or are otherwise more attractive, we may be unable to compete effectively with other companies.

The medical technology industry is characterized by intense competition and rapid technological change, and we will face competition on the basis of product features, clinical outcomes, price, services and other factors. Competitors may include large medical device and other companies, some of which have significantly greater financial and marketing resources than we do, and firms that are more specialized than we are with respect to particular markets. Our competition may respond more quickly to new or emerging technologies, undertake more extensive marketing campaigns, have greater financial, marketing and other resources than ours or may be more successful in attracting potential customers, employees and strategic partners.

Our competitive position will depend on multiple, complex factors, including our ability to achieve regulatory clearance and market acceptance for our products, develop new products, implement production and marketing plans, secure regulatory approvals for products under development and protect our intellectual property. In some instances, competitors may also offer, or may attempt to develop, alternative systems that may be delivered without a medical device or with a medical device superior to ours. The development of new or improved products, processes or technologies by other companies may render our products or proposed products obsolete or less competitive. The entry into the market of manufacturers located in low-cost manufacturing locations may also create pricing pressure, particularly in developing markets. Our future success depends, among other things, upon our ability to compete effectively against current technology, as well as to respond effectively to technological advances or changing regulatory requirements, and upon our ability to successfully implement our marketing strategies and execute our research and development plan. Our research and development efforts are aimed, in part, at solving increasingly complex problems, as well as creating new technologies, and we do not expect that all of our projects will be successful. If our research and development efforts are unsuccessful, our future results of operations could be materially harmed.

We face competition from other medical device companies that focus on similar markets.
We face competition from other companies that have longer operating histories and may have greater name recognition and substantially greater financial, technical and marketing resources than us. Many of these companies also have FDA or other applicable governmental approval to market and sell their products, and more extensive customer bases, broader customer relationships and broader industry alliances than us, including relationships with many of our potential customers. Increased competition from any of these sources could result in our failure to achieve and maintain an adequate level of customers and market share to support the cost of our operations.

Unsuccessful clinical trials or procedures relating to products under development could have a material adverse effect on our prospects.
The regulatory approval process for new products and new indications for existing products requires extensive clinical trials and procedures, including early clinical experiences and regulatory studies. Unfavorable or inconsistent clinical data from current or future clinical trials or procedures conducted by us, our competitors, or third parties, or perceptions regarding this clinical data, could adversely affect our ability to obtain necessary approvals and the market's view of our future prospects. Such clinical trials and procedures are inherently uncertain and there can be no assurance that these trials or procedures will be completed in a timely or cost- effective manner or result in a commercially viable product. Failure to successfully complete these trials or procedures in a timely and cost-effective manner could have a material adverse effect on our prospects. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials or procedures may be contradicted by subsequent clinical analysis. In addition, results from our already completed clinical trials or procedures may not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long-term studies or clinical experience, our business could be adversely affected. Clinical trials or procedures may be suspended or terminated by us, the FDA or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products.
The medical device industry in which we operate is characterized by extensive intellectual property litigation and, from time to time, we might be the subject of claims by third parties of potential infringement or misappropriation. Regardless of outcome, such claims are expensive to defend and divert the time and effort of our management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in our payment of significant monetary damages and/or royalty payments, or it could negatively impact our ability to sell current or future products in the affected category and could have a material adverse effect on business, cash flows, financial condition or results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to obtaining intellectual property protections we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We will seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We will seek to protect our confidential proprietary information, in part, by entering into confidentiality and invention or intellectual property assignment agreements with our employees and consultants. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. In general, any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

If we are unable to protect our proprietary rights, or if we infringe on the proprietary rights of others, our competitiveness and business prospects may be materially damaged.

We have filed for and were granted a number of utility patents in the U.S as well as through PCT covering international markets. We will continue to seek patent protection for our inventions and may seek patent protection for our proprietary designs if warranted. Seeking patent protection is a lengthy and costly process, and there can be no assurance that patents will be issued from any pending applications, or that any claims allowed from existing or pending patents will be sufficiently broad or strong to protect our designs or our proprietary technology. There is also no guarantee that any patents we hold will not be challenged, invalidated or circumvented, or that the patent rights granted will provide competitive advantages to us. Our competitors have developed and may continue to develop and obtain patents for technologies that are similar or superior to our technologies. In addition, the laws of foreign jurisdictions in which we develop, manufacture or sell our products may not protect our intellectual property rights to the same extent, as do the laws the United States.

Adverse outcomes in legal disputes regarding patent and other intellectual property rights could result in the loss of our intellectual property rights, subject us to significant liabilities to third parties, require us to seek licenses from third parties on terms that may not be reasonable or favorable to us, prevent us from manufacturing, importing or selling our products, or compel us to redesign our products to avoid infringing third parties' intellectual property. As a result, we may be required to incur substantial costs to prosecute, enforce or defend our intellectual property rights if they are challenged. Any of these circumstances could have a material adverse effect on our business, financial condition and resources or results of operations.

Dependence on our proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may result in our payment of significant monetary damages or impact offerings in our product portfolios.

Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, we may not be able to prevent third parties from using our proprietary technologies or may lose access to technologies critical to our products. Also, our currently pending industrial design patent or any future patents applications may not result in issued patents, and issued patents are subject to claims concerning priority, scope and other issues.

Furthermore, to the extent we do not file applications for patents domestically or internationally, we may not be able to prevent third parties from using our proprietary technologies or may lose access to technologies critical to our products in other countries.

Enforcement of federal and state laws regarding privacy and security of patient information may adversely affect our business, financial condition or operations.

The use and disclosure of certain health care information by health care providers and their business associates have come under increasing public scrutiny. Recent federal standards under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, establish rules concerning how individually-identifiable health information may be used, disclosed and protected. Historically, state law has governed confidentiality issues, and HIPAA preserves these laws to the extent they are more protective of a patient's privacy or provide the patient with more access to his or her health information. As a result

of the implementation of the HIPAA regulations, many states are considering revisions to their existing laws and regulations that may or may not be more stringent or burdensome than the federal HIPAA provisions. We must operate our business in a manner that complies with all applicable laws, both federal and state, and that does not jeopardize the ability of our customers to comply with all applicable laws. We believe that our operations are consistent with these legal standards. Nevertheless, these laws and regulations present risks for health care providers and their business associates that provide services to patients in multiple states. Because these laws and regulations are recent, and few have been interpreted by government regulators or courts, our interpretations of these laws and regulations may be incorrect. If a challenge to our activities is successful, it could have an adverse effect on our operations, may require us to forego relationships with customers in certain states and may restrict the territory available to us to expand our business. In addition, even if our interpretations of HIPAA and other federal and state laws and regulations are correct, we could be held liable for unauthorized uses or disclosures of patient information as a result of inadequate systems and controls to protect this information or as a result of the theft of information by unauthorized computer programmers who penetrate our network security. Enforcement of these laws against us could have a material adverse effect on our business, financial condition and results of operations.

We may become subject, directly or indirectly, to federal and state health care fraud and abuse laws and regulations and if we are unable to fully comply with such laws, the Company could face substantial penalties.

Although not affected at this time, our operations may in the future become directly or indirectly affected by various broad state and federal health care fraud and abuse laws, including the Federal Healthcare Programs' Anti-Kickback Statute and the Stark law, which among other things, prohibits a physician from referring Medicare and Medicaid patients to an entity with which the physician has a financial relationship, subject to certain exceptions. If our future operations are found to be in violation of these laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare and Medicaid program participation. If enforcement action were to occur, our business and results of operations could be adversely affected.

We may be subject to federal and state false claims laws which impose substantial penalties.

Many of the physicians and patients whom we expect to use our services will file claims for reimbursement with government programs such as Medicare and Medicaid. As a result, we may be subject to the federal False Claims Act if we knowingly "cause" the filing of false claims. Violations may result in substantial civil penalties, including treble damages. The federal False Claims Act also contains "whistleblower" or "qui tam" provisions that allow private individuals to bring actions on behalf of the government alleging that the defendant has defrauded the government. In recent years, the number of suits brought in the medical industry by private individuals has increased dramatically. Various states have enacted laws modeled after the federal False Claims Act, including "qui tam" provisions, and some of these laws apply to claims filed with commercial insurers. We are unable to predict whether we could be subject to actions under the federal False Claims Act, or the impact of such actions. However, the costs of defending claims under the False Claims Act, as well as sanctions imposed under the False Claims Act, could adversely affect our results of operations.

Risks Related To Common Stock

The price of our Common Stock and Warrants may be subject to wide fluctuations.

A consistently active trading market for our Common Stock and Warrants does not exist and may not develop or be maintained. You may not be able to sell your shares quickly or at the current market price if trading in our stock is not active. You may lose all or a part of your investment. The market price of our Common Stock and Warrants may be highly volatile and subject to wide fluctuations in response to a variety of factors and risks, many of which are beyond our control. In addition to the risks noted elsewhere in this prospectus, some of the other factors affecting our stock price may include:

- variations in our operating results;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- announcements by third parties of significant claims or proceedings against us;
- future sales of our Common Stock or other equity securities;
- any delay in our regulatory filings for our product and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product;

- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- additions or departures of key scientific or management personnel;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- our ability to successfully treat additional types of indications or at different stages;
- actual or anticipated variations in annual and quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our Common Stock by our stockholders in the future;
- trading volume of our Common Stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our or our licensee's technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions, including war and its unknown impact on our Serbia development team; and
- other events or factors, many of which are beyond our control.

We are an "emerging growth company," and any decision on our part to comply with certain reduced disclosure requirements

We are an "emerging growth company" as defined in the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies including, but (i) not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) not being required to comply with any new requirements adopted by the Public Company Accounting Oversight Board (the "PCAOB"), requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer, (iii) not being required to comply with any new audit rules adopted by the PCAOB after April 5, 2012 unless the SEC determines otherwise, (iv) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and (v) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could remain an emerging growth company until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.24 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer. We cannot predict if investors will find our securities less attractive if we choose to rely on these exemptions. If some investors find our securities less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our securities and our stock price may be more volatile. Further, as a result of these scaled regulatory requirements, our disclosure may be more limited than that of other public companies and you may not have the same protections afforded to stockholders of such companies.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the "Securities Act"), for complying with

new or revised accounting standards. We have opted for taking advantage of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the Jobs Act.

We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a smaller reporting company under Rule 12b-2 of the Securities Exchange Act of 1934. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on smaller reporting company exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

Future sales and issuances of our Common Stock or rights to purchase Common Stock, including pursuant to our equity incentive plans and other equity securities could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell Common Stock or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell Common Stock or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our Common Stock. Our Certificate of Incorporation authorizes the issuance of 100,000,000 shares of Common Stock and 10,000,000 shares of Preferred Stock. Initially, the aggregate number of shares of our Common Stock that may be issued pursuant to stock awards under our 2022 Equity Incentive Plan ("2022 Plan") is 1,900,000 shares, increased to 5,900,000 shares at the last shareholders' meeting. As of December 31, 2023, there are 849,171 shares available for issuance under the 2022 Plan. The number of shares available for issuance under the 2022 Plan will be increased on the first day of each fiscal year beginning with the 2023 fiscal year by five percent (5%) of the total number of shares of common stock outstanding on the last day of the immediately preceding fiscal year as defined in the Plan. Further increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline.

Nasdaq Capital Market, may delist our Common Stock if we fail to comply with ongoing listing standards.

Nasdaq Capital Market requires us to meet certain financial, public float, bid price and liquidity standards on an ongoing basis in order to continue the listing of our Common Stock and Warrants. If we fail to meet these continued listing requirements, our Common Stock or Warrants may be subject to delisting. If our Common Stock or Warrants are delisted and we are not able to list such Common Stock and Warrants on another national securities exchange, we expect our securities would be quoted on an over-the-counter market; However, if this were to occur, our stockholders could face significant material adverse consequences, including limited availability of market quotations for our Common Stock and Warrants and reduced liquidity for the trading of our securities. In addition, in the event of such delisting, we could experience a decreased ability to issue additional securities and obtain additional financing in the future.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our Common Stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our Company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our need for future financing may result in the issuance of additional securities which will cause investors to experience dilution.

Our cash requirements may vary from those now planned depending upon numerous factors, including the result of future research and development activities, our ability to estimate future expenses and acceptance of our products in the market.

There are no significant commitments for future financing of the commercial phase of our telehealth Product and other future products. In the future, our securities may be offered to other investors at a price lower than the price per share paid

by our investors, or upon terms which may be deemed more favorable than previously offered. In addition, the issuance of securities in any future financing using our securities may dilute an investor's equity ownership. Moreover, we may issue other equity securities with derivative features to procure qualified personnel or for other business reasons. The issuance of any such derivative securities, which is at the discretion of our board of directors, may further dilute the equity ownership of our stockholders, including the investors in this offering. No assurance can be given as to our ability to procure additional financing, if required, and on terms deemed favorable to us. To the extent additional capital is required and cannot be raised successfully, we may then have to limit our then current operations and/or may have to curtail certain, if not all, of our business objectives and plans.

If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.
The SEC has adopted regulations, which generally define "penny stock" to be an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The market price of our Common Stock is less than $5.00 per share and therefore may be a "penny stock." Brokers and dealers effecting transactions in "penny stock" must disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our Common Stock and may affect your ability to sell shares of our Common Stock in the future.

Liability of directors for breach of duty is limited under Delaware law.
Our certificate of incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to us or our stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- transaction from which the directors derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under the federal or state securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission.

Our bylaws provide that we will indemnify for our directors and officers to the fullest extent permitted by law, and may indemnify employees and other agents. Our bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding.

We entered into separate indemnification agreements with our directors and officers. These agreements, among other things, require us to indemnify our directors and officers for any and all expenses (including reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by such directors or officers or on his or her behalf in connection with any action or proceeding arising out of their services as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request provided that such person follows the procedures for determining entitlement to indemnification and advancement of expenses set forth in the indemnification agreement. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might provide a benefit to us and our stockholders. Our results of operations and financial condition may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

In so far as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future and, as such, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.

We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, and any future loan arrangements we enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our Common Stock. As a result, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments

None

Item 1C. Cybersecurity

Cybersecurity Risk Management

In the ordinary course of our business, we use, store, and process data including data of our employees, partners, collaborators, and vendors. We also have implemented advanced data protection measures, including encryption, data masking, and secure data storage solutions, to protect patient data and other sensitive information from unauthorized access or disclosure. We are in the process of implementing a cybersecurity risk management program that is evolving to identify, assess, and manage cybersecurity risks associated with our digital healthcare technologies and operations. This encompasses continuously enhancing our safeguarding measures for proprietary ECG telemedicine technology, cloud-based software, and sensitive health data from cyber threats, ensuring compliance with relevant healthcare and data protection regulations, and actively maintaining the integrity, availability, and confidentiality of patient and company information.

Our cybersecurity risk management program includes a number of components, such as ongoing information security program assessments and continuous monitoring of critical risks from cybersecurity threats using automated tools. We leverage a combination of internal and external resources to continuously update our intelligence about emerging cybersecurity threats. This includes subscribing to threat intelligence feeds, participating in industry-specific security forums, and collaborating with cybersecurity organizations. We also employ state-of-the-art automated security systems that are regularly updated to recognize and respond to the latest cybersecurity threats. Automated alerts notify our security team of potential threats in real-time, enabling rapid assessment and response. Additionally, we have implemented an employee education program that is regularly updated to raise awareness of cybersecurity threats, including phishing awareness, secure password practices, and the proper handling of sensitive information. This training is included during the employee onboarding process and is revisited periodically. As part of our cybersecurity risk management program, we maintain processes to assess and review the cybersecurity practices of third-party vendors on an ongoing basis. Prior to engaging third-party vendors, all vendors are subjected to rigorous security assessments before engagement and are regularly re-assessed, and, as appropriate, include cybersecurity requirements in contracts. We, like other companies in our industry, face a number of cybersecurity risks in connection with our business. Although our business strategy, results of operations, and financial condition have not, to date, been materially affected by risks from cybersecurity threats, including as a result of previously identified cybersecurity incidents, we have, from time to time, experienced threats to and security incidents related to our data and systems, including phishing attacks. For more information on our cybersecurity related risks, see "Risk Factors-*We rely significantly on information technology and any failure, inadequacy, or security lapse of that technology, including any cybersecurity incidents, could harm us."*

Governance

Under the ultimate direction of our chief executive officer (CEO), our executive management team, including our President, Chief Technology Officer (CTO), Director of Platform IT and Chief Information Security Officer (CISO), and Vice President of Regulatory Affairs, along with oversight from our Audit Committee of the Board of Directors, is tasked

with the continuous assessment, operation, and management of our cybersecurity threat management program. Our CTO leads the ongoing development of the Company's cybersecurity program, oversees the implementation of cybersecurity measures, and manages the response to cybersecurity incidents. The Director of Platform IT and CISO meets periodically with our Vice President of Regulatory Affairs to discuss the evolving cybersecurity landscape and our cybersecurity risk management program, including providing updates regarding the sources and nature of critical risks we face and how the IT department assesses those risks, including the likelihood of such risks, the severity of impact, and the progress on vulnerability remediation.

