Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

☒

For the fiscal year ended April 30 , 2024

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 001-41422

HEART TEST LABORATORIES, INC.
(Exact name of Registrant as specified in its Charter)

TEXAS	**26-1344466**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
550 Reserve Street , Suite 360	
Southlake , Texas	**76092**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (682)- 237-7781

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	HSCS	The Nasdaq Stock Market LLC
Warrants	HSCSW	The Nasdaq Stock Market LLC

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 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	☐

☒ Smaller reporting company

Non-accelerated filer

☒

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 Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter ended October 31, 2023, was approximately $

21.1

million, based on the closing price of $24.90. The stock price and the number of shares at October 31, 2023 takes into account a 1-for-100 reverse stock split which became effective on May 17, 2024 (the "Reverse Stock Split"). For the sole purpose of making this calculation, the term "non-affiliate" has been interpreted to exclude directors, executive officers, affiliated holders of 10% or more of the registrant's common stock and their affiliates.

At July 26, 2024, the registrant had

855,966

shares of Common Stock, par value $0.001 per share, issued and outstanding post the Reverse Stock Split.

DOCUMENTS INCORPORATED BY REFERENCE - NONE

HEART TEST LABORATORIES, 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"). Some of the statements made under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and elsewhere in this Annual Report on Form 10-K constitute forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "aims," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "intends," or "continue," or the negative of these terms or other comparable terminology.

These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, statements that contain projections of results of operations or of financial condition, expected capital needs and expenses, statements relating to the research, development, completion and use of our device, and all statements (other than statements of historical facts) that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things:

- our expectation regarding the sufficiency of our existing cash and cash equivalents to fund our current operations;
- our ability to receive regulatory clearance for the MyoVista *wav*ECG or the MyoVista Insights cloud platform and associated AI-ECG algorithms from the U.S. Food and Drug Administration (the "FDA"), state regulators, if any, or other similar foreign regulatory agencies, including approval to conduct clinical trials, the timing and scope of those trials and the prospects for regulatory approval or clearance of, or other regulatory action with respect to the our current products or other future potential products;
- our ability to further advance the development of the MyoVista *wav*ECG, our 12-lead electrocardiograph ("ECG") device that also incorporates an additional proprietary AI-ECG algorithm that we have been designing to detect cardiac dysfunction, as well as future potential products;
- our ability to develop a cloud-based hardware agnostic platform and to develop and incorporate AI-ECG algorithms on that platform;
- our ability to launch sales of the MyoVista *wav*ECG device, MyoVista Insights cloud platform and AI-ECG algorithms or any future potential products into the U.S.;
- our assessment of the potential of the MyoVista *wav*ECG device, MyoVista Insights cloud platform and AI-ECG algorithms and any future potential products;
- our planned level of capital expenditures and liquidity;
- our plans to continue to invest in research and development to develop technology for new products;
- our failure to maintain the continued listing requirements of Nasdaq (as defined below) could result in a de-listing of our shares and penny stock trading;
- the regulatory environment and changes in the health policies and regimes in the countries in which we intend to operate, including the impact of any changes in regulation and legislation that could affect the medical device industry;
- our ability to meet our expectations regarding the commercial supply of our current products and any future products;

- our ability to retain key executives;
- our ability to internally develop new inventions and intellectual property;
- the overall global economic environment;
- the ultimate impact of the COVID-19 pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare system or the global economy as a whole;
- the impact of competition and new technologies;
- general market, political and economic conditions in the countries in which we operate;
- our ability to develop new product offerings and intellectual property;
- changes in our strategy; and
- potential litigation.

These statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. You should not rely upon forward-looking statements as predictions of future events.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this Annual Report on Form 10-K.

The Company will continue to file annual, quarterly and current reports, proxy statements and other information with 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, "HeartSciences," the "Company," "we," "us" and "our" refer to Heart Test Laboratories, Inc. References to "Fiscal 2025" refer to the 12-months ending April 30, 2025, references to "Fiscal 2024" refer to the 12-months ended April 30, 2024, and references to "Fiscal 2023" refer to the 12-months ended April 30, 2023. References to our "IPO" refer to the initial public offering of Heart Test Laboratories, Inc. which closed on June 17, 2022.

Unless defined elsewhere, capitalized terms used in this Annual Report on Form 10-K are defined in the "Glossary of Terms" appearing directly before Part III.

REVERSE STOCK SPLIT

Effective May 17, 2024, the Company effected a 1-for-100 reverse stock split of its issued and outstanding shares of Common Stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, every 100 shares of the Company's issued and outstanding pre-reverse split shares of common stock, par value $0.001 per share (the "Common Stock"), were combined into one share of Common Stock, except to the extent that the Reverse Stock Split resulted in any of the Company's shareholders owning a fractional share, which was rounded up to the next highest whole share. In connection with the Reverse Stock Split, there was no change in the par value per share of $0.001. As a result of the Reverse Stock Split, equitable adjustments corresponding to the Reverse Stock Split ratio were made to the

Company’s outstanding warrants and its other convertible instruments and upon the exercise or vesting of all stock options such that every 100 shares of Common Stock that may be issued upon the exercise of the Company's warrants and stock options and conversion of its other convertible instruments held immediately prior to the Reverse Stock Split represent one share of Common Stock that may be issued upon exercise of such warrants and stock options and conversion of the other convertible instruments immediately following the Reverse Stock Split. Correspondingly, the exercise price per share of Common Stock attributable to the Company's warrants and stock options and the conversion price of its other convertible instruments immediately prior to the Reverse Stock Split was proportionately increased by a multiple of 100 following the Reverse Stock Split.

All Common Stock share and per share data, and exercise price data for applicable Common Stock equivalents, included in these financial statements have been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated.

Table of Contents

PART I

Item 1. Business.

Company Overview

We are a medical technology company focused on applying innovative AI-based technology to an ECG, also known as an "EKG," to expand and improve an ECG's clinical usefulness. Our objective is to make an ECG a far more valuable cardiac screening tool by expanding its clinical capability to detect a broader range of heart disease conditions through the development of AI-based ECG algorithms ("AI-ECG"). We are seeking to provide AI-ECG solutions in any care setting worldwide in a manner that best suits different providers, either via our cloud-based application that can receive an upload from one of the millions of ECG devices currently in clinical use or via our proprietary MyoVista *wav*ECG device. The MyoVista *wav*ECG, is a resting 12-lead ECG that will incorporate HeartSciences' proprietary AI-ECG algorithm designed to provide diagnostic information related to cardiac dysfunction as well as conventional ECG information in the same test. We are also developing a cloud-based platform to host AI-ECG algorithms, both developed by us internally or by third-parties, on an ECG hardware agnostic basis (the "MyoVista Insights Cloud Platform"). In the future, we intend to deliver a range of AI-ECG algorithms, via each product. Neither the MyoVista *wav*ECG, MyoVista Insights Cloud Platform nor any of our AI-ECG algorithms are yet cleared for marketing by the FDA.

The AI-ECG algorithms are intended to provide diagnostic information which has traditionally required cardiac imaging. We believe, the combination of a device agnostic cloud platform and MyoVista *wav*ECG device would allow us to offer AI-ECG solutions across a wide range of healthcare settings from large heath systems to frontline or point of care environments such as primary care. The initial revenue model for the MyoVista *wav*ECG device, which involves the use of the MyoVista hardware, associated software and consumables for each test, is expected to be "razor-razorblade" as the cable connection to the electrodes used with the MyoVista *wav*ECG are proprietary to HeartSciences, and new electrodes are used for every test performed. As further algorithms are made commercially available via the MyoVista *wav*ECG or the MyoVista Insights Cloud Platform, we would expect to adopt revenue models based on algorithm usage and/or recurring subscriptions. Our MyoVista Insights Cloud Platform is being designed to fit simply into existing clinical workflows and be available to host third party AI-ECG algorithms, which increases its clinical value and our speed to market as well as reducing research and development ("R&D") costs associated with internal algorithm development.

On September 20, 2023, we entered into multiple definitive license agreements (each a "License Agreement" and collectively, the "License Agreements") with Icahn School of Medicine at Mount Sinai ("Mount Sinai") to commercialize a range of AI-ECG algorithms covering a range of cardiovascular conditions developed by Mount Sinai as well as a memorandum of understanding for ongoing cooperation encompassing de-identified data access, on-going research, and the evaluation of the MyoVista *wav*ECG device.