Our Director of Platform IT and CISO regularly consults with other members of our information technology department, and with third parties with expertise in cybersecurity, to develop strategies to assess, address and align our continuous cybersecurity efforts with our business objectives and operational requirements. The Director of Platform IT and CISO role is currently held by an individual who has over 12 years of experience with information security and business systems, including digital infrastructure and cybersecurity.

As part of our Board of Directors', or Board's, enterprise risk management program, our Board has responsibility for oversight of cybersecurity risk management. Our Board has delegated to our Audit Committee oversight of our cybersecurity risk management program, including oversight of information security and cybersecurity threats and related compliance and disclosure requirements. On a quarterly basis, our finance team provides an update to our Audit Committee regarding our cybersecurity risk management program, including as relates to critical cybersecurity risks, ongoing cybersecurity initiatives and strategies, and applicable regulatory requirements and industry standards. The Audit Committee periodically reports on cybersecurity risk management to the full Board of Directors.

Item 2. Properties

Our headquarters are located at 2118 Walsh Avenue, Suite 210, Santa Clara, CA 95050 which we lease pursuant to a monthly lease agreement entered into in May 2019 by our Chief Executive Officer Branislav Vajdic. The terms of the lease are month to month and either party can terminate with one months notice. We terminated this lease effective on January 11, 2024, and entered into a new lease in name of the Company with the same landlord. The new lease commenced on February 1, 2024, for initial period of 3 years

We believe that the facilities described above are suitable and adequate for our present purposes and needs in the near future.

Item 3. Legal Proceedings.

There are no actions, suits, proceedings, inquiries or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the executive officers of our company or any of our subsidiaries, threatened against or affecting our company, our Common Stock, any of our officers or directors in their capacities as such, in which an adverse decision could have a material adverse effect.

Item 4. Mine Safety Disclosures

Not applicable

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock and warrants are traded on the NASDAQ Capital Market under the symbols “BEAT” and “BEATW”, respectively. The closing price of our common stock and warrants on the Nasdaq Capital Market on March 19, 2024 was $2.31 and $0.20 respectively.

Use of Proceeds

Not Applicable

Holders of Record

As of March 19, 2024, there were approximately 84 holders of record of our common stock. As our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We have not paid any cash dividends on our common stock to date. The payment of dividends in the future will be contingent upon our revenues and earnings, if any, capital requirements and general financial condition, and will be within the discretion of our then-existing board of directors.

Transfer Agent, Warrant Agent and Registrar

Our transfer agent and registrar for our common stock and warrant agent for our warrants is VStock Transfer, LLC.

Performance Graph and Purchases of Equity Securities

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Recent Sales of Unregistered Securities

The following sets forth information regarding all unregistered securities sold by the registrant in the three years preceding the date of this Annual Report on Form 10-K;

- On November 11, 2021, we issued 1,497,216 shares of Common Stock from the conversion of the 2015 Notes.
- On November 15, 2021, in connection with the IPO, we issued 192,500 warrants (the “Underwriter Warrants”) to purchase Common Stock as compensation to the Underwriter, exercisable at a per share exercise price equal to $7.50 per share. The Underwriter Warrants will expire five years from the date of issuance.
- On January 14, 2022, we issued 78,025 shares of Common Stock to a consulting firm for services that were related to the IPO.
- On February 28, 2023 we entered into a securities purchase agreement and a note purchase agreement, each as amended March 7, 2023 (“SPA”, “NPA” or together “Agreements”) with Maverick Capital Partners, LLC (“Maverick” or “Investor”). Pursuant to the terms of the Agreements, as amended, we agreed to sell up to $4,000,000 of our common stock at 75% of the average calculated Volume Weighted Average Price (“VWAP”) per share during a Drawdown Pricing Period as defined in the Agreements. We issued a $500,000 Convertible Note to the Investor pursuant to the NPA. On March 9, 2023 the Convertible Note was settled upon the execution of a SPA and related issuance of 0.2 million shares of common stock pursuant to the SPA drawdown notice dated

March 7, 2023. The 0.2 million shares of common stock were registered under our registration statement on Form S-3 dated February 10, 2023 and the related prospectus supplement dated March 9, 2023.

- On May 2, 2023, we issued 1,666,666 placement agent warrants to purchase shares of Common Stock sold in the offering, with an exercise price of $1.875 per share and are exercisable for five years from the date of issuance.

These issuances were made in reliance on an exemption from registration set forth in Section 4(a)(2) of the Securities Act, as transactions by an issuer not involving a public offering.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no issuer purchases of equity securities during the year ended December 31, 2023.

Equity Compensation Plan Information

On August 12, 2015 we adopted the HeartBeam, Inc. 2015 Equity Incentive Plan ("2015 Plan"), the 2015 Plan provided for the grant of stock options and RSUs to purchase common stock of which 1,636,362 were authorized by the board, of these 970,704 are outstanding as of December 31, 2023. At the Annual Stockholder meeting held on June 15, 2022 the 2015 Plan was terminated upon stockholder approval of the 2022 Equity Incentive Plan ("2022 Plan") whereby no new awards can be issued under the 2015 Plan. Initially, the aggregate number of shares of our Common Stock that may be issued pursuant to stock awards under our 2022 Plan is 1,900,000 shares and increased to 5,900,000 at the 2023 annual shareholders' meeting. As of December 31, 2023, there are 849,171 shares available for issuance under the 2022 Plan. The number of shares available for issuance under the 2022 Plan will be increased on the first day of each fiscal year beginning with the 2023 fiscal year by five percent (5%) of the total number of shares of common stock outstanding on the last day of the immediately preceding fiscal year as defined in the Plan.

The principal provisions of our equity compensation plan is summarized below.

Administration

The plan generally is administered by our Board of Directors. The Board of Directors will have authority to establish rules and regulations for the proper administration of our equity incentive plan, to select the employees, directors and consultants to whom awards are granted, and to set the date of grant, the type of award and the other terms and conditions of the awards, consistent with the terms of the 2022 Plan.

Eligibility

Persons eligible to participate in the 2022 Plan include all of our officers, employees, directors and consultants.

Awards

The 2022 Plan provides for the grant of: (i) incentive stock options; (ii) nonstatutory stock options; (iii) stock appreciation rights; (iv) restricted stock; and (v) other stock-based and cash-based awards to eligible individuals. The terms of the awards will be set forth in an award agreement, consistent with the terms of the 2022 Plan. No stock option will be exercisable later than ten years after the date it is granted. The 2022 Plan permits the grant of awards intended to qualify as "performance-based compensation" under Section 162(m) of the Internal Revenue Code of 1986, as amended.

Stock Options

The Board of Directors may grant incentive stock options as defined in Section 422 of the Code, and nonstatutory stock options. Options shall be exercisable for such prices, shall expire at such times, and shall have such other terms and conditions as the Board of Directors may determine at the time of grant and as set forth in the award agreement; however, the exercise price must be at least equal to 100% of the fair market value at the date of grant. The option price is payable in cash or other consideration acceptable to us.

Stock Appreciation Rights

The Board of Directors may grant stock appreciation rights with such terms and conditions as the Board of Directors may determine at the time of grant and as set forth in the award agreement. The grant price of a stock appreciation right shall be determined by the Board of Directors and shall be specified in the award agreement; however, the grant price must be at least equal to 100% of the fair market value of a share on the date of grant. Stock appreciation rights may be exercised upon such terms and conditions as are imposed by the Compensation Committee and as set forth in the stock appreciation right award agreement.

Restricted Stock

Restricted stock may be granted in such amounts and subject to the terms and conditions as determined by the Board of Directors at the time of grant and as set forth in the award agreement. The Board of Directors may impose performance goals for restricted stock.

Other Awards

The Board of Directors may grant other types of equity-based or equity-related awards not otherwise described by the terms of the 2022 Plan, in such amounts and subject to such terms and conditions, as the Board of Directors shall determine. Such awards may be based upon attainment of performance goals established by the Board of Directors and may involve the transfer of actual shares to participants, or payment in cash or otherwise of amounts based on the value of shares.

Item 6. RESERVED

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to, those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K. See Cautionary Statement Regarding Forward-Looking Statements."

Overview

We are a medical technology company focused on transforming cardiac care through the power of personalized insights. Our aim is to deliver innovative, higher resolution ambulatory cardiac monitoring solutions that can be used by patients anywhere to enable the detection and monitoring of cardiac disease outside of a healthcare facility. Our ability to develop higher resolution ECG solutions is achieved through the development of our proprietary and patented VECG technology platform. Our VECG technology is capable of capturing 3D vector images of the heart's electrical activity and synthesizing a 12L ECG from these signals. In early studies, our approach demonstrated equal or superior diagnostic capability than traditional hospital-based 12L ECG systems.

Our Products require FDA clearance and have not been cleared for marketing.

We believe our Products and services will benefit many stakeholders, including patients, healthcare providers, and healthcare payors. We are developing our telehealth Product, HeartBeam AIMIGo, to address the rapidly growing field of ambulatory cardiac health monitoring. HeartBeam AIMIGo is comprised of a credit card sized electrocardiogram device, a patient application, a physician portal, and powerful cloud-based algorithms. We believe that we are uniquely positioned to play a central role in ambulatory cardiac monitoring including high-risk coronary artery disease patients, because the initial studies have shown that our ischemia detection system may be more accurate than existing ambulatory monitoring solutions. CAD patients are at increased risk for a heart attack or MI.

To date, we have developed a working prototype for HeartBeam AIMIGo and have filed a 510(k) submission with the FDA. This submission is for the initial Product, a device which is a 3 lead X, Y, Z vector VECG. We expect this to be the first patient-held VECG device to be cleared by the FDA and this will be a major milestone for the company. Following

the FDA clearance of the AIMIGo device, we plan to file a submission for the software algorithms that synthesize a 12L ECG from the HeartBeam AIMIGo device. The result of these two 510(k) submissions, once cleared by the FDA, will be an ambulatory device, carried by patients, which can synthesize a 12L ECG for physician review.

We have had productive discussions with the FDA on both products. On the first submission, we are in the substantive review phase of answering questions posed by the FDA. We have clarified the information requested in meetings with FDA representatives and are in the process of preparing our official responses. We currently anticipate clearance by the end of Q2 2024.

In addition, we have held two Pre-submission meetings with FDA on the 12L synthesis submission. These meetings have been focused primarily on the performance goals of our clinical study that is designed to demonstrate the similarity between our synthesized 12L signal and the output of a standard 12L ECG. Based on feedback from FDA and our clinical experts, we have designed our clinical study, "Clinical Validation of AIMIGo 12 Lead ECG Synthesis Software for Arrhythmia Detection: A Prospective Multicenter Pivotal Study," (the "VALID-ECG Study").

On March 13, 2024, we enrolled the first patient in the VALID-ECG study. The VALID-ECG study is a prospective single-arm multicenter trial designed with the goal to validate the AIMIGo 12L ECG Synthesis Software by comparing its results with those of a standard FDA-cleared 12L ECG using both quantitative and qualitative assessment methodologies. We plan to enroll a total of approximately198 patients presenting to an outpatient cardiology clinic or arrhythmia center for symptoms suggestive of cardiac arrhythmia or for routine checkup of previously diagnosed arrhythmia. The study is expected to include up to 5 sites. The primary objective is to demonstrate the equivalence of ECG waveforms between AIMIGo Synthesized 12L ECG and Standard 12L ECG, recorded simultaneously in each subject, by assessing intervals and amplitudes.

We expect to complete enrollment in the VALID-ECG study in Q2 2024 and submit the second 510(k) application by Q3 2024. We continue to anticipate that our limited launch of AIMIGo will occur by the end of 2024.

In 2023, we withdrew the FDA application of our AIMI Product, which is a software-only product designed for use in hospitals. We are exclusively focusing on the large market of ambulatory cardiac monitoring,

We also have an active AI program underway. Our AI team includes 5 PhDs. The leadership has deep AI expertise, including prior positions at Apple, Microsoft and Google. We have acquired approximately one million 12L ECGs from various sources, a key element in our fast-paced AI development efforts.

We have developed initial deep learning algorithms, focused on the ability to detect various cardiac arrhythmias. HeartBeam has had data on its deep learning algorithm accepted for presentation at two prestigious Electrophysiology conferences: the European Heart Rhythm Association, to be held in Berlin, Germany in April 2024 and the Heart Rhythm Society, to be held in Boston MA in May 2024. We believe that, when combined with our Products, HeartBeam's AI will provide additional value to patients and physicians in a number of ways, including:

- Providing automated classification of cardiac conditions, including common arrhythmias;
- The potential to further enhance user experience and simplify the onboarding process, and
- In the longer run, we believe that applying deep learning algorithms on top of the rich VECG data, especially with the longitudinal dataset from patients taking repeated readings, may result in unsurpassed predictive and diagnostic capabilities.

The custom software and hardware of our Products are classified as Class II medical devices by the FDA, running on an FDA registered Class I software platform. Premarket review and clearance by the FDA for Class II devices is generally accomplished through the 510(k) premarket notification process or De Novo process. Given the proposed intended use of our device, the 510(k) submission is expected to require clinical data to support FDA clearance.

A landmark clinical study on the HeartBeam technology was published in the August 2023 issue of the journal JACC: Advances. The publication, "Coronary Artery Occlusion Detection Using 3-Lead ECG System Suitable for Credit Card-Size Personal Device Integration" demonstrated that HeartBeam's VECG technology detects the presence of a coronary occlusion, the cause of heart attacks, with the same accuracy as a standard 12L ECG.

The study showed that the automated analysis of the VECG and 12L ECG signals had similar performance in determining whether a coronary artery was occluded. Also in the study, the human interpretation of the 12L ECGs had significant intra- and inter-observer variability, which does not occur with automated readings. The study also showed that the presence of the "normal baseline" recording, a novel feature that is integral to HeartBeam's VECG technology, dramatically improved the accuracy of interpretation, increasing the Area Under the Curve ("AUC"), a standard measure of diagnostic performance, from 0.72 to 0.95. This is particularly important since physicians who are analyzing 12L ECGs often do not have access to a normal baseline, implying that the HeartBeam system could outperform this approach.

The study was a collaboration of Harvard Medical School Faculty at Beth Israel Deaconess Medical Center in Boston, Massachusetts, and Clinical Center of Serbia in Belgrade.

HeartBeam has 13 issued and allowed U.S. patents (U.S. 10,433,744, U.S. 10,117,592, U.S. 11,071,490, U.S. 11,419,538, U.S. 11,445,963, U.S. 11,701,049, U.S. 11,529,085, U.S. 10,980,433, U.S. 11,412,972, U.S. 11,234,658, U.S. 11,793,444, U.S. 11,877,853, and allowed U.S. patent application no. 18/068,481), and nine pending U.S applications. Outside of the U.S., HeartBeam has four issued patents in Germany, France, Netherlands and United Kingdom and fourteen pending applications in Canada, China, the European Union, Japan, South Korea and Australia. HeartBeam has two pending Patent Cooperation Treaty applications. The issued patents are predicted to expire between April 11, 2036 and April 21, 2042.

As of December 31, 2023, we had 15 employees. We intend to hire or engage additional full-time professionals, employees, and / or consultants in alignment with our growth strategy. Although the market is highly competitive for attracting and retaining highly qualified professionals in our industry, we continue our endeavor to find such candidates for our Company. Our management team and additional personnel that we may hire in the future will be primarily responsible for executing and implementing growth opportunities, making tactical decisions related to our strategy and pursuing opportunities to invest in new technologies through strategic partnerships and acquisitions.

Significant Developments during 2023 and early 2024

Appointment of President

In January 2023, our Board of Directors appointed Robert P. Eno as President of the Company effective as of January 18, 2023.

Appointment of Board of Directors

We increased the size of our Board of Directors (the "Board") this year to eight, adding individuals that broadened the scope and experience of our then 5-person Board.

On June 5, 2023, the Board appointed Mark Strome and Ken Nelson as directors of the Company.

- Mr. Strome combines over 40 years of experience in the investment management and securities industry. Mark is the Founder, Chief Investment Officer, and Chairman at Strome Investment Management, L.P. and Strome Group, Inc. Mark earned a Bachelor of Science in Engineering from Old Dominion University and Master of Science in Economics from the University of California at Berkeley.

- Mr. Nelson is a 20-year digital health, medical device, and remote patient monitoring executive and innovator. Over the past 10 years, Ken has led commercial efforts for disruptive technologies in the digital health, wearables, and cardiac remote patient monitoring industries for 3 of the top 4 market share players in cardiac digital health and remote patient monitoring. Ken earned a Bachelor of Arts in Economics from Vanderbilt University and is a graduate of Phillips Exeter Academy.

On July 24, 2023, the Board appointed Dr. Michael R. Jaff as a director of the Company. Dr. Jaff is currently Chief Medical Officer and Vice President of Clinical Affairs, Technology, and Innovation of the Peripheral Interventions division at Boston Scientific Corporation. Dr. Jaff received a B.S. from Dickinson College, a D.O. from Kirksville College of

Osteopathic Medicine, a Business degree from Harvard Business School and an honorary Doctorate of Arts from Harvard Medical School.

Appointment of Additional Senior Management Team members

- On August 8, 2023, we announced the appointment of Deborah Castillo, PhD, as Vice President of Regulatory Affairs. Ms. Castillo is an experienced biomedical engineer with extensive knowledge of and background at the FDA, EU, and Health Canada regulations. She has held various roles at the FDA, including overseeing 510(k) submissions encompassing a wide-range of cardiovascular devices.

- On September 26, 2023, we announced the appointment of Richa Gujarati as Senior Vice President, Product, and Pooja Chatterjee as Vice President, Clinical. Ms. Gujarati has over 13 years of experience collecting market-level insights and translating them into business needs, driving overall product portfolio and go-to-market strategy. Previously at Apple, as Head of Health Products, Apple Watch, she built and launched applications in the wearable sensor space. Ms. Chatterjee brings over 15 years of extensive clinical leadership experience in the medical device industry and was responsible for multiple FDA approvals in medical technologies including heart failure and cardiac rhythm management. Additionally, while at Abbott Medical Devices her role included focus on obtaining peer reviewed publications in key journals.

Expanded the Scientific Advisory Board

On November 9, 2023, we announced the expansion of our Scientific Advisory Board (SAB) to include several leading cardiologists. The SAB is led by Peter J. Fitzgerald, MD, PhD, the company's Chief Medical Officer and C. Michael Gibson, MD. The newly announced members of the HeartBeam SAB are:

- Charles L. Brown III, MD, CEO of the Piedmont Healthcare Physician Enterprise.
- Tony Das, MD, a nationally recognized board-certified interventional cardiology specialist, leader, and educator in the field of cardiovascular diseases.
- Robert Harrington, MD, Dean of Weill Cornell Medicine, and provost for medical affairs of Cornell University.
- Campbell Rogers, MD, Executive Vice President and Chief Medical Officer at HeartFlow, Inc.
- Niraj Varma, MD, Ph.D., Professor of Medicine, and consultant electrophysiologist at the Cleveland Clinic.

Retirement of Chief Financial Officer

On December 29, 2023, Richard Brounstein, informed the Company of his plans to retire from his position as Chief Financial Officer effective as of February 1, 2024. Mr. Brounstein has been an important member of the executive team at HeartBeam since 2015. Mr. Brounstein will provide CFO advisory services as a consultant to the Company to assist with a smooth transition of his former duties.

New Patent Assignments

During 2023, we were granted three U.S. patents:

- We were granted two patents (US 11,877,853 and US 11,701,049) on mobile cardiac monitoring devices and methods for providing automated diagnosis of cardiac issues to patients, by the United States Patent and Trademark Office. These innovations build on our growing intellectual property portfolio enabling ECG diagnostics outside of a medical setting.

- We were also granted a patent (US 11,793,444) on electrocardiogram patch devices and methods by the United States Patent and Trademark Office. This patent further expands our coverage of wearable and patch-based patient monitoring.

- We now have a total of eleven patents issued as of December 31, 2023.

- Subsequently in 2024 we received two additional patents on our core VECG technology. One patent covers apparatuses and methods that facilitate the comparison of cardiac signals over time for the automated or assisted detection of heart attacks, The other covers methods and apparatuses around HeartBeam's wrist-based ECG system.

At-the-Market Offering

On February 1, 2023, we entered into a sales agreement (the "Sales Agreement") with AGP pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $13.0 million in at-the-market offerings ("ATM") sales. At the same time, we filed a prospectus supplement under a shelf registration on Form S-3 relating to the Sales Agreement. The registration statement was declared effective on February 10, 2023. AGP will act as sales agent and will be paid a 3% commission on each sale under the Sales Agreement. Our common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. There have been no sale of shares under the ATM since February 2023, nor under the Form S-3 since May 2023. As of December 31, 2023 there was approximately $11.0 million available for issuance under the ATM.

Note Purchase Agreement and Security Purchase Agreement

On February 28, 2023, we entered into Agreements, each as amended on March 7, 2023, with Maverick. Pursuant to the terms of the Agreements, as amended, we agreed to sell up to $4,000,000 of our common stock at 75% of the average calculated Volume Weighted Average Price ("VWAP") per share during a Drawdown Pricing Period as defined in the Agreements. We issued a $500,000 Convertible Note to the Investor pursuant to the NPA. On March 9, 2023, the Convertible Note was settled upon the execution of a SPA and related issuance of 0.2 million shares of common stock pursuant to the SPA drawdown notice dated March 7, 2023. These 0.2 million shares of common stock were registered under our registration statement on Form S-3 dated February 10, 2023, and the related prospectus supplement dated March 9, 2023.

Public Offerings under Forms S-1 and S-3

On April 20, 2023, we entered into a Placement Agency Agreement with Public Ventures, LLC to consummate an offering of 16,666,666 shares of Common Stock at an offering price of $1.50 per share, which closed in accordance with the subscription agreement dated May 2, 2023. The Company received $23.2 million in net proceeds from the offering after deducting placement agent discounts and commission and other estimated offering expenses. In addition, the subscription agreement granted 1,666,666 placement agent warrants as part of this transaction.

On May 2, 2023, we completed a Registered Direct Offering of 1,000,000 shares of our common stock at an offering price of $1.50 per share. We received net proceeds of $1.1 million after deducting financial advisory and legal fees as well as other estimated offering expenses.

Results of operations for the years ended December 31, 2023 and 2022

The following table summarizes our results of operations for the periods presented on our statement of operations data. The year over year comparison of results of operations is not necessarily indicative of results of operations for future periods.

	Years ended December 31,			
	2023	2022	$ Change	% Change
	(In thousands, except percentages)			
Operating expenses:				
General and administrative	$ 8,516	$ 7,354	$ 1,162	16 %
Research and development	6,798	5,677	1,121	20 %
Total operating expenses	15,314	13,031	2,283	18 %
Loss from operations	(15,314)	(13,031)	(2,283)	18 %
Interest income	675	69	606	878 %
Income tax provision	—	—	—	— %
Net loss	$ (14,639)	$ (12,962)	$ (1,677)	13 %

Summary of Statements of Operations for the year ended December 31, 2023 compared with the year ended December 31, 2022:

General and administrative expenses ("G&A") are largely related to personnel and professional services. G&A expense increased $1.2 million or 16% when compared to the same period in 2022. The $1.2 million increase is primarily related to non-cash stock-based compensation expense amounting to $1.6 million associated with additional awards granted since December 31, 2022, primarily offset by costs associated with our commercial team during the year ended December 31, 2022, and lower investor relation costs, marketing costs and legal costs incurred in this year compared to the prior year.

Research and development expenses ("R&D") are primarily from software development and hardware related to our credit-card sized collection device for HeartBeam AIMIGo. R&D expense increased $1.1 million or 20% when compared with the same period in 2022. The $1.0 million increase is primarily due to non-cash stock-based compensation expense amounting to $0.5 million associated with additional awards granted since December 31, 2022 as well as the increase in headcount and professional services supporting the FDA clearance process, primarily offset by completion of the initial development costs of the AIMIGo platform when compared to December 31, 2022.

Other income is primarily interest income. The increase is primarily related to our increased cash balance coupled with higher interest rates following the $26.5 million financing in May 2023.

Liquidity and Capital Resources

Our cash requirements are and will continue to be, dependent upon a variety of factors. We expect to continue devoting significant capital resources to R&D and following FDA clearance of our AIMIGo device, our commercialization go to market strategies.

As of December 31, 2023, we had approximately $16.2 million in cash and cash equivalents, an increase of $12.6 million from $3.6 million as of December 31, 2022.

During the year ended December 31, 2023, we raised $24.8 million is primarily the issuance of common stock from the secondary financing in May 2023.

Based on its current business plan assumptions and expected cash burn rate, the Company believes that the existing cash is insufficient to fund operations for the next twelve months following the issuance of these financial statements. These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

Our cash is as follows (in thousands):

	December 31,	
	2023	2022
Cash and cash equivalents	$ 16,189	$ 3,594

Cash flows for the year ended December 31, 2023 and 2022 (in thousands):

	December 31	
	2023	2022
Net cash used in operating activities	$ (12,093)	$ (9,948)
Net cash used in investing activities	(256)	—
Net cash provided by financing activities	24,994	350

***Operating Activities*:**

Net cash used in our operating activities of $12.1 million during the year ended December 31, 2023, is primarily due to our net loss of $14.6 million less $3.2 million in stock-based compensation expense and $0.7 million of net changes from changes in operating assets and liabilities.

Net cash used in our operating activities of $9.9 million during the year ended December 31, 2022, is primarily due to our net loss of $12.9 million less $1.1 million in stock-based compensation expense and $1.9 million from changes in operating assets and liabilities.

Investing Activities:

Net cash used in investing activities during the year ended December 31, 2023, of $0.3 million, is primarily due to the purchase of property and equipment.

***Financing Activities*:**

During the year ended December 31, 2023, net cash provided by financing activities of $24.9 million, is primarily the issuance of common stock from the secondary financing in May 2023.

During the year ended December 31, 2022, net cash provided by financing activities of $0.3 million, is primarily from the issuance of common stock under the February Stock Purchase Agreement.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Estimates

The financial statements have been prepared in accordance with accounting principles generally accepted in the US, ("US GAAP".) The preparation of these financial statements in accordance with US GAAP requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, assumptions and judgments. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions and the impact of such differences may be material to our financial statements.

We consider an accounting estimate to be critical if: (1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (2) changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations.

Management has discussed the development and selection of these critical accounting estimates with the Audit Committee of our Board of Directors.

Stock-based compensation

The compensation cost for all stock-based awards is measured at the grant date, based on the fair value of the award, determined using a Black-Scholes option pricing model for stock options and fair value on the date of grant for non-vested restricted stock, and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity award). Determining the fair value of stock-based awards at the grant date requires significant estimates and judgments. Management has determined the fair value and vesting period of stock-based compensation to be a critical accounting estimate due to certain options containing performance-based vesting condition.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

The financial statements and supplementary data of the Company required by this Item are described in Item 15 of this Annual Report on Form 10-K and are presented beginning on page F-1.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosures

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We adopted and maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Annual Report on Form 10-K, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As required under Exchange Act Rule 13a-15, our management, including the Chief Executive Officer (our principal executive and accounting officer) after evaluating the effectiveness of disclosure controls and procedures, identified material weaknesses in our internal control over financial reporting. The material weaknesses identified include (i) lack of formal risk assessment under COSO framework (ii) policies and procedures which are not yet adequately documented, (iii) lack of proper approval processes and review processes and documentation for such reviews, (iv) insufficient GAAP experience regarding complex transactions and reporting, and (v) insufficient number of staff to maintain optimal segregation of duties and levels of oversight.

During the second half of 2023, we have undertaken specific remediation actions to address the material weaknesses in our financial reporting. We are establishing more robust processes related to the review of complex accounting transactions, the preparation of account reconciliations and the review of journal entries. These remediation actions included hiring a Controller in July 2023, who has extensive experience in developing and implementing internal controls and executing

plans to remediate control deficiencies. We will continue to assess the weaknesses as this individual progress through our onboarding process and as we continue to implement and refine control policies and procedures.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This Annual Report on Form 10-K does not include an audit or attestation report from our registered public accounting firm regarding our internal control over financial reporting. Our management's report was not subject to audit or attestation by our registered public accounting firm since we are not an accelerated filer or a large accelerated filer as defined in Rule 12b-2 under the Securities Exchange Act of 1934.

Changes in Internal Control

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fourth quarter of the year ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevent Inspections.

Not applicable

Part III

Item 10. Directors, Executive Officers and Corporate Governance

Information About our Executive Officers and Directors

Our business and affairs are organized under the direction of our board of directors, which currently consists of five members.

The following table sets forth certain information with respect to the current directors of our Company:

NAME	AGE	POSITION
Richard Ferrari	70	Executive Chairman of the Board of Directors
Branislav Vajdic, PhD	69	Chief Executive Officer, Director
George A. de Urioste	68	Director
Marga Ortigas-Wedekind	62	Director
Willem Elfrink	71	Director
Mark Strome	66	Director
Kenneth Nelson	48	Director
Michael Jaff	65	Director

Richard Ferrari - *Executive Chairman of the Board of Directors*
Mr. Richard Ferrari, 70, joined our Board in 2019 and was appointed Executive Director of the Board of Directors in June 2021. Mr. Ferrari combines over 40 years of experience in Medical Device Start-ups as CEO, and entrepreneur. Also Mr. Ferrari is co-founder of De Novo Ventures which has $650M under management and has been Managing Director since 2000. Mr. Ferrari has also co-founded 6 more companies, two of which have been successful IPO's and subsequent acquisitions, CTS one of the companies he co-founded was the fastest start-up to an IPO in the last 22 years in the medical device industry. Mr. Ferrari most recently from 2018 to 2021 was Chairman and CEO of PQ Bypass which was recently acquired by Endologix. Mr. Ferrari sits on the board of Pulmonx, a public company and is the Chairman of the Compensation Committee. Additionally, Mr. Ferrari is Executive Chairman of Tenon Medical, Vice-Chairman of ABS Interventional, Executive Chairman of Medlumics, and holds board positions with several other medical device start-ups. Mr. Ferrari has an undergraduate degree from Ashland University and an MBA from University of South Florida.

We believe that Mr. Ferrari is qualified to serve on our board of directors because of his experience in leadership and management roles in the field of medicine, as well as his experience as a member in the healthcare industry.