Our future success is dependent upon receiving FDA clearances for our products and additional funding may be required as part of achieving FDA clearance and thereafter would be required to support the sales launch, provide working capital and support further R&D.

We believe that there is currently no low-cost, front-line, medical device that is effective at screening broadly for many types of heart disease. As a result, we believe that frontline physicians face a significant challenge in determining if a patient has heart disease. Although many think of the ECG as the frontline test for heart disease, in 2012, the United States Preventive Services Task Force conducted an evaluation of conventional ECG testing and stated: "There is no good evidence the test, called an ECG, helps doctors predict heart risks any better than traditional considerations such as smoking, blood pressure and cholesterol levels in people with no symptoms."

ECG devices record the electrical signals of a patient's heart. The ECG is a ubiquitous, relatively low-cost, simple and quick test; it is portable and can be performed in a wide range of clinical settings by a non-specialist clinician or clinical aide. There are three basic categories of heart disease: electrical (such as an arrhythmia), structural (such as valvular disease) and ischemic (such as coronary artery disease, or CAD). Conventional resting ECGs have limited sensitivity in detecting structural and ischemic disease and are typically used for diagnosing cardiac rhythm abnormalities, such as atrial fibrillation, or acute coronary syndrome, such as a myocardial infarction which

is also known as a heart attack. However, traditional ECGs have a limited role in identifying cardiac dysfunction associated with structural and ischemic disease.

HeartSciences has designed or licensed algorithms designed to help address these limitations and extend the clinical capability of an ECG to detect cardiac dysfunction and other heart disease types.

Our first AI-ECG algorithm to be incorporated into the MyoVista *wav*ECG device has been designed by the Company and applies AI-machine learning to the signal processed ECG signal to develop a proprietary algorithm designed to detect impaired cardiac relaxation, or cardiac dysfunction, caused by heart disease and/or age-related cardiac dysfunction. We have been adjusting the algorithm to reflect updated echo measurement thresholds in respect of ≥60 year old patients. The change was made, and agreed with the FDA, to reflect recent clinical findings which we believe will further increase the clinical value of this algorithm.

We expect the first AI-ECG algorithm to be submitted as part of the MyoVista Insights Cloud Platform will be for the detection of low ejection fraction, or systolic dysfunction, based on one of the licensed algorithms from Mount Sinai.

The editorial comment associated with the study titled “Prediction of Abnormal Myocardial Relaxation from Signal Processed Surface ECG” presented below discusses recent applications of machine learning to data derived from surface 12-lead ECGs in relation to cardiac dysfunction:

> “These represent some of the most significant advances in electrocardiography since its inception, which has historically had a limited, if any, role in the evaluation of cardiac dysfunction. In the past, our cardiovascular community was resigned to the fact that surface ECGs are poor indicators for cardiac dysfunction.”
>
> Khurram Nasir, MD, MPH, MSC, Department of Cardiology, Houston Methodist DeBakey Heart & Vascular Center, Houston, Texas, et. al., *Journal of American College of Cardiology Editorial Comment Volume 76 Number 8 2020.*

Almost all forms of heart disease, including CAD and structural disease, affect heart muscle, or cardiac function prior to symptoms. Impaired cardiac function is first observed as impaired cardiac relaxation which is an early indicator of diastolic dysfunction and usually continues to increase in severity as heart disease progresses. The diastolic phase of the cardiac cycle occurs when the heart muscle relaxes (following contraction). Diastolic dysfunction may also be related to age-related cardiac dysfunction. Low ejection fraction, or systolic dysfunction, is a later stage of cardiac dysfunction and occurs when the heart pumps a reduced level of blood from the ventricles during contraction.

If we receive FDA clearances for our product candidates, our main target markets would be frontline healthcare environments in the U.S., to assist physician decision making in the cardiology referral process. Currently, cardiology referral decisions are often based on a patient’s risk factors and/or a conventional ECG test. Accordingly, many patients with heart disease are left undetected while no current treatment or intervention is required for most patients referred for cardiac imaging. We believe that adding the capability to detect a broader range of cardiac conditions to the standard 12-lead resting ECG could help improve cardiac referral pathways and be valuable for patients, physicians, health systems and third-party payors.

New Class II devices, such as our products, require FDA premarket review. The MyoVista *wav*ECG device along with its proprietary software and hardware is classified as a Class II medical device by the FDA. Premarket review and clearance by the FDA for these devices is generally accomplished through the 510(k) premarket notification process or De Novo classification request, or petition process. We previously submitted an FDA De Novo classification request in December 2019 and, following feedback and communications with the FDA during and since that submission, we have been making modifications to our device, including our proprietary algorithm. We have finished the patient recruitment and core lab work for our FDA validation study and have been undertaking device and algorithm development testing for a revised FDA submission. We had been planning a revised submission under the De Novo pathway, however, in December 2023 the FDA confirmed that we could submit the MyoVista *wav*ECG device for clearance under the 510(k) pathway following the grant by the FDA in August 2023 of an industry-first De Novo clearance which created a new Class II product code for cardiovascular machine learning-based notification

software. This was in respect of a hypertrophic cardiomyopathy algorithm and in late September 2023, the FDA cleared an algorithm for low ejection fraction (less than 40%) under the 510(k) pathway using this new product code. Accordingly, we are now preparing for a 510(k) FDA submission and are aiming for a submission in the first calendar quarter of 2025. If successful, FDA clearance would provide us the ability to market and sell the MyoVista *wav*ECG device in the U.S. and additional funding would be required to support the sales launch of the MyoVista *wav*ECG device in the U.S., provide working capital and support further R&D.

To date we have not yet entered into a discussion with the FDA regarding the MyoVista Insights Cloud Platform or Mount Sinai licensed AI-ECG algorithms but are aiming to start that process in the current calendar year. We expect these products to fall under the 510(k) pathway and are aiming for an FDA submission of our MyoVista Insights Cloud Platform and low ejection fraction algorithm in the middle of 2025.

Heart Disease Facts and Current ECG Testing Limitations

Heart disease refers to a variety of conditions that affect the heart — including heart rhythm problems, heart valve problems, genetic defects and blood-vessel diseases such as CAD. It is often referred to as the “silent killer.” According to the American Heart Association, one in three patients are not properly diagnosed until after a heart attack occurs and 50% of men and 64% of women who died suddenly of coronary heart disease showed no previous symptoms. Statistics published by the U.S. Centers for Disease Control and Prevention (the “CDC”), show that in the United States, heart disease is the leading cause of death for both men and women, across most racial and ethnic groups. According to the CDC, in the United States, one person dies from cardiovascular disease every 34 seconds. In 2020, about 20.1 million adults aged 20 and older in the United States have CAD (about 7.2%), with approximately one in five heart attacks being a silent heart attack therefore the person is not even aware of it, but the damage is done. Approximately 695,000 people in the U.S. died from heart disease in 2021: that’s one in every five deaths. The scale of the problem is similar worldwide. In 2020, the World Health Organization confirmed that heart disease has remained the leading cause of death at the global level for the last 20 years. Cardiovascular diseases are the leading cause of death globally. An estimated 17.9 million people died from cardiovascular diseases in 2019, representing 32% of all global deaths.

The 2019 National Ambulatory Medical Care Survey showed there were approximately 1 billion ambulatory care visits in the U.S. with a high incidence of patients with risk factors for heart disease (33% had hypertension, 15% had diabetes and 7% had a history of CAD, ischemic heart disease or myocardial infarction).

As heart disease progresses to more acute stages, the cost to treat patients increases significantly. Cardiovascular disease is the leading cost to the healthcare system and is estimated to be responsible for one in every six healthcare dollars spent in the United States. Heart disease cost the United States about $240 billion in each of 2018 and 2019, including the cost of health care services, medicines, and lost productivity due to death. Governments, healthcare providers and payors are motivated to shift the diagnosis and management of these conditions to earlier stages where better patient outcomes can be delivered at lower costs.

We believe that there is currently no low-cost, front-line, medical device that is effective at screening for heart disease. As a result, frontline physicians face a significant challenge in determining if a patient has heart disease. The conventional ECG is thought of by many to be the front-line tool in cardiac testing, but it has poor sensitivity in detecting CAD or structural heart disease.