Branislav Vajdic, PhD - *Chief Executive Officer and Director*
Dr. Branislav Vajdic, 69, Chief Executive Officer and Founder of HeartBeam, Inc, combines over 30 years of experience in technology development and senior management positions. Dr. Vajdic has been deeply involved with the development of HeartBeam's technology to fit his vision for the Company. Prior to HeartBeam from 2007 to 2010, Dr. Vajdic was CEO and Founder of NewCardio, a publicly traded company in the cardiovascular devices space, from 1984 to 2007, Dr. Vajdic was at Intel, where he held various senior management positions. At Intel, Dr. Vajdic 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. Dr. Vajdic was awarded two Intel Achievement Awards, the highest level of award for outstanding contributions to Intel. Dr. Vajdic is author of numerous patents and publications in the fields of cardiovascular devices as well as chip design. Dr. Vajdic holds a PhD degree in Electrical Engineering from the University of Minnesota.

We believe that Dr. Vajdic is qualified to serve on our board of directors because of his experience in leadership and management roles in the field of medicine, as well as his experience as a member in the healthcare industry.

George A. de Urioste - *Director*
Mr. de Urioste, 68, combines over 40 years of experience in high technology industry senior management. Previously, Mr. de Urioste has been involved in over 10 companies, holding positions including Board Director, Chief Operating Officer and Chief Financial Officer. Mr. de Urioste was Chief Financial Officer of Remedy Corporation (software) from 1992 to 1998 and led the IPO, Chief Executive Officer of Aeroprise, Inc., from 2000 to 2003 (software), from 2004 to 2006 he was Chief Operating Officer and Chief Financial Officer for Chordiant Software, Inc. (software), interim Chief Operating Officer and Chief Financial Officer for Marvell Technology, Inc. (semiconductors) during 2008, Chief Financial Officer for Pluribus Networks, Inc. (software) 2014 to 2018, Chief Financial Officer for 4iQ, Inc. (software) 2019 to 2020 and interim Chief Financial Officer for Mozilla, Inc. (software). Mr. de Urioste's Board Director experience includes Audit Committee chairman roles for the following companies: Rainmaker Systems, Inc. (business outsourcing), from 2003 to 2005, Saba Software, Inc. (software) from 2008 to 2010, GCT, Inc. (semiconductors), from 2009 to 2011 Villa Montalvo (performing arts center), from 2011 to 2013, Bridgelux, Inc., from 2011 to 2016 (LED lighting), and Vendavo, Inc., from 2013 to 2014 (software). Mr. de Urioste was also chairman of the Board of Directors for Aeroprise, Inc. from 2000 to 2005 (software). Mr. de Urioste is currently a Board Director at Roambee Corporation (supply chain intelligence software) and Silicon Valley Directors Exchange, (a not-for-profit for Board education events). Mr. de Urioste has an undergraduate degree from University of Southern California and an MBA from University of California at Berkeley. Mr. de Urioste is also a Certified Public Accountant (inactive) in the State of California and is a member of the Latino Corporate Directors Association.

We believe that Mr. de Urioste is qualified to serve on our board of directors because of his experience in leadership and management roles in high technology industries, as well as his experience as a board member including Audit Committee Chairman roles.

Marga Ortigas-Wedekind - *Director*
Ms. Marga Ortigas-Wedekind, 62, Board member, has over 30 years of experience in health technology senior management. Ms. Ortigas-Wedekind has been Chief Commercial Strategy Officer of Fogarty Innovation, a non-profit educational incubator for early stage medtech companies since December 2019, Executive Vice President of Marketing and Payer Relations for iRhythm Technologies Inc., a publicly-traded digital healthcare company from July 2015 through July 2019, Executive Vice President, Global Marketing and Product Development of Omnicell Inc., a publicly-traded developer of automated medication dispensing and analytics systems where she led the Marketing, International and Engineering departments from 2009 to 2015, Senior Vice President, Marketing, Development, and Clinical Affairs at Xoft, Inc, a developer of disruptive technology to deliver radiation therapy with capital equipment and high-end disposables from 2002 to December 2008. She started her medtech career at Guidant Vascular, now Abbott Vascular. Ms. Ortigas-Wedekind was on the board of Itamar Medical (NASDAQ: ITMR), which provides digitally-enabled systems for sleep apnea management until its sale to Zoll Medical in December 2021, Total Flow Cannula, an early stage company developing a mechanism to improve safety during on-pump open heart surgery and, the Bay Area Cancer Coalition, a non-profit organization that supports those affected by breast or ovarian cancer. Ms. Ortigas-Wedekind is a limited partner and advisory board member for Launchpad Digital Health, a venture fund focused on digital heath technologies and is also an angel investor with Health Tech Capital. Ms. Ortigas-Wedekind has an undergraduate degree from Wellesley College and an MBA from the Stanford Graduate School of Business.

We believe that Ms. Ortigas-Wedekind is qualified to serve on our board of directors because of her experience in leadership and management roles in the field of medicine, as well as her experience as a member in the healthcare industry.

Willem Elfrink - *Director*
Mr. Willem Elfrink, 71, was Chairman of the Board since our founding and in June 2021 stepped down from this position but remains a Board member. Mr. Elfrink has over 40 years of experience in bringing new technologies to the market. Mr. Elfrink actively contributes to portfolio companies via board participation, strategic marketing, governance and capital structure. Mr. Elfrink is also the Founder and President of WPE Ventures Digitized Solutions, a security and digitization solutions investment firm. Mr. Elfrink joined Cisco in 1997 and was Cisco's Executive Vice President of Industry Solutions and Chief Globalization Officer from 2000 to 2006 and 2007 to 2015 respectively, where Mr. Elfrink made and contributed to key strategic and operational decisions of the Company. Widely recognized as Cisco's Corporate Entrepreneur in residence, his global charter was to identify significant technology opportunities. Mr. Elfrink also led an industry initiative — called the Internet of Things World Forum. Before joining Cisco, Mr. Elfrink held management and senior management positions at Olivetti, Xerox, HP, Digital Equipment Corporation and Philips. Mr. Elfrink earned a Bachelor of Engineering degree from the Institute of Technology in Rotterdam, the Netherlands.

We believe that Mr. Elfrink is qualified to serve on our board of directors because of his experience in leadership and management roles in bringing new technologies to the market, as well as his globalization experience.

Mark Strome - *Director*
Mr. Strome, 66, combines over 40 years of experience in the investment management and securities industry. Mr. Strome is the Founder, Chief Investment Officer, and Chairman at Strome Investment Management, L.P. and Strome Group, Inc. Under his leadership, Mr. Strome's investment management company has managed private placement hedge fund investments focusing on non-traditional investments including commodities, currencies, bankruptcy reorganizations, and numerous venture capital and private equity investments. Previously, he was a Portfolio Manager at Kayne Anderson. Mr. Strome has also been involved in the founding and incubation of numerous publicly traded companies and several successful private companies. These include Pulse Biosciences, and iWood Studios, a company that creates original content for film and TV. Mr. Strome has been a member of the Board of Directors of multiple companies over the last three decades. Mr. Strome has served as a Director at Endurance Ventures, National Water and Power, Eco-Duro Corporation, NWP Services Corporation and Mobil Satellite Ventures. Mr. Strome serves as Member of Advisory Board at Global Analytics, Inc. Mr. Strome is a Trustee for New Roads School and Big Bear Foundation and serves on the Board of Advisors of John Hopkins Medical Center. Mark earned a Bachelor of Science in Engineering from Old Dominion University and Master of Science in Economics from the University of California at Berkeley.

We believe that Mr. Strome is qualified to serve on our board of directors because of his experience in leadership and management roles, as well as his experience as a member in the healthcare industry.

Kenneth Nelson - *Director*
Mr. Nelson, 48, is a 20 year digital health, medical device, and remote patient monitoring executive and innovator. Over the past 10 years, Mr. Nelson has led commercial efforts for disruptive technologies in the digital health, wearables, and cardiac remote patient monitoring industries for 3 of the top 4 market share players in cardiac digital health and remote patient monitoring including BioTelemetry as VP of Sales, iRhythm as VP of Sales & Marketing, and Bardy Diagnostics as Chief Commercial Officer. Most recently, he served as Head of Digital Health, Diagnostics, and Monitoring for Biotronik, a leading cardiac digital health and medical device company. Mr. Nelson currently serves as partner in the Medtech Advantage Fund, which has an exclusive partnership with Medtech Innovator, the largest medtech and digital health startup accelerator globally. In addition, he serves as Chairman of the Board for CardiaCare, and is an active board member in a handful of other disruptive cardiac digital health and medtech startups. Mr. Nelson earned a Bachelor of Arts in Economics from Vanderbilt University and is a graduate of Phillips Exeter Academy.

We believe that Mr. Nelson is qualified to serve on our board of directors because of his experience in leadership and management roles in the field of medicine, as well as his experience as a member in the healthcare industry.

Michael Jaff, MD - *Director*
Dr. Jaff, age 65, is currently Chief Medical Officer and Vice President of Clinical Affairs, Technology and Innovation of the Peripheral Interventions division at Boston Scientific Corporation. Previously, Dr. Jaff was a professor of medicine at Harvard Medical School and served as President of Newton-Wellesley Hospital. Prior to that, Dr. Jaff was the inaugural Paul and Phyllis Fireman Endowed Chair of Vascular Medicine and Medical Director of the Fireman Vascular Center at the Massachusetts General Hospital. Dr. is a recognized expert in all aspects of vascular medicine and is the founder of VasCore, the Vascular Ultrasound Core Laboratory. Dr. Jaff has published over 300 peer-reviewed publications and 10 textbooks and is the Past-President of the Society for Vascular Medicine. Dr. Jaff received a B.S. from Dickinson College, a D.O. from Kirksville College of Osteopathic Medicine, a Business degree from Harvard Business School and an honorary Doctorate of Arts from Harvard Medical School.

We believe that Mr. Jaff is qualified to serve on our board of directors because of his experience in leadership and management roles in the field of medicine, as well as his experience as a member in the healthcare industry.

There are no agreements or understandings for any of our executive officers or directors to resign at the request of another person and no officer or director is acting on behalf of nor will any of them act at the direction of any other person.

Directors are elected to serve until their successors are duly qualified and elected.

Board Diversity

The table below provides information relating to certain voluntary self-identified characteristics of our directors. Each of the categories listed in the table below has the meaning as set forth in NASDAQ Rule 5605(f).

Board Diversity Matrix (As of December 31, 2023)				
Total Number of Directors	8			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	1	7	0	0
Part II: Demographic Background				
African American or Black				
Alaskan Native or Native American				
Asian				
Hispanic or Latinx		1		
Native Hawaiian or Pacific Islander				
White		6		
Two or More Races or Ethnicities	1			
LGBTQ				
Did Not Disclose Demographic Background				

Director Independence

The Board has affirmatively determined that seven of the directors are "independent directors" under NASDAQ Listing Rule 5605(a)(2) and the related rules of the U.S. Securities and Exchange Commission (the "SEC"). In making this determination, our Board considered the current and prior relationships that each non-employee director has with the Company and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. The Company's independent directors conduct executive sessions at regularly scheduled meetings as required by NASDAQ Listing Rule 5605(b)(2).

Family Relationships

There are no family relationships among any of our directors and executive officers.

Board Leadership Structure

The Board does not have an express policy regarding the separation of the roles of Chief Executive Officer ("CEO") and Board Chairman, as the Board believes it is in the best interests of the Company to make that determination based on the position and direction of the Company and the membership of the Board. Currently, Dr. Branislav Vajdic serves as the Company's CEO and Richard Ferrari serves as the Chairman of the Board. The Board believes that its current leadership structure best serves the objectives of the Board's oversight of management; the ability of the Board to carry out its roles and responsibilities on behalf of the stockholders; and the Company's overall corporate governance. The Board also believes that the current separation of the Chairman and CEO roles allows the CEO to focus his time and energy on operating and managing the Company and leverages the experience and perspectives of the Chairman.

Board Oversight of Risk Management

The full Board has responsibility for general oversight of risks facing the Company. The Board is informed by senior management on areas of risk facing the Company and periodically conducts discussions regarding risk assessment and risk management. The Board believes that evaluating how the executive team manages the various risks confronting the Company is one of its most important areas of oversight. While the Board has the ultimate oversight responsibility for the risk management process, various committees of the Board also have responsibility for risk management. For example, the

Audit Committee reviews and assesses the Company's processes to manage financial reporting risk and to manage investment, tax, and other financial risks; the Compensation Committee oversees risks relating to the compensation and incentives provided to our executive officers; and the Nominating and Governance Committee oversees risks associated with our overall compliance and corporate governance practices, as well as the independence and composition of our Board. Finally, management periodically reports to the Board or relevant committee, which provides guidance on risk assessment and mitigation. In December 2023 the Board also formed a Commercialization Committee to support the strategy development and implementation of all defined areas of commercialization.

Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, requires the Company's directors and executive officers, and persons who own more than 10% of a registered class of the Company's equity securities, to file reports of securities ownership and changes in such ownership with the SEC.

Based solely upon a review of such forms filed electronically with the SEC or written representations that no Form 5s were required, the Company believes that all Section 16(a) filing requirements were timely met during the year ended December 31, 2023, except for Mr. George de Urioste submitted one late Form 4 filing in regards to disclosing initial securities.

Code of Ethics

The Company has adopted a code of ethics policy during 2022 for its principal executive officer and senior financial officers and that is applicable to all directors, officers and employees, a copy of which is available online at www.Heartbeam.com. Stockholders may also request a free copy of this document from: HeartBeam, Inc., 2118 Walsh Avenue, Suite 210, Santa Clara, CA 95050, Attn: Corporate Secretary.

Director Meeting Attendance

During the year ended December 31, 2023, the Board held four meetings of the full Board, The Board also took action by written consent on eighteen occasions. During the year ended December 31, 2023, each member of the Board attended at least 75% of the aggregate of all meetings of the Board and the meetings of the committees on which he or she served (during the periods for which he or she served).

The Company does not have a written policy requiring directors to attend the annual meeting.

Board Committees

Our board of directors has established an audit committee, a compensation committee, a nominating and governance committee, and a commercialization committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. The charter of each committee is available on our corporate website at https://ir.heartbeam.com/corporate-governance/governance-documents.

Committee Composition

The following description below outlines our current membership for each committee of our board of directors:

Audit Committee
The Audit Committee, among other things, will be responsible for:

- appointing; approving the compensation of; overseeing the work of; and assessing the independence, qualifications, and performance of the independent auditor;
- reviewing the internal audit function, including its independence, plans, and budget;
- approving, in advance, audit and any permissible non-audit services performed by our independent auditor;
- reviewing our internal controls with the independent auditor, the internal auditor, and management;
- reviewing the adequacy of our accounting and financial controls as reported by the independent auditor, the internal auditor, and management;

- overseeing our financial compliance system; and
- overseeing our major risk exposures regarding the Company's accounting and financial reporting policies, the activities of our internal audit function, and information technology.

The Audit Committee will consist of Mr. de Urioste, Ms. Ortigas-Wedekind and Mr. Ferrari. Mr. de Urioste will chair the Audit Committee. We believe the Audit Committee will comply with the applicable requirements of the rules and regulations of the Nasdaq listing rules and the SEC.

Compensation Committee

The Compensation Committee will be responsible for:

- reviewing and making recommendations to the Board with respect to the compensation of our officers and directors, including the CEO;
- overseeing and administering the Company's executive compensation plans, including equity-based awards;
- negotiating and overseeing employment agreements with officers and directors; and
- overseeing how the Company's compensation policies and practices may affect the Company's risk management practices and/or risk-taking incentives.

The Compensation Committee will consist of Mr. Ferrari, Mr. Elfrink, Mr. Strome and Mr. de Urioste, Mr. Ferrari will serve as chairman of the Compensation Committee. The board of directors has affirmatively determined that each member of the Compensation Committee meets the independence criteria applicable to compensation committee members under SEC rules and Nasdaq listing rules.