Overuse of Expensive Cardiology-Based Diagnostic Testing

We believe that the absence of cost-effective front-line or primary-care-based testing has resulted in the over-use of costly cardiology-based diagnostic tests. Noninvasive cardiac tests are significant contributors to healthcare costs, accounting for greater than 40% of Medicare Part B spending on medical imaging, or over $17 billion annually according to the U.S. Centers for Medicare & Medicaid Services (“CMS”). There are a variety of effective, though expensive, diagnostic tests used for patients to detect heart disease. These diagnostic tests are typically performed in a specialist cardiology or hospital setting and may include:

- *Stress* ECG *testing*, a non-invasive diagnostic test with a cost of approximately $200 with, according to the American College of Cardiology, a sensitivity of 68% in the detection of CAD;

- *Echocardiogram*, or echo, a non-invasive diagnostic imaging test, similar to an ultrasound, which is effective in the detection of heart disease; however, the Medicare cost of an echo in a hospital is approximately $600 and can be as much as $3,000 if performed privately;
- *Cardiac imaging tests*, such as nuclear stress tests and coronary computerized tomography angiograms alternatively can be conducted noninvasively, but typically cost $1,000 or more; or
- *Coronary angiogram*, an invasive test in which dye that is visible by X-ray is injected into the blood vessels of the heart. A coronary angiogram can cost in excess of $5,000.

Diastolic Dysfunction, an Early Indicator of Heart Disease

The symptoms and causes of cardiac dysfunction have been researched for many years. The causes of cardiac dysfunction during the contraction (systolic) phase, also called reduced left ventricular ejection fraction, have been well understood for many years. However, according to the American Heart Association Statistics Committee report in 2013, approximately 50% of patients with heart failure ("HF") symptoms have ejection fraction measures that are not markedly abnormal. In addition, multiple articles published by the National Institutes of Health ("NIH"), state that approximately 50% of HF cases are due to severe diastolic dysfunction, also called heart failure with preserved ejection fraction. HF with preserved ejection fraction ("HFpEF") is a clinical syndrome in which patients have symptoms and signs of HF with normal or near-normal left ventricular ejection fraction ("LVEF") (LVEF ≥50%). Roughly half of all patients with HF worldwide have an LVEF ≥50% and nearly half have an LVEF <50%. Thanks to the increased scientific attention about the condition and improved characterization and diagnostic tools, the incidence of HF with reduced ejection fraction ("HFrEF") dropped while that of HFpEF has increased by 45%. As a result, understanding the causes and progression of diastolic dysfunction has become a key area of scientific and clinical interest. This research has led to the understanding that almost all patients with systolic dysfunction also have diastolic dysfunction and almost all types of heart disease including CAD, valvular disease, cardiomyopathy, hypertension, congenital heart disease, and pericardial disease induce diastolic dysfunction.

According to an article by Dr. Dalane W. Kitzman, MD and Dr. William C. Little, MD published in the February 14, 2012 issue of the *Journal of the American Heart Association*, diastolic performance is sensitive to nearly all of the common disease processes that affect cardiovascular function. The article indicates that left ventricular, or LV, diastolic function is impaired by all of the common disease processes that affect LV function or produce LV hypertrophy or fibrosis, including hypertension, diabetes, ischemia, myocarditis, toxins and infiltrative cardiomyopathies. LV diastolic dysfunction ("LVDD") begins early in the heart disease process and continues to increase in severity as heart disease progresses. LVDD is now recognized as one of the earliest signs of heart disease and typical onset occurs when a patient is still asymptomatic. We believe that the early detection of diastolic dysfunction can be a clinically valuable marker for almost all forms of heart disease and age-related cardiac abnormalities that may otherwise be missed by current conventional ECG devices.

MyoVista Insights Cloud Platform and Related AI-ECG Algorithms

We are currently developing a reporting platform to host the provision of cloud-based AI-ECG algorithms. The platform is being designed to be ECG device agnostic to allow clinical institutions to access AI-ECG algorithms without the need to replace existing devices. Our objective for the MyoVista Insights Cloud Platform is to develop an AI-ECG marketplace to include integration and hosting of AI-ECG algorithms developed and FDA cleared by third parties. This would be expected to provide clinical and commercial benefit by increasing the number of available algorithms and clinical use indications, increase our speed of roll-out, and reduce the burden and cost of algorithm R&D on the Company.

We have engaged an experienced firm with significant experience developing and delivering healthcare software platforms, including other cloud platforms. We plan to deliver the MyoVista Insights Cloud Platform on a phased basis. Phase 1 has been designed to provide an initial functional platform as a basis for FDA clearance contemporaneous with our first cloud-based AI-ECG algorithm. The Phase 1 platform is designed to receive an acquired ECG signal and then process and report/provide the results of an AI-ECG algorithm which in combination with the AI-ECG algorithm forms a software based medical device for regulatory purposes. As such FDA clearance of the Phase 1 platform would be sought contemporaneously with FDA clearance of our first cloud-based AI-ECG

algorithm as the two form an initial software based medical device for regulatory purposes. This type of algorithm cloud platform is generally well defined for regulatory purposes. We already have built a working beta version of the MyoVista Insights Cloud Platform and expect it to be complete in calendar Q4 2024.

We expect our first AI-ECG cloud-based algorithm to be a low ejection fraction (LVEF ≤ 40) algorithm licensed from Mount Sinai. There is a well-defined predicate for this algorithm which provides greater clarity for the regulatory pathway which we expect to be 510(k), accordingly, we expect this process will be relatively straightforward, assuming appropriate clinical performance of the algorithm. This algorithm was developed using over 100,000 patient records and published clinical data demonstrated strong performance comparable to the predicate. We are in the process of undertaking further work to assess and, if necessary, adjust the algorithm, and prepare for an FDA validation study and submission. We expect the validation study will be performed using retrospective data, i.e. validation using pre-existing ECG's rather than requiring active patient recruitment, which would reduce costs and timescales compared to prospective clinical validation.

We have yet to engage with the FDA on the MyoVista Insights Cloud Platform and low ejection fraction algorithm but expect to do so in the coming months and are currently targeting FDA 510(k) submission in the middle of 2025.

Phase 2 and beyond of the MyoVista Insights Cloud Platform would expand user functionality and connectivity as well as integration with electronic medical record systems, ECG management systems and direct to devices.

Following clearance of the Phase 1 platform, we then expect to bring forward a pipeline of other AI-ECG algorithms. As they would be delivered on the pre-cleared MyoVista Insights Cloud Platform, the regulatory focus would then be focused primarily on the clinical performance of each algorithm. We have already licensed a number of AI-ECG algorithms from Mount Sinai and have relationships with other clinical institutions which would enable us to develop further algorithms. We are also developing the MyoVista Insights Cloud Platform to be able to host third-party algorithms.

MyoVista *wav*ECG Product and Technology

The HeartSciences developed cardiac dysfunction algorithm is being incorporated into the MyoVista *wav*ECG device. It has been developed in response to the relatively recent understanding in cardiology that most forms of heart disease are associated with LV relaxation abnormalities and diastolic dysfunction. The MyoVista *wav*ECG is a 12-lead resting ECG device featuring our proprietary AI-ECG algorithm designed to detect cardiac dysfunction in the diastolic phase, specifically, slower than normal left ventricular relaxation rates, in accordance with recent clinical findings and the American Society of Echocardiology Guidelines.

The MyoVista *wav*ECG also includes the capabilities of a full-featured conventional 12-lead resting ECG including analysis using the Glasgow Algorithm, also known as the Glasgow ECG Interpretation Algorithm. Developed by the University of Glasgow in the United Kingdom, the 12-lead ECG Analysis Algorithm has been relied upon for more than 35 years and is a widely used resting ECG interpretive algorithm. The Glasgow Algorithm has been improved over the years and is licensed to us pursuant to a licensing agreement with The University Court of the University of Glasgow. Under this licensing agreement, we obtained a non-exclusive, worldwide license with automatic renewal provisions and the right to license: (i) software modules for an Android-based platform for the analysis of resting 12-lead electrocardiograms and (ii) all intellectual property rights (including patents, copyright, trademarks, trade secrets and know-how) relating to the software modules to be used in the MyoVista *wav*ECG (the "Glasgow Licensing Agreement").

The MyoVista *wav*ECG combines both, the conventional ECG capabilities (including the Glasgow Algorithm) and our proprietary AI-ECG algorithm, designed to detect impaired left ventricular cardiac relaxation abnormalities, as a single test with results presented separately. The MyoVista *wav*ECG has a high-resolution touchscreen display and incorporates many intuitive features commonly associated with a tablet device. In the future we would expect to incorporate further AI-ECG algorithms in the MyoVista *wav*ECG.

MyoVista wavECG device with 1 lead view of signal processed waveform

Market Opportunity

Diagnostic Gap

We believe that the most significant diagnostic gap in heart disease is early identification. Heart disease often remains asymptomatic for many years until it reaches an acute stage, at which point many patients have a heart attack or die without prior diagnosis of disease. For this reason, heart disease is often referred to as the "silent killer." In 2012, the United States Preventative Services Task Force stated that there is no good evidence that an ECG helps physicians predict heart risks in people with no symptoms any better than traditional considerations such as smoking, blood pressure and cholesterol levels, acknowledging the diagnostic gap that currently exists.

According to the CDC, cardiovascular disease remains the largest cost for the U.S. healthcare system at approximately $219 billion per year. The cost of treating acute cardiac events and heart failure is especially high in comparison to preventative treatment. Governments, healthcare providers and third-party payors are focused on shifting the diagnosis and management of heart disease to earlier stages where better patient outcomes can be delivered at lower cost; however, to make substantial progress the existing diagnostic gap needs to be closed.

We believe that the scale of cardiac disease as well as changing demographics, growing ECG market, impetus to identify risks earlier through low-cost testing, along with the increasing number and type of health care settings creates a significant opportunity for a device such as the MyoVista *wav*ECG.

Changing Demographics

Heart disease is most commonly found in individuals age 65 and older with incidences of heart disease increasing at 65 years for men and 71.8 years for women. According to the Organization for Economic Co-operation and Development, advances in the field of medicine have led to an increase in life expectancy which, as of 2020, was estimated to average 77.3. years for a person in the U.S., up from 75.4 years in 1990. As life expectancy increases, the average age of the population is expected to increase. According to the U.S. Health and Human Services — Office of the Inspector General (the "HHS"), the population age 65 and older increased from 38.8 million in 2008 to 52.4 million in 2018 (a 35% increase) and is projected to reach 94.7 million by 2060. By 2030, more than 20 percent of U.S. residents are projected to be age 65 and over. Since heart disease is most commonly found in individuals age 65 years and older, and that population pool is increasing, we believe there is a significant opportunity for a device such as the MyoVista *wav*ECG as well as the MyoVista Insights Cloud Platform.

Growing ECG *Market*

The demand for electrocardiograph devices and related supplies known as electrodes is on the rise worldwide. Despite the limitations of the conventional ECG and healthcare guidance around the world that recommends against its use for screening, in the absence of a better alternative, the ECG remains a ubiquitous and widely used test throughout healthcare including non-cardiology settings. It is estimated that 1.5 million to 3.0 million ECGs are performed worldwide every day, making it one of the most commonly used cardiovascular diagnostic tests in healthcare and a fundamental tool in clinical practice. It is estimated that more than 100 million ECGs are performed each year in the United States. The 2019 National Ambulatory Medical Care Survey indicated that office-based patient care physicians, excluding anesthesiologists, radiologists and pathologists, ordered or provided 47 million ECG tests during office visits, and the 2020 National Hospital Ambulatory Medical Care Survey showed that during ambulatory care visits to hospital emergency departments, an additional 32 million ECG tests were ordered or performed by hospital emergency departments.

With the advent of advanced technology, ECG testing market research reports demonstrate that market growth in ECG devices and use is increasing. Precedence Research, a Canada/India based market research company recently released market research on the global electrocardiograph market for 2023, the market size is expected grow significantly from $10.93 billion in 2023 to $25.56 billion by 2032.

Impetus to Identify Risks Earlier for More Effective Low-Cost Testing

A key goal of the HHS is reducing healthcare costs. This places pressure on physicians and healthcare institutions to contain healthcare costs. Additionally, one of the key objectives of HHS's Healthy People 2030, is to increase preventive care for people of all ages. We believe that efforts towards preventive care and maintenance will lead to more testing for high-risk individuals and patients who have existing cardiac conditions. This trend, we believe, in tandem with the push to shorten hospital stays, has created an impetus to identify pre-symptomatic patients at risk more effectively at the front-line physician or clinic level and to treat recovering cardiac patients through outpatient care and rehabilitation.

It is our belief that the MyoVista *wav*ECG device and MyoVista Insights Cloud Platform incorporating AI-ECG algorithms, would be well positioned to respond to the global need for more effective, low-cost ECG testing to facilitate improved referral processes or heart disease.

Changing Nature of Healthcare Providers

The delivery of healthcare in the U.S. is evolving. Alternative treatment sites, such as retail clinics, concierge medicine, urgent care clinics and ambulatory surgical centers, deliver care from qualified providers in settings outside of emergency departments, hospitals or traditional physician offices. We expect this trend to accelerate the drive to provide more effective preventative care and represents a significant opportunity for the introduction of our AI-ECG algorithms that offer an enhanced ability to screen for heart disease.

Capitation Provides an Incentive to Identify Medicare Advantage Patients

Healthcare providers are paid either through fee-for-service or capitation. Fee-for-service is a payment model where services are unbundled and paid for separately. In health care, the fee-for-service payment model incentivizes physicians to provide more treatments because payment is dependent on the quantity, rather than quality, of care. Capitation is a payment arrangement that pays a physician or group of physicians a set amount for each enrolled person assigned to them, per period of time, whether or not that person seeks care. Under capitation, the amount of remuneration is based on the average expected healthcare utilization of that patient, with greater payment for patients with a significant history of medical problems.

Approximately 48% (approximately 28 million people) of those covered by Medicare according to CMS are enrolled in a Medicare Advantage plan. With respect to these patients, CMS pays capitation to healthcare providers. CMS uses risk adjustment to adjust capitation payments to health plans, either higher or lower, to account for the differences in the health costs of individuals with ailments such as heart failure, CAD, angina and valvular heart disease. Accordingly, under CMS guidelines, risk factor adjustments per patient will provide payment that is higher for sicker patients who have conditions where diagnosis codes are documented in the medical record as a result of a face-to-face visit. Therefore, there is a financial incentive to identify those Medicare Advantage patients who are sicker, including those who have undiagnosed ailments such as heart disease. We believe that undiagnosed heart

disease represents a significant problem, and we believe insurance plans that have a high number of Medicare Advantage patients could be a target market for the MyoVista cloud-based and hardware-based platforms.

Market Strategy

General

Our objective is to provide AI-ECG solutions in any care setting worldwide in a manner that best suits different providers, either via one of the millions of ECG's currently in clinical use or via our proprietary MyoVista *wav*ECG device in order to significantly improve front-line testing and referral processes for heart disease. Our business model is primarily focused on recurring revenues for each of the MyoVista Insights Cloud Platform and the MyoVista *wav*ECG device.

The initial revenue model for the MyoVista *wav*ECG device involves the capital sale of the device, recurring revenue from the sale of its proprietary supplies (electrodes) for each test. We would expect to charge for recurring software revenues from the use of AI-ECG algorithms delivered via the Cloud Platform or made available on the MyoVista *wav*ECG device. There are estimated to be millions of ECGs in use worldwide and the Cloud Platform is intended to be device-agnostic thereby facilitating the provision of AI-ECG algorithms to physicians from existing devices. In short, we expect to generate recurring supplies or software revenues and do not expect to rely on high initial capital or device pricing in order to encourage adoption of our AI-ECG algorithms.

Territories

Our initial sales focus will primarily be within the U.S. and European markets where we have established relationships. We intend to market our products in the U.S. using a direct sales force following FDA clearance. Outside of the U.S., for markets such as Europe and Latin America, we intend to utilize medical device distributors that have existing healthcare provider relationships and experience selling ECG devices, which will be supported by a small number of local field personnel.

Potential Markets

We believe that there is a large variety of potential markets for AI-ECG algorithms with new diagnostic capabilities that are not currently available for ECG devices. Conventional ECGs are used throughout healthcare in almost every clinical setting including clinics, doctor's offices, urgent care centers, and hospitals. We believe that, in many of those settings, the additional information provided by AI-ECG algorithms could be extremely valuable.