Nominating and Governance Committee

The Nominating and Corporate Governance Committee, among other things, will be responsible for:

- reviewing and assessing the development of the executive officers and considering and making recommendations to the Board regarding promotion and succession issues;
- evaluating and reporting to the Board on the performance and effectiveness of the directors, committees and the Board as a whole;
- working with the Board to determine the appropriate and desirable mix of characteristics, skills, expertise and experience, including diversity considerations, for the full Board and each committee;
- annually presenting to the Board a list of individuals recommended to be nominated for election to the Board;
- reviewing, evaluating, and recommending changes to the Company's Corporate Governance Principles and Committee Charters;
- recommending to the Board individuals to be elected to fill vacancies and newly created directorships;
- overseeing the Company's compliance program, including the Code of Conduct; and
- overseeing and evaluating how the Company's corporate governance and legal and regulatory compliance policies and practices, including leadership, structure, and succession planning, may affect the Company's major risk exposures.

The Nominating and Corporate Governance Committee will consist of Ms. Ortigas-Wedekind, Mr. Elfrink and Mr. Nelson. Ms. Ortigas-Wedekind will serve as chairperson. The Company's board of directors has determined that each member of the Nominating and Corporate Governance Committee is independent within the meaning of the independent director guidelines of Nasdaq listing rules.

Commercialization Committee

The Commercialization Committee, among other things, will be responsible for:

- advising on the Company's overall business strategy of bringing products to markets and all aspects of the sales process;
- advising on the Company's product strategy and roadmap;
- advising on the Company's target markets and market segmentation;

- advising on cross-functional elements of the Company's go-to-market effort, including the commercial support functions;
- reviewing, evaluating, and recommending changes to the Company's Commercialization Committee Charter.

The Commercialization Committee will consist of Mr. Elfrink, Dr; Jaff, Mr. Strome and Mr. Nelson. Mr. Elfrink will serve as chairperson.

Stockholder Communications with the Board

The Company's Stockholders who wish to communicate with the Board of Directors or with an individual director may do so by writing to the Corporate Secretary, HeartBeam, Inc., 2118 Walsh Avenue, Suite 210, Santa Clara, CA 95050. The letter should indicate that you are a stockholder and whether you own your shares in street name. Letters received will be reviewed by the Corporate Secretary and retained until the next Board meeting when they will be available to the addressed director. Such communications may receive an initial evaluation to determine, based on the substance and nature of the communication, a suitable process for internal distribution, review and response or other appropriate treatment. There is no assurance that all communications will receive a response.

Hedging, Short Sales and Related Policies

Pursuant to the Company's insider trading policy, the Company prohibits all directors, officers and employees of the Company (collectively, "Team Members"), as well as their spouses, minor children, other persons living in their household and entities over which they exercise control, from engaging in the following transactions involving Company's securities without the advance unanimous written approval from members of the compliance committee designated by the Board:

- **Hedging.** Team Members may not enter into hedging or monetization transactions or similar arrangements with respect to the Company's securities.

- **Short sales**. Team Members may not sell the Company's securities short;

- **Options trading**. Team Members may not buy or sell puts or calls or other derivative securities on the Company's securities; and

- **Trading on margin**. Team Members may not hold the Company's securities in a margin account or pledge the Company's securities as collateral for a loan.

Item 11. Executive Compensation

Summary Compensation Table

The following table sets forth information concerning all cash and non-cash compensation awarded to, earned by or paid to our Named Executive Officers ("NEOs") for services rendered in all capacities during the noted periods. The fiscal years ended December 31, 2023 and December 31, 2022 are indicated below:

Name and Principal Position	Year	Salary ($)	Bonus ($)(1,2)	Stock Awards ($)(3)	Option Awards ($)(3)	All Other Compensation ($)	Total ($)
Branislav Vajdic, PhD [1]	2023	$ 428,000	$ 192,600	$ —	$2,630,143	$ —	$ 3,250,743
Chief Executive Officer [2]	2022	$ 428,000	$ 203,642	$ —	$ 387,720	$ —	$ 1,019,362
Robert Eno[1]	2023	$ 345,000	$ 102,970	$ —	$2,086,639	$ —	$ 2,534,609
President and Chief Business Officer	2022	$ —	$ —	$ —	$ —	$ —	$ —
Kenneth Persen[1]	2023	$ 300,000	$ 78,780	$ —	$1,033,930	$ —	$ 1,412,710
Chief Technology Officer[2]	2022	$ 125,000	$ 32,413	$ —	$ 152,800	$ —	$ 310,213

1. Cash bonuses awarded to the Chief Executive Officer, President and Chief Business Officer, Chief Financial Officer and Chief Technology Officer in 2023 were paid early 2024.

2. In 2022 the Board of Directors ratified the Compensation Committee approval of cash bonuses to its Chief Executive Officer, Chief Financial Officer and Chief Technology Officer based on the Company's achievements of the performance metrics as defined in the bonus plan. The Bonuses were paid in the second quarter of 2023.

3. Represents the full grant date fair value of the stock award or option grant, as applicable, calculated in accordance with FASB ASC Topic 718. Our policy and assumptions made in the valuation of share-based payments are contained in Note 5 to our December 31, 2023 financial statements. The value of stock awards presented in the Summary Compensation Table reflects the grant date fair value of the awards and does not correspond to the actual value that will be recognized by the named executive officers.

Employment Agreements

We have entered into employment agreements, with Branislav Vajdic, the Company's Chief Executive Officer, Robert Eno, the Company's President and Kenneth Persen, the Company's Chief Technology Officer .

Branislav Vajdic Employment Agreement
On September 10, 2021 we entered into an employment agreement with Dr. Vajdic as its Chief Executive Officer and a member of the board of directors ("2021 Vajdic Agreement"), Dr. Vajdic will receive an annual salary of $325,000, commencing on September 15, 2021. During 2022 the Board of Directors approved an amendment to the 2021 Vajdic Agreement, whereby effective January 1, 2022 Dr. Vajdic's annual salary increased to $428,000 and he was awarded 359,000 stock options. The stock option will vest as to 25% on the 1-year anniversary of the vesting commencement date, and the remainder will vest monthly thereafter on the same day of the month as the vesting commencement date until fully vested. During 2023 Dr. Vajdic was awarded a total of 1,194,000 options, these stock options vest as follows: Sixty percent (60%) are milestone based vesting on FDA clearance for marketing of HeartBeam's synthesized 12L product and the remaining forty percent (40%) are time based vesting monthly over 48 months. Pursuant to the amended 2021 Vajdic Agreement, Dr. Vajdic will be eligible to receive an annual bonus up to 60% of his annual compensation, subject to adjustment on an annual basis, based on his performance and overall progress of the Company.

Robert Eno Employment Agreement
On January 18, 2023 we entered into an employment agreement with Mr. Eno as its President, Mr. Eno will receive an annual salary of $360,000, commencing on January 18, 2023 and was awarded 240,000 stock options. The stock option will vest as to 25% on the 1-year anniversary of the vesting commencement date, and the remainder will vest monthly thereafter on the same day of the month as the vesting commencement date until fully vested. Additionally, during 2023 Mr. Eno was awarded a total of 536,000 options, these stock options vest as follows: Sixty percent (60%) are milestone based vesting on FDA clearance for marketing of HeartBeam's synthesized 12L product and the remaining forty percent (40%) are time based vesting monthly over 48 months. Mr. Eno will be eligible to receive an annual bonus up to 40% of his annual compensation, subject to adjustment on an annual basis, based upon his performance and overall progress of the Company.

Kenneth Persen Employment Agreement

On August 2, 2022 we entered into an employment agreement with Mr. Persen as its Chief Technology Officer ("2022 Persen Agreement"), Mr. Persen will receive an annual salary of $300,000, commencing on August 2, 2022 and was awarded 80,000 stock options. The stock option will vest as to 25% on the 1-year anniversary of the vesting commencement date, and the remainder will vest monthly thereafter on the same day of the month as the vesting commencement date until fully vested. During 2023 Mr. Persen was awarded a total of 481,000 options, of these stock options, 421,000 will vest as follows: Sixty percent (60%) are milestone based vesting on FDA clearance for marketing of HeartBeam's synthesized 12L product and the remaining forty percent (40%) are time based vesting monthly over 48 months, and the remaining 60,000 will vest as to 25% on the 1-year anniversary of the vesting commencement date, and the remainder will vest monthly thereafter on the same day of the month as the vesting commencement date until fully vested. Mr. Persen will be eligible to receive an annual bonus up to 30% of his annual compensation, subject to adjustment on an annual basis, based upon his performance and overall progress of the Company. Pursuant to the 2022 Persen Agreement, at the Board of Directors meeting held on August 21, 2023, Mr. Persen's annual eligible bonus was increased to 35% effective January 1, 2023.

2023 Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information with respect to the value of all equity awards that were outstanding at December 31, 2023:

Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Equity: Unearned Shares, Units or Other Rights That Have Not Vested (#)	Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Branislav Vajdic, PhD(1)	26,532	769,468	$ 2.90	08/02/2033	—	$ —
(2)	23,219	374,781	$ 2.08	05/14/2033	—	$ —
(3)	172,019	186,981	$ 1.30	06/14/2032	—	$ —
Robert Eno(4)	11,900	345,100	$ 2.90	08/02/2033	—	$ —
(5)	10,444	168,556	$ 2.08	05/14/2033	—	$ —
(6)	—	240,000	$ 4.47	01/18/2033	—	$ —
(7)	4,699	4,301	$ 4.25	11/12/2031	—	$ —
(8)	36,363	—	$ 0.28	11/01/2030	—	$ —
Kenneth Persen(9)	8,400	243,600	$ 2.90	08/02/2033	—	$ —
(10)	9,856	159,144	$ 2.08	05/14/2033	—	$ —
(11)	—	60,000	$ 2.50	03/21/2033	—	$ —
(12)	26,668	53,332	$ 1.91	09/17/2032	—	$ —

1. Dr. Vajdic was awarded 796,000 options on August 2, 2023, these options are scheduled to vest sixty percent (60%) upon FDA Clearance for marketing of HeartBeam's synthesized 12L product and remainder forty percent (40%) one forty-eighth (1/48th) shall vest on each one-month anniversary of the vesting commencement date.
2. Dr. Vajdic was awarded 398,000 options on May 14, 2023, these options are scheduled to vest sixty percent (60%) upon FDA Clearance for marketing of HeartBeam's synthesized 12L product and remainder forty percent (40%) one forty-eighth (1/48th) shall vest on each one-month anniversary of the vesting commencement date.
3. Dr. Vajdic was awarded 359,000 options on June 15, 2022, these options are scheduled to vest over 4 years with 25% vesting on January 1, 2023 and the remainder vesting and exercisable monthly thereafter.
4. Mr. Eno was awarded 357,000 options on August 2, 2023, these options are scheduled to vest sixty percent (60%) upon FDA Clearance for marketing of HeartBeam's synthesized 12L product and remainder forty percent (40%) one forty-eighth (1/48th) shall vest on each one-month anniversary of the vesting commencement date.

5. Mr. Eno was awarded 179,000 options on May 14, 2023, these options are scheduled to vest sixty percent (60%) upon FDA Clearance for marketing of HeartBeam's synthesized 12L product and remainder forty percent (40%) one forty-eighth (1/48th) shall vest on each one-month anniversary of the vesting commencement date.
6. Mr. Eno was awarded 240,000 options on January 18, 2023, these options are scheduled to vest over 4 years with 25% vesting on January 18, 2024 and the remainder vesting and exercisable monthly thereafter
7. Mr. Eno was awarded 9,000 options on November 12, 2021, these options are scheduled to vest monthly over 4 years from the vesting commencement date.
8. Mr. Eno was awarded 36,363 options on November 1, 2020, these options are scheduled to vest monthly over 4 years from the vesting commencement date.
9. Mr. Persen was awarded 252,000 options on August 2, 2023, these options are scheduled to vest sixty percent (60%) upon FDA Clearance for marketing of HeartBeam's synthesized 12L product and remainder forty percent (40%) one forty-eighth (1/48th) shall vest on each one-month anniversary of the vesting commencement date.
10. Mr. Persen was awarded 169,000 options on May 14, 2023, these options are scheduled to vest sixty percent (60%) upon FDA Clearance for marketing of HeartBeam's synthesized 12L product and remainder forty percent (40%) one forty-eighth (1/48th) shall vest on each one-month anniversary of the vesting commencement date.
11. Mr. Persen was awarded 60,000 options on March 21, 2023, these options are scheduled to vest over 4 years with 25% vesting on January 18, 2024 and the remainder vesting and exercisable monthly thereafter.
12. Mr. Persen was awarded 80,000 options on September 17, 2022, these options are scheduled to vest over 4 years with 25% vesting on January 18, 2024 and the remainder vesting and exercisable monthly thereafter.

Options Exercised and Stock Vested

The following table summarizes, with respect to our named executive officers, all options that were exercised on stock that was vested during fiscal 2023:

Name	Option Awards	
	Number of Shares Acquired on Vesting (#)	Value Realized on Exercise ($)(1)
Branislav Vajdic, PhD	—	$ —
Robert Eno	—	$ —
Kenneth Persen	—	$ —

1. Based on the closing market price of our Common Stock as reported on the NASDAQ Capital Market on December 31, 2023.

DIRECTOR COMPENSATION

Directors who are also employees of the Company do not receive any separate compensation in connection with their Board service, and we pay cash fees to our non-employee directors. Prior to 2022, our non-employee directors received a non-qualified initial stock option award upon joining the Board, which vest monthly over a four-year period, beginning on the date of the director's election to the Board.

On June 15, 2022, the Board of Directors approved a plan for the annual cash compensation of directors effective January 1, 2022:

	Board	Audit Committee	Other Committees
Chair	$ 120,000	$ 25,000	$ 15,000
Member	$ 40,000	$ 10,000	$ 10,000

The following table presents the total compensation for each person who served as a non-employee member of our board of directors and received compensation for such service during the fiscal year ended December 31, 2023. Other than as set forth in the table and described more fully below:

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)	Stock Awards($)(2)(3)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation	Total ($)
Richard Ferrari	$ 138,587	$ —	$ 100,000	$ —	$ —	$ 238,587
George de Urioste	$ 77,500	$ —	$ 75,000	$ —	$ —	$ 152,500
Marga Ortigas-Wedekind	$ 65,000	$ —	$ 75,000	$ —	$ —	$ 140,000
Willem Elfrink	$ 65,639	$ —	$ 75,000	$ —	$ —	$ 140,639
Mark Strome	$ 29,722		$ 75,000	$ —	$ —	$ 104,722
Kenneth Nelson	$ 27,595		$ 75,000	$ —	$ —	$ 102,595
Michael Jaff(3)	$ 18,651		$ 130,000	$ —	$ —	$ 148,651

1. Represents director fees paid for nine months period to each of Messrs Ferrari, de Urioste, Elfrink, Strome, Nelson, Jaff and Mmes Ortigas-Wedekind. Fees for three months ended December 31, 2023 is accrued and paid early 2024.
2. The annual RSU grants to Messrs Ferrari, de Urioste, Elfrink, Strome, Nelson and Mmes Ortigas-Wedekind occur at each Annual Stockholder Meeting, vesting in full at the following annual meeting. The dollars convert to shares based on the FMV at the date of grant.
3. The RSU awarded to Dr. Jaff will vest in equal annual installments over three years on the day following the annual shareholders' meeting in 2024, 2025 and 2026. The dollars convert to shares based on the FMV at the date of grant.

Item 12. Security Ownership of Certain Beneficial Owner and Management and Related Stockholder Matters

The following table sets forth certain information regarding the Company's Common Stock, beneficially owned as of December 31, 2023 by:

- each person known to the Company to beneficially own more than 5% of its Common Stock,
- each executive officer, director and director nominee
- all officers, directors and director nominees as a group.

The Company calculated beneficial ownership according to Rule 13d-3 of the Securities Exchange Act of 1934, as amended as of that date. Shares of the Company's Common Stock issuable upon exercise of options or warrants or conversion of notes that are exercisable or convertible within 60 days after December 31, 2023 are included as beneficially owned by the holder, but not deemed outstanding for computing the percentage of any other stockholder for Percentage of Common Stock Beneficially Owned. For each individual and group included in the table below, percentage ownership is calculated by dividing the number of shares beneficially owned by such person or group by the sum of the 26,329,032 shares of Common Stock outstanding at December 31, 2023, plus the number of shares of Common Stock that such person or group had the right to acquire on or within 60 days after December 31, 2023. Beneficial ownership generally includes voting and dispositive power with respect to securities. Unless otherwise indicated below, the persons and entities named in the table have sole voting and sole dispositive power with respect to all shares beneficially owned.