Our AI-ECG algorithms range of applications and potential uses are vast, and include providing:

- Primary care — front-line cardiac testing/referral tool, heart disease screening.
- Retail Healthcare — access to ECG testing at retail sites such as CVS and Walgreens.
- Emergency Departments — enhanced ECG testing for emergency room patients.
- Cardiologists — prescreening cardiology patients.
- Hospitals — in-patient testing or testing prior to discharge, particularly cardiac wards.
- Surgery — pre-anesthesia testing, pre/post intervention.
- Life Insurance testing — ECGs when required in connection with the issuance of life insurance policies.
- Specialty Environments — screening for conditions such as cardiomyopathy, cardiac oncology, drug trials, heart failure, and diabetes.
- Athlete testing — cardiac screening programs for athletes.

Early Target Markets

Initially, our focus markets in the U.S. will include: cardiology; primary care providers that serve upper to middle income regions including concierge medicine providers; health systems; retail clinics; and insurers with high

levels of Medicare Advantage patients. As additional algorithms obtain FDA clearance, HeartSciences will extend its sales efforts to clinics and physicians that will benefit the most from the specific AI-ECG algorithm.

Reimbursement

In addition to targeting the health care settings described above, a key element of our strategy is to ensure each algorithm qualifies for reimbursement from third-party payors such as CMS (Medicare payor). CPT codes are numbers assigned to each task or service provided by a healthcare provider including medical, surgical and diagnostic services. Insurers use the numbers to determine the procedure and the amount to pay a provider. The American Medical Association has already issued a temporary Current Procedural Terminology (CPT) Category III code for novel AI assistive algorithmic ECG risk assessment for cardiac dysfunction. These codes are designed to facilitate the use, adoption, and potential reimbursement of emerging technologies. This provides physicians and clinical institutions the ability to bill for HeartSciences algorithms that detect different types of heart dysfunction such as systolic and diastolic dysfunction. While we cannot be certain that these new codes will ultimately lead to the issuance of permanent CPT Category I codes, or that insurance coverage or payment can be obtained, if successful, this could potentially provide total reimbursement that is larger than reimbursement for conventional ECG devices, which, in turn, could provide MyoVista *wav*ECG device and the MyoVista Insights Cloud Platform delivering AI-ECG algorithms with a competitive advantage as compared to conventional ECG testing and devices. The MyoVista *wav*ECG device also includes conventional ECG testing capabilities and is expected to also qualify for Medicare reimbursement for existing ECG testing procedures with interpretation and report ranges from approximately $17 to $55 depending on the type of healthcare facility. These charges would go directly to the healthcare facility/physician.

Competition

The medical device industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. There are many medical device companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to HeartSciences AI-ECG algorithms and MyoVista hardware. Competitors could include traditional ECG manufacturers such as GE Healthcare Technologies, Inc., (“GE Healthcare”), Koninklijke Philips N.V. (“Philips”), Baxter International, Inc. (“Baxter”), and Nihon Kohden Corporation that may seek to innovate, and new commercial entrants to the AI-ECG market, such as Anumana, Inc. or companies involved in AI healthcare, such as Tempus Labs, Inc. or VIZ.ai that also see the opportunity to bring innovation in a market that, we believe, has significant need for improved products and technology change.

Intellectual Property

Our technology is protected by a patent portfolio as well as trade secrets, which together comprise an important part of the intellectual property protection for our existing and licensed proprietary algorithms (especially when developing proprietary algorithms). We believe that the combination of patents and trade secrets creates valuable competitive barriers in favor of HeartSciences.

The USPTO has issued eight utility patents and one design patent to us, and a patent allowance for a utility patent exclusively licensed to us. The patent expiration dates range from March 2031 to August 2040. We also have fourteen international design registrations and eighteen international utility patents granted (with expiration dates ranging from September 2036 to March 2037) in jurisdictions such as China, Japan, South Korea, the United Kingdom, France, Germany, Mexico, the United Arab Emirates, Brazil, and Australia. We currently have two patent allowances in Europe and Canada, and also have additional pending patent applications in various jurisdictions.

In addition, we have entered into two agreements that are material to our rights to the intellectual property utilized in the MyoVista *wav*ECG:

- In January 2014, we entered into an invention assignment agreement under which certain specified MyoVista *wav*ECG technology and proprietary and intellectual property rights thereto (including patents, copyright, trademarks, trade secrets and know-how) were transferred and assigned to us by the inventor; and

- In December 2015, we entered the Glasgow Licensing Agreement with The University Court of the University of Glasgow under which we obtained a non-exclusive, worldwide license to software modules for an Android platform for analysis of resting 12-lead electrocardiograms and all intellectual property rights (including patents, copyright, trademarks, trade secrets and know-how) relating to the software modules to be used in the MyoVista *wav*ECG.

Research and Development

The Company's R&D staff designs our hardware, software and internally developed AI-ECG algorithms. Hardware development assistance is provided by outside consulting firms. The Company internally develops the software for the device along with the assistance of multiple software development contractors. The data science work necessary to build the AI-ECG algorithms is performed both internally and externally using outside data science experts.

Incorporation of all software elements into the MyoVista *wav*ECG hardware is performed internally. We currently employ six full-time R&D staff.

We believe, based on our research and other published research, that further algorithms could be developed for a range of additional clinical indications. To accelerate HeartSciences' route to market with additional algorithms we entered into multiple license agreements with Mount Sinai on September 20, 2023. Please see the section, "*Agreements with Mount Sinai related to Commercialization of Multiple AI*-ECG *Cardiovascular* ECG *Algorithms developed by Mount Sinai*" for additional information regarding these license agreements. Studies involving the use of the MyoVista *wav*ECG along with proof of concept algorithms for alternative clinical indications have already been published in addition to the growing body of third-party published research in this field.

On November 29, 2022, we entered into a multi-year collaboration agreement with Rutgers, The State University of New Jersey, to research and develop additional AI-ECG algorithms.

FDA and Other Government Regulation

General

Our 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 medical device 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. We will also encounter in the future industry-specific government regulations that would govern our device, if and when developed for commercial use. It may become the case that other regulatory approvals will be required for the design and manufacture of our device.

FDA Requirements and Other Regulatory Approval Requirements

Our products are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the "FDCA") as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in the European Economic Area (the "EEA") governing clinical trials and the commercial sales and distribution of our products. Whether or not we have or are required to obtain FDA clearance or approval for a product, we will be required to obtain authorization before commencing clinical trials and to obtain marketing authorization or approval of our products under the comparable

regulatory authorities of countries outside of the United States before we can commence clinical trials or launch sales of our products in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval. Medical devices are generally subject to varying levels of regulatory control based on risk level of the device.

A clearance or authorization letter from the FDA authorizes commercial marketing of the device for one or more specific indications of use. After clearance or authorization, the Company will be required to comply with a number of 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 the QSR. The FDA periodically inspects manufacturing facilities to assess compliance with QSRs, 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 the QSR and other types of regulatory controls.

The FDA and the Federal Trade Commission, or FTC, will also regulate the advertising claims of the Company'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.

FDA Clearance Process and FDA Validation Clinical Study

Unless an exemption applies, each medical device commercially distributed in the United States requires FDA clearance of a 510(k) premarket notification, granting of a de novo request, or approval of an application for premarket approval, or PMA. Under the FDCA, 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 regulatory controls needed to ensure its safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising and promotional materials.

Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to class II controls is generally described as 510(k) clearance.

Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified but are subject to FDA's premarket notification and clearance process in order to be commercially distributed.

510(k) Clearance Marketing Pathway

To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is “not substantially equivalent” to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements or can request a risk-based classification determination for the device in accordance with the “De Novo” process, which is a route to market novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) or possibly a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer’s determination. If the FDA disagrees with our determination not to seek a new 510(k) clearance, the FDA may retroactively require us to seek 510(k) clearance or possibly a PMA. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or a PMA is obtained. Also, in these circumstances, we may be subject to significant regulatory fines and penalties.

PMA Approval Pathway

Class III devices require approval of a PMA before they can be marketed, although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA application, the manufacturer must demonstrate that the device is safe and effective, and the PMA application must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA application must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA application, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA application, although in practice, the FDA’s review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel’s recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers’ or suppliers’ manufacturing facility or facilities to ensure compliance with the QSR. PMA devices are also subject to the payment of user fees.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA application constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). A PMA may include post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported the PMA or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. None of our currently developed products require a PMA to be marketed.