Name	Shares Beneficially Owned	%
Richard Ferrari[(1)]	291,458	1.10 %
Branislav Vajdic. PhD[(2)]	1,203,019	4.52 %
George A. de Urioste[(3)]	39,671	*
Marga Ortigas-Wedekind[(4)]	119,496	*

Willem Pieter Elfrink[5]	457,658	1.73 %
Mark Strome[6]	3,150,000	11.96 %
Kenneth Nelson[7]	70,001	*
Michael Jaff MD[8]	—	*
Richard Brounstein[9]	207,106	*
Robert Eno [10]	137,714	*
Kenneth Persen[11]	55,274	*
All directors and executive officers as a group (11 persons)	5,731,397	21.05 %
Public Ventures[12] 9454 Wilshire Blvd., Suite 600 Beverly Hills, CA 90212	2,624,910	9.41 %
Andrew Schwartzberg[13] 1135 Rivas Canyon Road Pacific Palisades, CA 90272	1,899,536	7.21 %

* Less than 1 percent ownership

1. Includes (i) 65,653 shares acquired from the conversion of 2015 Convertible Notes. (ii) 73,529 shares acquired from the vesting of RSUs and (iii) 152,276 options exercisable within 60 days after December 31, 2023. Does not include 56,814 unvested stock options and 39,948 unvested RSUs.
2. Includes (i) 794,545 shares acquired as founders equity, (ii) 115,559 shares acquired from the conversion of 2015 Convertible Notes, (iii) 256,628 options exercisable within 60 days after December 31, 2023, (iv) 1,287 shares acquired from the exercise of warrants acquired from the short-term loan investment program and (v) 35,000 BEATW exercisable warrants. Does not include 1,296,373 unvested stock options.
3. Includes (i) 12,168 shares acquired from the vesting of RSUs and (ii) 27,503 options exercisable within 60 days after December 31, 2023. Does not include 16,497 unvested stock options and 23,961 unvested RSUs.
4. Includes (i) 9,000 shares and 9,000 BEATW warrants purchased November 11, 2021, (ii) 7,824 shares acquired from the conversion of 2015 Convertible Notes, (iii) 55,147 shares acquired from the vesting of RSUs and (iv) 38,525 options exercisable within 60 days after December 31, 2023. Does not include 5,110 unvested stock options and 23,961 unvested RSUs.
5. Includes (i) 101,818 shares acquired under the 2015 Incentive Plan (ii) 207,056 shares acquired from the conversion of 2015 Convertible Notes, (iii) 55,147 shares acquired from the vesting of RSUs (iv) 29,997 options exercisable within 60 days after December 31, 2023, (v) 60,000 BEATW exercisable warrants and (vi) 3,640 shares acquired from the exercise of warrants acquired from the short-term loan investment program. Does not include 13,639 unvested stock options and 23,961unvested RSUs.
6. Includes 3,150,000 shares purchased on May 2, 2023. Does not include 23,961 unvested RSUs.
7. Includes 70,001 shares purchased on May 2, 2023. Does not include 23,961 unvested RSUs.
8. No securities held. Does not include 41,935 unvested RSUs.
9. Includes (i) 72,725 shares acquired under the 2015 Incentive Plan, (ii) 5,000 shares and 5,000 BEATW warrants purchased November 11, 2021, (iii) 5,000 shares and 10,000 BEATW warrants acquired on the open market, (iv) 29,197 shares acquired from the conversion of 2015 Convertible Notes, (v) 184 shares acquired from the exercise of warrants acquired from the short-term loan investment program and (vi) 80,000 options which vest within 60 days after December 31, 2023.
10. Includes 55,274 options exercisable within 60 days after December 31, 2023. Does not include 505,726 unvested stock options.
11. Includes 137,714 options exercisable within 60 days after December 31, 2023. Does not include 683,649 unvested stock options.

12. Represents 1,058,633 shares issued pursuant to a subscription agreement of the Company dated May 2, 2023, 1,562,666 shares of Common Stock issuable under a warrant issued by the Issuer and 3,911 shares of Common Stock held by Christopher A. Marlett Living Trust.

13. Represents 1,833,334 shares issued pursuant to a subscription agreement of the Company dated May 2, 2023, 46,600 shares in open market purchases on May 4, 2023, and 19,602 shares in open market purchases on May 25, 2023.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The Company has established policies and other procedures regarding approval of transactions between the Company and any employee, officer, director, and certain of their family members and other related persons. These policies and procedures are generally not in writing but are evidenced by long standing principles adhered to by our Board. The disinterested members of the Board review, approve and ratify transactions that involve "related persons" and potential conflicts of interest. Related persons must disclose to the disinterested members of the Board any potential related person transactions and must disclose all material facts with respect to such transaction. All such transactions will be reviewed by the disinterested members of the Board and, in their discretion, approved or ratified. In determining whether to approve or ratify a related person transaction the disinterested members of the Board will consider the relevant facts and circumstances of the transaction, which may include factors such as the relationship of the related person with the Company, the materiality or significance of the transaction to the Company and the related person, the business purpose and reasonableness of the transaction, whether the transaction is comparable to a transaction that could be available to the Company on an arms-length basis, and the impact of the transaction on the Company's business and operations.

Since the beginning of fiscal year 2023, the Company did not have any transactions to which it has been a participant that involved amounts that exceeded or will exceed the lesser of (i) $120,000 or (ii) one percent of the average of the Company's total assets at year-end for the last two completed fiscal years, and in which any of the Company's directors, executive officers or any other "related person" as defined in Item 404(a) of Regulation S-K had or will have a direct or indirect material interest.

Item 14. Principal Accounting Fees and Services

Based on the Audit Committee's evaluation and determination that Marcum LLP ("Marcum") is independent, our Audit Committee has retained the firm of Marcum as our independent registered public accounting firm for fiscal year 2023. In making this determination, the Company is requesting its stockholders to ratify the appointment of Marcum at its next Annual Stockholder Meeting. In the event the stockholders fail to ratify the appointment, the Audit Committee will consider in its direction to select other auditors for the subsequent year. Even if the selection is ratified, the Audit Committee, in its discretion, may select a new independent registered public accounting firm at any time during the year if it feels that such a change would be in the best interest of the Company and its stockholders. Representatives of Marcum will be present at the 2024 Annual Stockholders' Meeting and will have the opportunity to make a statement and be available to answer questions.

Fees to Independent Registered Public Accounting Firm.

The merger of Marcum and Friedman LLP ("Friedman") was effective as September 1, 2022. The following table sets forth the fees that the Company was billed by Friedman and Marcum in 2022 and Marcum in 2023, our independent registered public accountants for fiscal years 2023 and 2022:

	2023	2022
Audit Fees [1]	$ 142,200	$ 126,000
Audit Related Fees [2]	45,342	12,722
Tax Fees	—	—
Total	$ 187,542	$ 138,722

1. Audit fees relate to professional services rendered in connection with the audit of the Company's annual financial statements, quarterly review of financial statements and audit services provided in connection with other statutory and regulatory filings.

2. Fees related to services provided for registration statements during the first half of 2023 and the fourth quarter of 2022.

Policy on Audit Committee Pre-Approval of Fees

The Audit Committee must pre-approve all services to be performed for us by our independent registered public accounting firm. Pre-approval is granted usually at regularly scheduled meetings of the Audit Committee. If unanticipated items arise between regularly scheduled meetings of the Audit Committee, the Audit Committee has delegated authority to the chairman of the Audit Committee to pre-approve services, in which case the chairman communicates such pre-approval to the full Audit Committee at its next meeting. The Audit Committee also may approve the additional unanticipated services by either convening a special meeting or acting by unanimous written consent.

Part IV

Item 15. Exhibits and Financial Statement Schedules

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed or Furnished Herewith
		Form	Exhibit	Filing Date	
3.1	Articles of Incorporation filed with the State of Delaware on June 11, 2015	S-1	3.1	09/07/2021	
3.2	Bylaws	S-1	3.2	09/07/2021	
3.3	Amendment to Articles of Incorporation filed with the State of Delaware on September 27, 2021	S-1	3.3	09/07/2021	
3.4	Second Amended and Restated Articles of Incorporation dated November 15, 2022	S-1	3.4	02/10/2023	
4.1	Form of Representative's Warrant	S-1/A	4.13	11/09/2021	
4.2	Form of Warrant Agency Agreement	S-1/A	4.14	11/09/2021	
4.3	Form of Placement Agent's Warrant	S-1/A	4.13	04/17/2023	
10.1	Employment Agreement with Branislav Vajdic †	S-1/A	10.1	10/12/2021	
10.2	Employment Agreement with Richard Brounstein †	S-1/A	10.2	10/12/2021	
10.3	Employment Agreement with Jon Hunt †	S-1/A	10.3	10/12/2021	
10.4	Employment Agreement with Alan Baumel †	8-K	10.1	10/12/2021	
10.5	Employment Agreement with Ken Persen †	8-K	10.2	08/08/2022	
10.6	Employment Agreement with Robert Eno †	8-K	10.2	01/24/2023	
10.7	Stock Purchase Agreement, dated February 18, 2022 by and between HeartBeam, Inc. and the Purchaser with the Form of Warrant	8-K	10.1	02/22/2022	
10.8	Form of Professional Services Agreement between Triple Ring and HeartBeam, Inc. dated March 7, 2022	8-K	10.1	03/10/2022	
10.9	Partnership Agreement between HeartBeam, Inc. and LIVMOR, Inc. dated January 31, 2022	8-K	10.1	02/02/2022	
10.10	Supplemental Agreement between HeartBeam, Inc. and LIVMOR, Inc. dated August 2, 2022	8-K	10.1	08/08/2022	
10.11	Sales Agreement by and between HeartBeam, Inc. and A.G.P./ Alliance Global Partners, dated February 1, 2023	8-K	10.1	02/02/2023	
10.12	Securities Purchase Agreement dated February 28, 2023 between HeartBeam Inc. and Investors	8-K	10.1	03/03/2023	
10.13	Note Purchase Agreement dated February 28, 2023 between HeartBeam Inc. and Investors	8-K	10.1	03/03/2023	
10.14	First Amendment to Securities Purchase Agreement dated March 7, 2023 to the Securities Purchase Agreement dated February 28, 2023 between HeartBeam, Inc. and Investors	8-K	10.1	03/09/2023	
10.15	First Amendment to Note Purchase Agreement dated March 7, 2023 to the Note Purchase Agreement dated February 28, 2023 between HeartBeam, Inc. and Investors	8-K	10.2	03/09/2023	
10.16	Form of Subscription Agreement	S-1/A	10.16	04/10/2023	
10.17	Form of Escrow Agreement for the Offering	S-1/A	10.17	04/10/2023	
10.18	Form of Securities Purchase Agreement dated as of May 2, 2023 between HeartBeam, Inc. and Investor	8-K	10.1	05/05/2023	
10.19	2022 Equity Incentive Plan	8-K	10.1	06/16/2022	
10.20	First Amendment to the HeartBeam, Inc. 2022 Equity Incentive Plan	8-K	10.1	07/11/2023	
14.1	Code of Business and Ethics	10-K	14.1	03/16/2023	
23.1	Consent of Marcum LLP Independent Registered Public Accounting Firm				X

24.1	Power of Attorney *	X
31.1	Certification Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 #	X
97.1	HeartBeam, Inc. Compensation Recovery Policy	X
101.INS	XBRL Instance Document+	X
101.SCH	XBRL Taxonomy Extension Schema Document+	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document+	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document+	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document+	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document+	X
104	Cover Page Interactive Data File - The cover page iXBRL tags are embedded within the inline XBRL document.	X

†	Management or compensatory plan or arrangement.
#	This certification is being furnished and shall not be deemed "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.
+	Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

Item 16. Form 10-K Summary

None

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HEARTBEAM, Inc.

By: /s/ Branislav Vajdic
Name: **Branislav Vajdic**
Title: Chief Executive Officer
(Principal Executive and Accounting Officer)

Dated: March 20, 2024

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Branislav Vajdic his attorney-in-fact, with the power of substitution, for him in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Name	Title	Date
/s/ Richard Ferrari **Richard Ferrari**	**Executive Chairman**	March 20, 2024
/s/ George de Urioste **George de Urioste**	**Director**	March 20, 2024
/s/ Marga Ortigas-Wedekind **Marga Ortigas-Wedekind**	**Director**	March 20, 2024
/s/ Willem Elfrink **Willem Elfrink**	**Director**	March 20, 2024
/s/ Mark Strome **Mark Strome**	**Director**	March 20, 2024
/s/ Kenneth Nelson **Kenneth Nelson**	**Director**	March 20, 2024
/s/ Michael Jaff **Michael Jaff**	**Director**	March 20, 2024
/s/ Branislav Vajdic **Branislav Vajdic**	**Chief Executive Officer** (Principal Executive and Accounting Officer)	March 20, 2024

Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
HeartBeam Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of HeartBeam, Inc. (the "Company") as of December 31, 2023 and 2022, the related statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum LLP

We have served as the Company's auditor since 2020
East Hanover, New Jersey
March 20, 2024

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

	December 31, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 16,189	$ 3,594
Prepaid expenses and other current assets	636	445
Total Current Assets	$ 16,825	$ 4,039
Property and equipment, net	256	—
Other assets	50	—
Total Assets	$ 17,131	$ 4,039
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses (includes related party $2 and $2, respectively)	1,194	1,665
Total Liabilities	1,194	1,665
Commitments (Note 7)		
Stockholders' Equity		
Preferred Stock - $0.0001 par value; 10,000,000 shares authorized; 0 shares outstanding at December 31, 2023 and 2022	—	—
Common stock - $0.0001 par value; 100,000,000 shares authorized; 26,329,032 and 8,009,743 shares issued and outstanding at December 31, 2023 and 2022	3	1
Additional paid in capital	52,759	24,559
Accumulated deficit	(36,825)	(22,186)
Total Stockholders' Equity	$ 15,937	$ 2,374
Total Liabilities and Stockholders' Equity	$ 17,131	$ 4,039

See accompanying notes to the financial statements

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

	December 31,	
	2023	**2022**
Operating Expenses:		
General and administrative	$ 8,516	$ 7,354
Research and development	6,798	5,677
Total operating expenses	15,314	13,031
Loss from operations	(15,314)	(13,031)
Other income		
Interest income	675	66
Other income	—	3
Total other income	675	69
Loss before provision for income taxes	(14,639)	(12,962)
Income tax provision	—	—
Net Loss	$ (14,639)	$ (12,962)
Net loss per share, basic and diluted	$ (0.72)	$ (1.59)
Weighted average common shares outstanding, basic and diluted	20,333,280	8,168,516

See accompanying notes to the financial statements

HEARTBEAM, INC.
Statement of Changes in Stockholders' Equity
(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance – December 31, 2021	7,809,912	$ 1	$ 22,633	$ (9,224)	$ 13,410
Stock based compensation expense		—	1,120	—	1,120
Stock issuance upon vesting and exercise of stock options	38,806	—	2	—	2
Stock issuance upon vesting of restricted stock units	25,000	—	—	—	—
Sale of Common Stock & Warrants	136,025	—	804	—	804
Net loss	—	—	—	(12,962)	(12,962)
Balance – December 31, 2022	8,009,743	$ 1	$ 24,559	$ (22,186)	$ 2,374
Stock based compensation expense	—	—	3,208	—	3,208
Sale of Common Stock, net of issuance costs	17,872,955	2	24,762	—	24,764
Stock issuance upon exercise of stock options	180,072	—	214	—	214
Stock issuance upon vesting of restricted stock units	258,970	—	—	—	—
Stock Issuance upon exercise of warrants	7,292	—	16	—	16
Net loss	—	—	—	(14,639)	(14,639)
Balance – December 31, 2023	26,329,032	3	52,759	(36,825)	15,937