De Novo Classification

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the De Novo classification procedure.

This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, a medical device could only be eligible for De Novo classification if the manufacturer first submitted a 510(k) pre-market notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the De Novo classification pathway by permitting manufacturers to request De Novo classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the De Novo application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

After initial authorization, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, another De Novo classification request, or PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

The MyoVista *wav*ECG device along with its proprietary software and hardware is classified as a Class II medical device by the FDA. We previously submitted and intended to seek authorization to market the device through submission under the De Novo pathway, however in December 2023 the FDA confirmed that we could submit the MyoVista *wav*ECG device for clearance under the 510(k) pathway following the grant by the FDA in August 2023 of an industry-first De Novo clearance which created a new Class II product code for cardiovascular machine learning-based notification software. Accordingly, we are now preparing for a 510(k) FDA submission and are aiming for a submission in the first calendar quarter of 2025. To date we have not yet entered into a discussion with the FDA regarding the MyoVista Insights Cloud Platform or Mount Sinai licensed AI-ECG algorithms but are aiming to start that process in the current calendar year. We expect these products to fall under the 510(k) pathway and are aiming for an FDA submission of our MyoVista Insights Cloud Platform and low ejection fraction algorithm in the middle of 2025. Delays in receipt or failure to receive the necessary clearances, or the failure to comply with existing or future regulatory requirements, could reduce our business prospects.

Clinical Trials

Clinical trials are almost always required to support a De Novo request and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk

to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies us that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it 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, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. 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 must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- clearance or approval of product modifications to 510(k)-cleared devices, or those re-classified to 510(k) cleared devices, that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of a supplement for certain modifications to PMA devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;

- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with the new federal law and regulations requiring Unique Device Identifiers (UDI) on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database (GUDID);
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. These requirements impose certain procedural and documentation requirements upon us and our third-party manufacturers related to the methods used in and the facilities and controls used for designing, manufacturing, packaging, labeling, storing, medical devices. As a manufacturer, we will be subject to periodic scheduled or unscheduled inspections by the FDA. Following these inspections, the FDA may assert noncompliance with QSR requirements on a Form 483, which is a report of observations from an inspection, or by way of "untitled letters" or "warning letters" that could cause us or any third-party manufacturers to modify certain activities. A Form 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated QSR or other FDA requirements. We cannot be certain that we or our present or any future third-party manufacturers or suppliers will be able to comply with QSR or other FDA regulatory requirements to the agency's satisfaction. Failure to comply with these obligations may lead to possible legal or regulatory enforcement action by the FDA.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our device;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export or import approvals for our device; or
- criminal prosecution.

Advertising and Promotion

The FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of medical devices, including standards and regulations for direct-to-consumer advertising, communications about unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the internet. Devices may be marketed only for the approved or cleared indications and in accordance with the provisions of the approved or cleared label.

Foreign Regulation

As we plan to market our device 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 device 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 also vary greatly from country to country and such regulatory requirements have been changing and increasing in some countries. We may be unable to maintain regulatory qualifications, clearances, approvals or CE Certificates of Conformity in these countries or to obtain clearances or approvals in other countries. We may incur significant costs in attempting to obtain, renew, or modify foreign regulatory clearances or approvals, qualifications or CE Certificates of Conformity. If we experience difficulties in receiving, maintaining, renewing or modifying necessary qualifications, clearances, approvals or CE Certificates of Conformity to market our products outside the United States, or if we fail to receive, renew, modify or maintain those qualifications, clearances, approvals or CE Certificates of Conformity, we may be unable to market our products or enhancements in certain international markets effectively, or at all.

On April 5, 2017, a new regulation on medical devices was adopted to establish a modernized and more robust European Union legislative framework, with the aim of ensuring better protection of public health and patient safety: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, which became applicable from May 26, 2021, (the "EU MDR"). The EU MDR repeals and replaces the EU Medical Devices Directive and unlike directives, which must be given effect through transposition into the national domestic laws of the Relevant States, regulations are directly applicable (i.e., without the need for transposition into national laws implementing them) in all Relevant States. The EU MDR is also applicable in the EEA. Regulations (as EU law instruments) must be applied in their entirety across the EU so that legal acts are automatically and uniformly applied to all EU countries as soon as they enter into force to minimize variations that may arise in transposition of EU law into national law. These modifications may have an effect on the way we design and manufacture products and conduct our business in the EU and EEA. For example, as a result of the transition towards the new regime, Notified Bodies have lengthened their review times, and product introductions or modifications could be delayed or cancelled or otherwise rejected, which could adversely affect our ability to grow our business.

The Company previously achieved a CE Mark under the EU Medical Devices Directive (the "MDD") in February 2017. The Medical Device Directive was established on June 14, 1993 but the MDD regulatory framework, has since been replaced by EU MDR. In order to sell in member countries of the EEA, our devices must now comply with the essential requirements of the EU MDR. Our CE Mark issued under the MDD lapsed in February 2022 and we will need to establish compliance under EU MDR. An updated CE mark certificate under EU MDR, which we have not yet obtained, would entitle the Company to market the MyoVista *wav*ECG in the European Economic Area as well as other countries for which CE Mark represents an appropriate regulatory standard.

Implications of Being an "Emerging Growth Company" and a "Smaller Reporting Company"

We qualify as an "emerging growth company" under the Jumpstart our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we may take advantage of relief from certain reporting requirements and other burdens generally applicable to public companies. In particular, as an emerging growth company we:

- are not required to obtain an attestation and report from our auditors on our management's assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- are not required to provide a detailed narrative disclosure discussing our compensation principles, objectives and elements and analyzing how those elements fit with our principles and objectives (commonly referred to as "compensation discussion and analysis");
- are not required to obtain a non-binding advisory vote from our shareholders on executive compensation or golden parachute arrangements (commonly referred to as the "say-on-pay," "say-on-frequency" and "say-on-golden-parachute" votes);

- are exempt from certain executive compensation disclosure provisions requiring a pay-for-performance graph and CEO pay ratio disclosure;
- may present only two years of audited financial statements and only two years of related Management's Discussion & Analysis of Financial Condition and Results of Operations ("MD&A"); and
- are eligible to claim longer phase-in periods for the adoption of new or revised financial accounting standards under §107 of the JOBS Act.

We intend to take advantage of these reduced reporting requirements and exemptions, including the longer phase-in periods for the adoption of new or revised financial accounting standards under §107 of the JOBS Act. Our election to use the phase-in periods may make it difficult to compare our financial statements to those of non-emerging growth companies and other emerging growth companies that have opted out of the phase-in periods under §107 of the JOBS Act. Please see "Risk Factors—We are an 'emerging growth company,' and any decision on our part to comply with certain reduced disclosure requirements applicable to emerging growth companies could make the Common Stock less attractive to investors."

Under the JOBS Act, we may take advantage of the above-described reduced reporting requirements and exemptions for up to five years after our initial sale of common equity pursuant to a registration statement declared effective under the Securities Act, or such earlier time that we no longer meet the definition of an emerging growth company. In this regard, the JOBS Act provides that we would cease to be an "emerging growth company" if we have more than $1.235 billion in annual revenue, have more than $700 million in market value of our Common Stock held by non-affiliates (and are not otherwise eligible to be a smaller reporting company), or issue more than $1 billion in principal amount of non-convertible debt over a three-year period. Further, under current SEC rules we will continue to qualify as a "smaller reporting company" for so long as we have a public float (i.e., the market value of common equity held by non-affiliates) of less than $250 million as of the last business day of our most recently completed second fiscal quarter.

Certain of the reduced reporting requirements and exemptions available to us as an "emerging growth company" are also available to us due to the fact that we also qualify as a "smaller reporting company" under the SEC rules. For instance, smaller reporting companies are not required to obtain an auditor attestation and report regarding internal control over financial reporting; are not required to provide a compensation discussion and analysis; are not required to provide a pay-for-performance graph or CEO pay ratio disclosure; and may present only two years of audited financial statements and related MD&A disclosure.

If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. We will continue to be a smaller reporting company so long as (i) the market value of our stock held by non-affiliates is less than $250 million as of the last business day of our second fiscal quarter or (ii) our annual revenue was less than $100 million during our most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of the last business day of our second fiscal quarter. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Corporate Information

We are a Texas corporation based in Southlake, Texas and were incorporated in Texas in August 2007. Our principal executive offices are located at 550 Reserve Street, Suite 360, Southlake TX 76092. Our telephone number is 682-237-7781. We are doing business under an assumed name, HeartSciences. Our website address is *www.heartsciences.com*. 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 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.

Employees and Independent Contractors

As of July 26, 2024, we had 15 employees (including our Chief Executive Officer), all of which are full-time employees, and 6 independent contractors. All of our employment and consulting agreements include employees' and consultants' undertakings with respect to non-competition and assignment to us of intellectual property rights developed in the course of employment and with respect to confidentiality.

Item 1A. Risk Factors

Our business is subject to numerous risks, as more fully described below in this "Risk Factors" section. The following is a summary of the most significant risks and uncertainties that we believe could adversely affect our business, financial condition, and results of operations. In addition to the following summary, you should read the other information set forth below in this “Risk Factors” section before you invest in our securities. In particular, our risks include, but are not limited to, the following:

Risks Related to Our Financial Condition and Capital Requirements:

- We have a limited operating history and we have incurred significant operating losses since our inception, and anticipate that we will incur continued losses for the foreseeable future;
- If we are unable to maintain compliance with all applicable continued listing requirements and standards of Nasdaq, our Common Stock could be delisted from Nasdaq.
- Our future operating results are dependent on regulatory approval for the MyoVista *wav*ECG and the MyoVista Insights Cloud Platform, which we have not received as of the date of filing of this Annual Report on Form 10-K;
- We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our development efforts and other operations;
- All of our assets are subject to security interests; and
- There is substantial doubt about our ability to continue as a going concern, which could prevent us from obtaining new financing either on reasonable terms or at all.

Risks Related to Our Business and Industry:

- Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce the MyoVista *wav*ECG device and the MyoVista Insights Cloud Platform to the market in a timely manner. If we do not obtain and maintain the regulatory registrations and clearances for our products, we will be unable to market and sell our products in the United States, Europe or other regions;
- Our success will be dependent upon physician acceptance;
- If third-party payors do not provide adequate coverage and reimbursement for the use of our AI-ECG algorithms, our revenue will be negatively impacted;
- We will be dependent upon third-party manufacturers and suppliers, making us vulnerable to supply shortages and problems, increased costs and quality or compliance issues, any of which could harm our business;
- Interruptions in computing and data management cloud systems could impair the delivery of our cardiac monitoring services; and
- Our proprietary data analytics engine may not operate properly, which could damage our reputation, give rise to claims against us or divert application of our resources from other purposes, any of which could harm our business and operating results.

Risks Related to Product Development and Regulatory Approval:

- Our products and operations are subject to extensive government regulation and oversight both in the U.S. and abroad, and our failure to comply with applicable requirements could harm our business;

• If and when our products are ready for sales launch into the U.S., modifications to our marketed products may require new 510(k) clearances, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained;

• Clinical studies may be necessary to support future product submissions to the FDA. The clinical trial process is lengthy and expensive with uncertain outcomes, and often requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical studies will prevent us from launching sales of modified or new products into the U.S. and will adversely affect our business, operating results and prospects;

• If the third parties on which we rely to conduct our clinical studies and to assist us with pre-clinical development do not perform as required or expected, we may be delayed or unable to obtain regulatory clearance or approval for sales launch of our products in the U.S.;

• We may encounter substantial delays in our clinical studies, or we may fail to demonstrate specificity and sensitivity to the satisfaction of applicable regulatory authorities;

• The results of future clinical studies may not support additional or new claims for future products or may result in the discovery of adverse side effects;

• Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market;

• The MyoVista *wav*ECG device must be manufactured in accordance with federal, state and foreign regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations; and

• Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations.

Risks Related to Our Intellectual Property:

• If we are unable to obtain and maintain effective patent rights for our products, we may not be able to compete effectively in our markets. If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us;

• Intellectual property rights of third parties could adversely affect our ability to market our products, and we might be required to litigate or obtain licenses from third parties in order to develop or market our products. Such litigation or licenses could be costly or not available on commercially reasonable terms; and

• We may be subject to claims challenging the inventorship of our intellectual property.

Risks Related to Our License Agreements with Mount Sinai:

• We are highly dependent on the Licenses, the termination of which may prevent us from commercializing our products, and which imposes significant obligations on us;

• Our future financial performance will depend in part on the successful integration, improvement and software updates from the Mount Sinai algorithms; and

• Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce the algorithms underlying the Mount Sinai Licenses to the market in a timely manner.

Risks Related to the Ownership of our Securities:

• The market price of our Common Stock may be highly volatile, and you could lose all or part of your investment;

- Future sales of a substantial number of shares of our Common Stock by our existing shareholders could cause our stock price to decline;
- If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they publish negative reports regarding our business or our securities, our share price and trading volume could decline;
- 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; and
- We are an “emerging growth company,” and any decision on our part to comply with certain reduced disclosure requirements applicable to emerging growth companies could make the Common Stock less attractive to investors.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including the financial statements and related notes, before deciding whether to purchase our securities. If any of the following risks are realized, our business, operating results, financial condition and prospects could be materially and adversely affected. In that event, the price of our Common Stock or IPO Warrants could decline, and you could lose part or all of your investment.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history and we have incurred significant operating losses since our inception, and anticipate that we will incur continued losses for the foreseeable future.

We are a development-stage medical device company with a limited operating history. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the medical device industry. To date, we have generated limited revenue from the sale of the MyoVista *wav*ECG devices during its development stage. We have incurred losses in each year since our inception, including net losses of approximately $6.6 million and $6.4 million for Fiscal 2024 and Fiscal 2023, respectively. As of April 30, 2024, we had an accumulated deficit of approximately $67.4 million and stockholder's equity of approximately $7.3 million. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations" for additional information.

Even if we obtain regulatory approval for sales launch of either the MyoVista *wav*ECG or the MyoVista Insights Cloud Platform into the U.S., our future revenue will depend upon the size of the market in which the device or any future product receives approval as well as our ability to achieve sufficient market acceptance, pricing, and reimbursement from third-party payors, which we may never achieve.

We also anticipate that our expenses will increase substantially if and as we:

- continue research and development;
- are granted regulatory and marketing approvals;
- establish a sales, marketing, and distribution infrastructure;
- seek to identify, assess, acquire, license, and/or develop subsequent generations of our current products and any new products;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company as well as our product development and planned future marketing efforts; and
- experience any delays or encounter issues with respect to any of the above, including, but not limited to, failed studies, complex results, safety issues or other regulatory challenges that require longer follow-up of existing studies or additional supportive studies in order to pursue marketing approval.

We expect to continue to incur significant operating losses for the foreseeable future. As a result of the numerous risks and uncertainties associated with developing medical devices, we are unable to predict the extent of any future losses or whether we will ever achieve and maintain profitability. Further, the operating losses that we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Other unanticipated costs may also arise.

If we are unable to maintain compliance with all applicable continued listing requirements and standards of Nasdaq, our Common Stock could be delisted from Nasdaq.

Our Common Stock and IPO Warrants are currently listed on Nasdaq. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price, and certain corporate governance requirements.

On December 21, 2022, we received notice from the Listing Qualifications Staff of Nasdaq indicating that we were not in compliance with the Minimum Stockholders' Equity Requirement, because our stockholders' equity of $1,082,676 as reported in our Quarterly Report on Form 10-Q for the period ended October 31, 2022 was below the required minimum of $2.5 million, and because, as of October 31, 2022, we did not meet the alternative compliance standards, relating to the market value of listed securities of $35 million or net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years.

On August 2, 2023, we received a letter from the Staff indicating that, based upon the closing bid price of the Company's Common Stock for the last 30 consecutive business days, the Company no longer met the requirement to maintain a minimum bid price of $1 per share (the "Minimum Bid Price Requirement"). In accordance with Nasdaq listing rules, we had until January 29, 2024 to regain compliance with the Minimum Bid Price Requirement. In the event we did not regain compliance during this period, we were eligible to seek an additional 180 calendar day compliance period if we met the Nasdaq continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the Minimum Bid Price Requirement, and provided written notice to Nasdaq of our intent to cure the deficiency during this second compliance period.