See accompanying notes to the financial statements

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

	December 31,	
	2023	**2022**
Cash Flows From Operating Activities		
Net loss	$ (14,639)	$ (12,962)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	3,208	1,120
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(191)	361
Accounts payable, accrued expenses and other current liabilities	(471)	1,533
Net cash used in operating activities	**(12,093)**	**(9,948)**
Cash Flows From Investing Activities		
Purchase of property and equipment	(256)	—
Net cash used in investing activities	**(256)**	**—**
Cash Flows From Financing Activities		
Proceeds from sale of equity, net of issuance costs	24,764	348
Proceeds from exercise of stock options	214	2
Proceeds from exercise of warrants	16	—
Net cash provided by financing activities	**24,994**	**350**
Net increase (decrease) in cash and restricted cash	12,645	(9,598)
Cash, cash equivalents and restricted cash - beginning of the year	**3,594**	**13,192**
Cash, cash equivalents and restricted cash - at end of the year	**$ 16,239**	**$ 3,594**
Supplemental Disclosures of Cash Flow Information:		
Taxes paid	$ —	$ —
Interest paid	—	—
Supplemental Disclosures of Non-cash Flow Information:		
Issuance of common stock and warrants to settle accrued expenses	$ —	$ 456
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 16,189	$ 3,594
Restricted cash (included in other assets)	$ 50	$ —
Total cash, cash equivalents and restricted cash	**$ 16,239**	**$ 3,594**

See accompanying notes to the financial statements

HEARTBEAM, INC.
NOTES TO FINANCIAL STATEMENTS

NOTE 1 – ORGANIZATION AND OPERATIONS

HeartBeam, Inc. ("HeartBeam" or the "Company") is a medical technology company primarily focusing on developing and commercializing higher resolution ambulatory Electrocardiogram ("ECG") solutions that enable the detection and monitoring of cardiac disease outside a healthcare facility setting. The Company's ability to develop higher resolution ECG solutions is achieved through the development of the Company's proprietary and patented Vector Electrocardiography ("VECG") technology platform. HeartBeam's VECG is capable of developing three-dimensional (3D) images of cardiac electrical activity by displaying the spatial locations of ECG waveforms that demonstrated in early studies to deliver equal or superior diagnostic capability than traditional hospital-based ECG systems.

The Company has validated this novel technology and is seeking U.S. Food and Drug Administration ("FDA") clearance of its initial telehealth products during 2024.

The Company was incorporated in 2015 as a Delaware corporation. The Company's operations are based in Santa Clara, California and operates as one segment.

NOTE 2 – GOING CONCERN AND OTHER UNCERTAINTIES

The Company is subject to a number of risks similar to those of early stage companies, including dependence on key individuals and products, the difficulties inherent in the development of a commercial market, the potential need to obtain additional capital, competition from larger companies, other technology companies and other technologies.

The Company has incurred losses each year since inception and has experienced negative cash flows from operations in each year since inception. As of December 31, 2023 and December 31, 2022, the Company had an accumulated deficit of approximately $36.8 million and $22.2 million, respectively. As of December 31, 2023 the Company had approximately $16.2 million cash and cash equivalents.

In February 2023, the Company entered into a sales agreement (the "Sales Agreement") with A.G.P./Alliance Global Partners ("AGP") pursuant to which the Company may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $13.0 million in at-the-market offerings ("ATM") sales. At the same time, the Company filed a prospectus supplement under a shelf registration relating to the Sales Agreement. AGP will act as sales agent and will be paid a 3% commission on each sale under the Sales Agreement. The Company's common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. As of December 31, 2023 there was approximately $11.0 million available for issuance under the ATM.

In February 2023, the Company entered into a securities purchase agreement and a note purchase agreement ("SPA", NPA" or together "Agreements") with Maverick Capital Partners, LLC ("Maverick" or "Investor"). Pursuant to the terms of the Agreements, as amended, the Company agreed to sell up to $4,000,000 of the Company's common stock at 75% of the average calculated Volume Weighted Average Price ("VWAP") per share during a Drawdown Pricing Period as defined in the Agreements.

In February 2023, the Company issued a $500,000 Convertible Note to the Investor pursuant to the NPA. On March 9, 2023 the Convertible Note was settled upon the execution of a SPA and related issuance of 0.2 million shares of common stock pursuant to the SPA drawdown notice dated March 7, 2023. These shares of common stock were registered under the Company's registration statement on Form S-3 dated February 10, 2023 and the related prospectus supplement dated March 9, 2023.

Based on its current business plan assumptions and expected cash burn rate, the Company believes that the existing cash is insufficient to fund operations for the next twelve months following the issuance of these financial statements. These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

The Company's continued operations will depend on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships and revenue. Management can provide no assurance that such

financing or strategic relationships will be available on acceptable terms, or at all, which would likely have a material adverse effect on the Company and its financial statements.

The accompanying financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that may result should the Company be unable to continue as a going concern.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

BASIS OF PRESENTATION

The accompanying audited financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("US GAAP") and in conformity with the instructions on Form 10-K and Rule 8-03 of Regulation S-X and the related rules and regulations of the Securities and Exchange Commission ("SEC") and have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

USE OF ESTIMATES

The preparation of financial statements in conformity with US GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Due to the inherent uncertainty involved in making estimates, actual results reported in future periods may be based on amounts that differ from those estimates. On an ongoing basis, management evaluates its estimate related to probability and timing related to vesting of the stock-based compensation related to probability and timing related to vesting of milestone options

CASH, CASH EQUIVALENTS AND RESTRICTED CASH

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. As of December 31, 2023 the Company has $15.9 million held as cash equivalents and as of December 31, 2022 there were $2.6 million held as cash equivalents. The Company maintains cash balances in accounts which exceed the federally insured limits during the year ended December 31, 2023 and 2022. The Company has made a deposit to the bank for their credit cards in the amount of $50,000 and is classified as restricted cash included in other non-current assets as of December 31, 2023.

PROPERTY AND EQUIPMENT, NET

Property and equipment are stated at cost less accumulated depreciation. Depreciation of property and equipment is calculated using the straight-line method over the estimated useful lives of the assets. The Company regularly evaluates the estimated remaining useful lives of the Company's property and equipment, net, to determine whether events or changes in circumstances warrant a revision to the remaining period of depreciation. Maintenance and repairs are expensed as incurred. As of December 31, 2023, property and equipment, net represents construction-in-progress of $256,000 related to tooling development that has not been placed into service. Construction-in-progress amounts are not subject to depreciation as such assets are not yet available for their intended use.

RESEARCH AND DEVELOPMENT EXPENSE

The Company expenses the cost of research and development as incurred. Research and development expenses consist primarily of professional services costs associated with the development of cardiovascular technologies and products.

FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company's financial instruments consist primarily of cash, accounts payable and accrued liabilities. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset transaction between market participants on the measurement date. Where available, fair value is based on observable market prices or is derived from such prices. The Company uses the market approach

valuation technique to value its investments. The market approach uses prices and other pertinent information generated from market transactions involving identical or comparable assets or liabilities. The types of factors that the Company may consider in fair value pricing the investments include available current market data, including relevant and applicable market quotes.

Financial assets and liabilities carried at fair value are classified and disclosed in one of the following three categories:

- Level 1 - Observable inputs such as quoted prices in active markets.
- Level 2 - Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.
- Level 3 - Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the assignment of an asset or liability within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

ACCOUNTING FOR WARRANTS

The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) gives the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). The Company accounts for its currently issued warrant instruments in conjunction with the Company's common stock in permanent equity. These warrants are indexed to the Company's stock and meet the requirements of equity classification as prescribed under ASC 815. Warrants classified as equity are initially measured at fair value, and subsequent changes in fair value are not recognized so long as the warrants continue to be classified as equity.

STOCK-BASED COMPENSATION

The Company periodically issues stock options and restricted stock awards ("RSUs") to employees and non-employees for services. The Company accounts for such grants issued and vesting to employees and non-employees based on ASC 718, whereby the value of the award is measured on the date of grant and recognized as compensation expense over the vesting period.

The fair value of stock options on the date of grant is calculated using the Black-Scholes option pricing model, based on key assumptions such as the fair value of common stock, expected volatility and expected term. These estimates require the input of subjective assumptions, including (i) the expected stock price volatility, (ii) the calculation of the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. These assumptions are primarily based on historical data, peer company data and the judgment of management regarding future trends and other factors. The Company has estimated the expected term of its employee stock options using the "simplified" method, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data. The risk-free interest rates for periods within the expected term of the option are based on the US Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid and does not expect to pay dividends in the foreseeable future. The Company accounts for forfeitures when they occur. Stock-based compensation expense recognized in the financial statements is reduced by the actual awards forfeited.

Compensation cost for RSUs issued to employees and non-employees is measured using the grant date fair value of the award, and expense is recognized over the service period, adjusted to reflect actual forfeitures.

INCOME TAXES

The Company accounts for income taxes using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and tax carryforwards. Deferred tax assets and liabilities are

measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

A valuation allowance is established to reduce net deferred tax assets to the amount expected to be realized The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being recognized. Changes in recognition and measurement are reflected in the period in which the change in judgment occurs. Interest and penalties related to unrecognized tax benefits are included in income tax expense.

NET LOSS PER COMMON SHARE

Basic net loss per share excludes the effect of dilution and is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding.

Diluted net loss per share is computed by giving effect to all potential shares of common stock, including stock options and warrants to the extent dilutive. Basic net loss per share was the same as diluted net loss per share for the years ended December 31, 2023 and 2022 as the inclusion of all potential common shares outstanding would have an anti-dilutive effect.

As of December 31, 2022, the penny warrants issued during 2019 have been excluded from the net loss per common share calculation following treatment of contingently issuable shares as there are circumstances under which these shares would not be issued and therefore not exercisable. These warrants expired as unissued in February 2023.

In accordance with ASC 260-10-45-13, exercisable penny options are included in the calculation of weighted average basic and diluted earnings per share. As of December 31, 2023, and 2022, 176,674 and 175,958 penny options have been included in the calculation of weighted average basic and diluted earnings per share.
The following is a summary of awards outstanding as of December 31, 2023 and 2022, which are not included in the computation of basic and diluted weighted average shares:

	Year ended December 31,	
	2023	**2022**
Stock options (excluding exercisable penny stock options)	5,915,851	2,020,819
Restricted stock units	217,881	253,970
Warrants	5,152,397	3,908,276
Total	11,286,129	6,183,065

RECENTLY ISSUED ACCOUNTING STANDARDS

Not Yet Adopted as of December 31, 2023:

In November 2023, the Financial Standards Accounting Board (FASB) issued Accounting Standards Update (ASU) 2023-07 "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures" which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for our annual periods beginning January 1, 2024, and for interim periods beginning January 1, 2025, with early adoption permitted. We do not expect that the updated standard will have a rather significant impact on our financial statement disclosures

In December 2023, the FASB issued ASU 2023-09 "Income Taxes (Topics 740): Improvements to Income Tax Disclosures" to expand the disclosure requirements for income taxes, specifically related to the rate reconciliation and income taxes paid. ASU 2023-09 is effective for our annual periods beginning January 1, 2025, with early adoption

permitted. We are currently evaluating the potential effect that the updated standard will have on our financial statement disclosures.

Adopted as of December 31, 2023:

In June 2016, the FASB issued ASU 2016-13 "Financial Instruments-Credit Losses-Measurement of Credit Losses on Financial Instruments". This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance applies to loans, accounts receivable, trade receivables and other financial assets measured at amortized cost, loan commitments, debt securities and beneficial interests in securitized financial assets, but the effect on the Company is projected to be limited to accounts receivable. In May 2019, the FASB issued ASU 2019-05 "Financial Instruments-Credit Losses (Topic 326)" which provides transition relief for companies adopting ASU 2016-13. This guidance amends ASU 2016-13 to allow companies to elect, upon adoption of ASU 2016-13, the fair value option on financial instruments that were previously recorded at amortized cost under certain circumstances. Companies are required to make this election on an instrument by instrument basis. The guidance is effective for the fiscal year beginning January 1, 2023, including interim periods within that year. The Company has adopted this guidance and it had an immaterial impact on Company's accounting.

NOTE 4 – STOCKHOLDERS' EQUITY

On November 14, 2022 the Company held a Special Meeting of Stockholders ("Special Meeting"), wherein the stockholders of the Company approved an amendment to the Company's Certificate of Incorporation ("Certificate of Incorporation") to increase the number of authorized shares of the Company's common stock, par value $0.0001 per share ("Common Stock") to 100,000,000, and to authorize 10,000,000 shares of the Company's preferred stock. The amendment to the Certificate of Incorporation became effective upon filing with, and acceptance for record by, the Secretary of State of Delaware on November 16, 2022.

COMMON STOCK

On January 14, 2022, the Company issued 78,025 shares of Common Stock to a consulting firm for services provided that were related to the IPO. The Company calculated the value of the common stock using closing stock price on November 11, 2022, resulting in a fair value of approximately $365,000. Additionally, the Company was required to issue 72,727 warrants based on performance metrics achieved in 2021, the warrants have an exercise price of $5.50 with an expiration of five years from the date of issuance. The Company calculated the fair value of $1.25 each for these warrants using the Black-Scholes option pricing model on the date the consulting firm achieved the milestone, using the following assumptions: (a) fair value of $2.28 per share, (b) expected volatility of 90.81%, (c) dividend yield of 0%, (d) risk-free interest rate of 0.87%, and (e) expected life of 5 years, resulting in the fair value of approximately $91,000.

On February 18, 2022, the Company entered into a stock purchase agreement ("Stock Purchase Agreement") pursuant to which the Company agreed to issue and sell ("Private Placement") to OpenSky Opportunities Fund Ltd. 58,000 shares of common stock par value $0.0001 and 58,000 warrants to purchase one share of common stock at a combined price of $6.00 per share. The common stock and the warrants were immediately separable and issued separately but were purchased together in the Private Placement. These securities issued pursuant to the Stock Purchase Agreement. The Company received $348,000 in proceeds from the Private Placement. The Warrants will expire five years from the date of issuance. The Company paid no underwriting discounts or commissions.

On May 2, 2023, the Company entered into a Securities Purchase Agreement with an accredited investor, for the purchase and sale in a registered direct offering of 1,000,000 shares of the Company's common stock at a price of $1.50 per share, generating net proceeds from the offering of approximately $1.1 million after deducting financial advisory and legal fees as well as other estimated offering expenses.

On April 20, 2023, the Company entered into a Placement Agency Agreement with Public Ventures, LLC to consummate an offering of 16,666,666 shares of Common Stock at an offering price of $1.50 per share, which closed in accordance with the subscription agreement dated May 2, 2023. The Company received $23.2 million in net proceeds from the offering after deducting placement agent discounts and commission and other estimated offering expenses payable by the Company. In addition, the subscription agreement grants placement agent warrants as part of this transaction. See Warrants section below.

On February 2, 2023, the Company entered into a securities purchase agreement and a note purchase agreement ("SPA", NPA" or together "Agreements") with Maverick Capital Partners, LLC ("Investor"). Pursuant to the terms of the Agreements, as amended, the Company agreed to sell up to $4,000,000 of the Company's common stock at 75% of the average calculated Volume Weighted Average Price per share.

On February 28, 2023, the Company issued a $500,000 Convertible Note to the Investor pursuant to the NPA. On March 9, 2023, the Convertible Note was settled upon the execution of the SPA and related issuance of 200,105 shares of common stock pursuant to the SPA draw down notice dated March 9, 2023. These shares of common stock were registered under the Company's registration statement on Form S-3 dated February 10, 2023 and the related prospectus supplement dated March 9, 2023, whereby, the Company received total proceeds of $500,000. These were the only transactions consummated under the SPA and NPA and the respective agreements expired on May 31 2023.

On February 1, 2023, the Company entered into an At-the-Market Sales Agreement ("ATM" or "Sales Agreement") with A.G.P./ Alliance Global Partners as placement agent, to issue and sell shares of the Company's common stock. The issuance and sale of shares of Common Stock to or through the placement agent are effected pursuant to the Registration Statement dated February 2, 2023. The Company shall pay to the sales agent in cash, upon each sale of placement shares through the placement agent pursuant to the Sales Agreement, an amount equal to 3.00% of the aggregate gross proceeds from each sale of placement shares. In connection to the Sales Agreement, on February 17, 2023 and February 22, 2023, the Company sold 6,184 shares at $3.76 per share for gross proceeds of approximately $23,000. As of December 31, 2023 there was approximately $11.0 million available for issuance under the ATM.

Total stock issuance costs, which consist primarily of legal, accounting and underwriting fees in connection with the above stated transactions related to the offerings and SPA was approximately $174,000, which as of December 31 2023, was recorded in additional paid in capital.

During the years ended December 31, 2023 and 2022 the Company issued 439,042 and 63,806 shares of common stock upon exercise of vested stock options and vesting of restricted stock units.

WARRANTS

During 2019, milestone warrants were issued to certain executives totaling 407,272 warrants ("Penny Warrants"). These warrants were valued on the date of grant at $0.0003 to vest upon meeting certain milestones. These warrants expired unissued in February 2023.

On January 14, 2022, the Company issued 72,727 warrants based on performance metrics achieved in 2021 to purchase 72,727 shares of common stock at an exercise price of $5.50 per share, with an expiration of five years from the date of issuance.

On February 28, 2022, the Company issued 58,000 warrants to purchase 58,000 shares of common stock at an exercise price of $6.00 per share.

On May 2, 2023 the Company issued 1,666,666 placement agent warrants to purchase shares of Common Stock sold in the offering, with an exercise price of $1.875 per share and are exercisable for five years from the date of issuance.

During the year ended December 31, 2023, 11,638 warrants were exercised, of which 5,817 were exercised in the form of a cashless exercise utilizing 4,346 warrants which resulted in the net issuance of 1,471 common shares. The remaining 5,821 warrants were exercised for cash for approximately $16,000.

A summary of the outstanding warrants as of December 31, 2023 and 2022 is as follows:

	Number of shares	Weighted average exercise price	Weighted average remaining life (years)	Aggregate intrinsic value (in thousands)
Outstanding and exercisable - December 31, 2021	3,777,549	$ 5.42	4.45	$ 1,259
Exercised	—	—	—	—
Issued	130,727	$ 5.72	—	—
Outstanding - December 31, 2022	3,908,276	$ 5.42	3.47	$ 2,020
Issued	1,666,666	1.88	—	—
Exercised	(11,638)	2.75	—	—
Expired	(410,907)	—	—	—
Outstanding and exercisable - December 31, 2023	5,152,397	$ 4.71	3.35	$ 792

NOTE 5 – STOCK-BASED COMPENSATION

In 2015, the Company's Board of Directors approved the HeartBeam, Inc. 2015 Equity Incentive Plan ("2015 Plan"), to attract and retain the best available personnel for positions of substantial responsibility, to provide additional incentive to employees, directors, and consultants, and to promote the success of the Company's business. The 2015 Plan provides for the grant of stock options and RSU's to purchase common stock of which 1,636,362 were authorized by the board of which 970,704 are outstanding as of December 31, 2023. The 2015 Plan was terminated upon shareholder approval of the 2022 Equity Incentive Plan ("2022 Equity Plan") whereby no new awards can be issued under the 2015 Plan.

The Company's shareholders approved the 2022 Equity Plan at the annual meeting of stockholders held on June 15, 2022, pursuant to which 1,900,000 shares of common stock were authorized for issuance. Under the 2022 Equity Plan, the number of shares available for issuance will be increased on the first day of each fiscal year beginning with the 2023 fiscal year, in an amount equal to the lesser of 3,800,000 shares, five percent (5%) of the total number of shares of all classes of common stock of the Company outstanding on the last day of the immediately preceding fiscal year, and a lesser number of shares determined by the administrator. On January 1, 2023 400,487 shares, equivalent to five percent (5%) of common stock outstanding were added to the shares available for issuance under the 2022 Equity Plan. Also see Note 9- Subsequent event section below.

At the July 7, 2023, Annual Shareholders' Meeting, the proposal to amend the 2022 Equity Incentive Plan to increase the number of authorized shares from 1,900,000 shares to 5,900,000 shares was approved.

The 2022 Equity Plan includes a provision to add-back any cancelled options from the 2015 Plan up to 1,372,816 shares. As of December 31, 2023, there are 252,856 shares from the 2015 Plan that are included in the 849,171 shares available for issuance under the 2022 Equity Plan.

During 2023, the Company granted 2,208,000 options to various executives and employees. Sixty percent (60%) of these options vest based on FDA Clearance for marketing of HeartBeam's synthesized 12L product and the remaining forty percent (40%) vest monthly over a period of 48 months. The Company calculated the fair value for each of these grants using the Black-Scholes option pricing model and it is expensed based on management's probability assessment of FDA clearance. The 60% milestone options are issued and outstanding as of December 31, 2023.

The Company received proceeds of $0.2 million from the exercise of stock options during the year ended December 31, 2023 and a de minimis amount during the year ended December 31, 2022.

STOCK OPTIONS

The following is a summary of stock option activity during the years ended December 31, 2023 and 2022:

	Number of options outstanding	Weighted average exercise price	Average remaining contractual life (in years)	Aggregate intrinsic value (in thousands) (*)
Outstanding – December 31, 2021	1,105,938	$ 2.03	8.8	$ 1,535
Options granted	1,251,000	1.70		
Forfeitures	(121,334)	2.98		
Options exercised	(38,806)	—		
Outstanding – December 31, 2022	2,196,798	$ 1.76	8.7	$ 6,770
Options granted	4,363,800	2.42		
Forfeitures	(288,001)	2.48		
Options exercised	(180,072)	1.19		
Outstanding – December 31, 2023	6,092,525	2.22	8.7	$ 2,945
Exercisable – December 31, 2023	1,212,312	$ 1.78	7.4	$ 1,203

(*) Intrinsic value is based on the fair market value of the Company's common stock.

The Company estimates the fair values of stock options using the Black-Scholes option-pricing model on the date of grant. For the years ended December 31, 2023 and 2022, the assumptions used in the Black-Scholes option pricing model, which was used to estimate the grant date fair value per option, were as follows:

	Year ended December 31,	
	2023	2022
Weighted-average Black-Scholes option pricing model assumptions:		
Volatility	110.23% - 117.62%	107.25% - 111.06%
Expected term (in years)	5.85 - 6.07	5.62 - 5.94
Risk-free rate	3.54% - 4.77%	1.47% - 3.17%
Expected dividend yield	$ —	$ —
Weighted average grant date fair value per share	$1.75 - 3.38	$1.08 - 3.34

RESTRICTED STOCK UNITS

The following is a summary of RSUs award activity:

	Year ended December 31,			
	2023		2022	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at beginning of the year	253,970	$ 1.47	30,000	$ 3.20
Shares granted	222,881	3.11	248,970	1.36
Shares vested	(258,970)	1.48	(25,000)	2.46
Non-vested at end of year	217,881	$ 3.12	253,970	$ 1.47

STOCK BASED COMPENSATION

The following is a summary of stock-based compensation expense:

	Year ended December 31,	
	2023	2022
General and administration		
Stock options	$ 2,069,556	$ 657,368
RSUs	488,971	235,035
Total general and administration	2,558,527	892,403
R&D		
Stock options	629,092	213,813
RSUs	20,457	13,601
Total R&D	649,549	227,414
Total stock based compensation	$ 3,208,076	$ 1,119,817

As of December 31, 2023 total compensation cost not yet recognized related to unvested stock options and unvested RSUs was approximately $8.1 million and $0.4 million, respectively, which is expected to be recognized over a weighted-average period of 2.66 years and 1.2 years, respectively.

NOTE 6 – RELATED PARTY TRANSACTIONS

During the course of business, the Company obtains accounting services from CTRLCFO, a firm in which the Company's former Chief Financial Officer has significant influence. The Company incurred accounting fees from these firms of approximately $20,000 and $21,000 during the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, the Company had balances due to these firms amounting to approximately $2,000.

NOTE 7 – COMMITMENTS

Lease Obligations

In May 2019, the Company entered into a month to month lease agreement for our headquarters. The agreement is for an undefined term and can be cancelled at any time, given one month's notice by either party. The Company's monthly rent expense associated with this agreement is approximately $1,440. The Company's month to month headquarters lease is in the name of the Company's Chief Executive Officer, and the cost is reimbursed monthly.

For the years ended December 31, 2023 and 2022, rent expense was approximately $17,000, for each year.

Partnership Agreement

In January 2022, the Company entered into a partnership agreement with LIVMOR Inc. ("LIVMOR") to build a Company-branded version of the LIVMOR's Halo+ FDA cleared turnkey solution for RPM to connect physicians and patients. As included in the agreement, the Company and LIVMOR have the right to enter into additional agreements as needed in order to further the Company's development of its products. The agreement with LIVMOR included a commitment in 2022 of $1.0 million.

In August 2022, the Company entered into a supplemental agreement with LIVMOR. The supplemental agreement stated the Company would pay an additional $0.2 million for the source code access under the partnership agreement. Payments totaling $0.2 million have been made by the Company and LIVMOR has delivered to the Company copies of source materials and codes. All licenses granted by LIVMOR will automatically be converted into a non-exclusive and perpetual license and become licenses granted on a royalty-free and fully paid-up basis, in which LIVMOR hereby expressly waives and relinquishes all HeartBeam payment obligations under the initial partnership agreement. Based on management's review of Topic ASC 805 and 730, it was determined that only the source code and perpetual license were purchased and it was determined there was no alternative future uses, therefore management recorded the expense as research and development expense.

As of December 31, 2022, the Company expensed a total of $1.2 million associated with the LIVMOR agreements, which has been recognized as R&D expense. In February 2023, the Company acquired LIVMOR's Halo+™ Atrial Fibrillation Detection System, the world's first FDA-cleared (K201208) prescription wearable for continuous cardiac rhythm monitoring, comprising of intellectual property, including 3 issued United States patents.

Professional Services Agreement

In March 2022, the Company entered into a professional services agreement with Triple Ring Technologies, Inc. ("TRT"), a co-development company, to assist in the design and development of the Company's telehealth complete solution 3D vector ECG collection device for remote heart attack or MI monitoring. This agreement was followed by several amendments. The agreement with Triple Ring includes a commitment totaling $1.7 million.

As of December 31, 2023 the Company has a remaining commitment of $0.4 million.

NOTE 8 - INCOME TAX

Income tax expense attributable to pretax loss from continuing operations differed from the amounts computed by applying the U.S. federal income tax rate of 21% to pretax loss from continuing operations as a result of the following:

	For the Years ended December 31,			
	2023		2022	
Computed "expected" tax benefit	(3,074,000)	21.00 %	(2,722,000)	21.00 %
Increase (reduction) in income taxes resulting from):				
State tax, net of federal benefit	—	— %	(1,024,900)	7.95 %
Permanent items	(80,500)	0.55 %	—	— %
Stock-based compensation	221,200	(1.51)%		
Research and development credits	(241,800)	1.65 %	(224,100)	1.70 %
Other	130,600	(0.89)%	(2,000)	— %
Change in valuation allowance	3,044,500	(20.80)%	3,973,000	(30.65)%
Total	—	— %	—	— %

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities are presented below as of December 31:

	2023	2022
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 5,799,000	$ 4,115,800
Research and development credits	619,000	377,200
Stock based compensation	647,000	349,900
Sec. 174	2,027,200	1,032,700
Other	—	172,100
Total deferred tax assets	9,092,200	6,047,700
Valuation Allowance	(9,092,200)	(6,047,700)
Net Deferred Tax Assets	—	—

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately $3,044,500 for the period ended December 31, 2023.

As of December 31, 2023, the Company had federal and state net operating loss ("NOL") carryforwards of approximately $21,496,500 and $18,394,200, respectively. The federal NOL carryforwards consist of $2,405,400 generated prior to 2018 which will begin to expire in 2035, however, are able to offset 100% of taxable income and $19,091,000 generated after December 31, 2017 that will carryforward indefinitely but will be subject to 80% taxable income limitation beginning tax years after December 31, 2021 as provided by the Coronavirus Aid, Relief, and Economic Security ("CARES") Act (PL 116-136).

The Company has federal R&D credit carryforwards of approximately $617,000 which will begin to expire in 2041 and state R&D credit carryforwards of approximately $338,400 which do not expire.

The utilization of NOLs and tax credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code ("IRC") a corporation that undergoes an ownership change may be subject to limitations on its

ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. The Company has not completed a formal study to determine if any ownership changes within the meaning of IRC Section 382 and 383 have occurred. If an ownership change has occurred, the Company's ability to use its NOLs or tax credit carryforwards may be restricted, which could require the Company to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

Effective for tax years beginning after December 31, 2021, taxpayers are required to capitalize any expenses incurred that are considered incidental to research and experimentation ("R&E") activities under IRC Section 174. While taxpayers historically had the option of deducting these expenses under IRC Section 174, the December 2017 Tax Cuts and Jobs Act mandates capitalization and amortization of R&E expenses for tax years beginning after December 31, 2021. Expenses incurred in connection with R&E activities in the US must be amortized over a 5-year period if incurred, and R&E expenses incurred outside the US must be amortized over a 15-year period. R&E activities are broader in scope than qualified research activities considered under IRC Section 41 (relating to the research tax credit). For the years ended December 31, 2023 and December 31, 2022, the Company performed an analysis based on available guidance and determined that it will continue to be in a loss position even after the required capitalization and amortization of its R&E expenses. The Company will continue to monitor this issue for future developments, but it does not expect R&E capitalization and amortization to require it to pay cash taxes now or in the near future.

The total amount of unrecognized tax benefits as of December 31, 2023 is approximately $286,600, which relates to federal and state R&D credits. If recognized none of the unrecognized tax benefits would affect the effective tax rate.

The Company's policy is to account for interest and penalties as income tax expense. As of the December 31, 2023 the Company had no interest related to unrecognized tax benefits. No amounts of penalties related to unrecognized tax benefits were recognized in the provision for income taxes. We do not anticipate any significant change within twelve months of this reporting date.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions, with varying statutes of limitations. The tax years from inception through 2023 remain open to examination due to the carryover of unused net operating losses that are being carried forward for tax purposes.

In August 2022, the U.S. Inflation Reduction Act of 2022 and the CHIPS and Science Act of 2022 were signed into law. These acts include, among other provisions, a corporate alternative minimum tax of 15%, an excise tax on the repurchase of corporate stock, various climate and energy provisions, and incentives for investment in semiconductor manufacturing. These provisions are not expected to have a material impact on the Company's results of operations or financial position.

NOTE 9 - SUBSEQUENT EVENTS

1. Under the 2022 Equity Plan, the number of shares available for issuance are increased on the first day of each fiscal year beginning with the 2023 fiscal year, in an amount equal to the lesser of 3,800,000 shares, five percent (5%) of the total number of shares of all classes of common stock of the Company outstanding on the last day of the immediately preceding fiscal year, and a lesser number of shares determined by the administrator. On January 1, 2024, 1,316,452 shares, equivalent to five percent (5%) of common stock outstanding were added to the shares available for issuance under the 2022 Equity Plan.

2. On March 8, 2024, the Company has entered into an agreement with Clinical Research Organization (CRO) to perform certain services related to project set up, clinical trial management and monitoring during next six months. As per terms of the agreement, the Company will pay CRO approximately $0.5 million for these services. Additionally, the Company has signed a Clinical Study Agreement with first of five planned sites to carry out the clinical study for which CRO will act as Company sponsor in relation to payment for these services. The total cost of the clinical trial including the CRO cost is expected to approximate $0.7 million.