We attended an August 17, 2023 hearing before the Nasdaq Hearing Panel (the "Panel"), and requested the continued listing of its securities on the Nasdaq Capital Market pending our return to compliance with the Minimum Stockholder's Equity Requirement and Minimum Bid Price Requirement.

On November 22, 2023, we were formally notified by the Panel that we have demonstrated compliance with the Minimum Stockholders' Equity Requirement. Pursuant to Nasdaq Listing Rule 5815(d)(4)(B), we will be subject to a Mandatory Panel Monitor through November 22, 2024.

On January 30, 2024, we received a letter from the Panel advising that we have been granted an additional 180-day extension to July 29, 2024, to regain compliance with the Minimum Bid Price Requirement.

On May 9, 2024, the Company received a staff determination from Nasdaq to delist the Company's securities from the Nasdaq Capital Market (the "Staff Determination"). The Staff Determination was issued because, as of May 8, 2024, the Company's Common Stock had a closing bid price of $0.10 or less for at least ten consecutive trading days. Accordingly, the Company is subject to the provisions contemplated under Nasdaq Listing Rule 5810(c)(3)(A)(iii) (the "Low Priced Stocks Rule").

On May 17, 2024, the Company effected the Reverse Stock Split, such that as a result of the Reverse Stock Split, every 100 shares of the Company's issued and outstanding pre-reverse split Common Stock were combined into one share of Common Stock.

On June 3, 2024, the Company received a letter from Nasdaq informing the Company that the Nasdaq Listing Qualifications staff has confirmed that the Company has regained compliance with the Minimum Bid Price Requirement, and that the Company is therefore in compliance with Nasdaq's listing requirements. The Company's Common Stock and public warrants continue to be listed on Nasdaq.

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 IPO Warrants. If we fail to meet these continued listing requirements, our Common Stock or IPO Warrants may be subject to delisting. If our Common Stock or IPO Warrants are delisted and we are not able to list such Common Stock and IPO 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 IPO 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. There can be no assurance that in the future the we will continue to be in compliance with the Nasdaq listing rules or remain listed on Nasdaq.

Our future operating results are dependent on regulatory approval for the MyoVista wavECG hardware, the MyoVista Insights Cloud Platform, and AI-ECG algorithms , which we have not received as of the date of filing of this Annual Report on Form 10-K.

The MyoVista *wav*ECG is our first product candidate for FDA clearance. As a result, the success of our business plan is entirely dependent on our ability to obtain regulatory approval and to subsequently develop, manufacture and launch sales of the MyoVista *wav*ECG into the U.S. Our failure to do so would likely cause our business to fail. Successful marketing of medical devices is a complex, lengthy, costly and uncertain process, dependent on the efforts of management, manufacturers, local operators, integrators, medical professionals, third-party payors, as well as general economic conditions, among other factors. For more information, see "—Risks Related to Our Business and Industry—Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce our products to the market in a timely manner. If we do not obtain and maintain the regulatory registrations and clearances for our products, we will be unable to market and sell in the United States, Europe or other regions." Any factor that adversely impacts the approval, development and sales launch of the MyoVista *wav*ECG device or the MyoVista Insights Cloud Platform into the U.S. will have a negative impact on our business, financial condition and results of operations. We are developing the MyoVista Insights Cloud Platform to offer access to multiple AI-ECG cardiovascular algorithms and, in the future, we also intend to incorporate multiple AI-ECG algorithms in the MyoVista *wav*ECG.

We may face several challenges with respect to launching sales of our products into the U.S. including, among others, that:

- we may fail to obtain regulatory clearance or approvals or, even if regulatory approval is obtained, we may face adverse regulatory and/or legal actions;
- we may not have adequate financial or other resources to properly market our products or sell them in economically viable quantities;
- we may not be able to manufacture in commercial quantities, at an adequate quality or at an acceptable cost;
- we may not be able to establish adequate sales, marketing and distribution channels;
- healthcare professionals and patients may not accept our products;
- we may not be able to compete with existing solutions for cardiac screening;
- technological breakthroughs in heart disease screening solutions may reduce the potential demand for our products;
- third-party payors may not agree to reimburse patients for any or all of the charges related to the use of our products, which may adversely affect physicians' adoption and use of our products; and
- we may face third-party claims of intellectual property infringement.

If we are unable to obtain regulatory approval and accomplish any one or more of the challenges listed above, our ability to effectively launch sales of the MyoVista *wav*ECG device, the MyoVista Insights Cloud Platform, and the associated AI-ECG algorithms into the U.S. could be limited, which in turn could have a material adverse effect on our business, financial condition and results of operations. For additional information regarding risks related to our ability to successfully develop, market and sell our products, see "—Risks Related to Our Business and Industry—Our success will be dependent upon physician acceptance."

We will need to raise substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our development efforts and other operations.

If we are unable to obtain funding on a timely basis, we may (i) not be able to complete the process of FDA clearance, (ii) need to significantly curtail, delay or discontinue our efforts to launch sales of our products into the U.S. if FDA clearance is achieved or (iii) be unable to continue operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. Even if we achieve FDA clearance with the proceeds of the IPO, we expect that we will require substantial additional capital for sales launch and marketing of our products. In addition, our planned expenses and operations may change as a result of many factors that could be currently unknown to us and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors including:

- the progress, results and costs of our ongoing and planned studies and, if applicable, clinical trials related to the use of our products as well as any future products and services;
- the cost, timing and outcomes of regulatory review of current and any future products and services;
- the scope, progress, results and costs of product development, testing, manufacturing, pre-clinical development and, if applicable, clinical trials for any other product that we may develop or otherwise obtain in the future;
- the cost of our future activities, including establishing sales, marketing and distribution capabilities for our products, in any particular geography, where we receive marketing and/or regulatory approval;
- the terms and timing of any collaborative, licensing, payment plan and/or other arrangements that we may establish;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the level of revenue, if any, received from commercial sales of our products if we receive approval for sales launch of our products into the U.S.

We could also be required to seek additional funds at an earlier stage than would otherwise be desirable and, as a result, we may be required to relinquish rights to some of our intellectual property, our device, or otherwise agree to terms unfavorable to us or our shareholders, any of which may have a material adverse effect on our business. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic objectives such as acquiring IP, partnering with a vendor or other worthwhile business endeavors.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and launch sales of our current products as wells as any future products into the U.S. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

All of our assets are subject to security interests.

Our ability to service our indebtedness will depend upon, among other things, further funding. A breach of the terms and conditions of our indebtedness would likely result in an event of default. If an event of default occurs (after any applicable notice and cure periods), the lenders would be entitled to accelerate the repayment of amounts outstanding (including accrued and unpaid interest and fees). Upon such a default, the lenders could also foreclose against any collateral securing such obligations, which consists of all of our assets. In addition to the assets securing our indebtedness, our obligation to pay certain royalties to the inventor of certain specified MyoVista *wav*ECG technology and proprietary and intellectual property rights thereto (including patents, copyright, trademarks, trade secrets and know-how) is secured by a first lien security interest. If we fail to pay those royalties, the inventor could foreclose on the technology. For more information, please see “Business—Intellectual Property.” If any such foreclosure occurred, we would likely not be able to continue to operate as a going concern.

There is substantial doubt about our ability to continue as a going concern, which could prevent us from obtaining new financing either on reasonable terms or at all.

Our independent registered public accounting firm has issued an opinion on our audited financial statements included in this Annual Report on Form 10-K that contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern because we have experienced recurring losses, negative cash flows from operations, and limited capital resources. These events and conditions indicate that a material uncertainty exists that may cast significant doubt on our ability to continue as a going concern. The perception that we may not be able to continue as a going concern may have a material adverse effect on our share price and our ability to raise new capital (whether it is through the issuance of equity or debt securities or otherwise), enter into critical contractual relations with third parties and otherwise execute our business objectives. Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through debt or equity financing. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

Risks Related to Our Business and Industry

Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce the MyoVista wav*ECG *device and MyoVista Insights Cloud Platform to the market in a timely manner. If we do not obtain and maintain the regulatory registrations and clearances for our products, we will be unable to market and sell our products in the United States, Europe or other regions.

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to, an existing product, we must first receive either approval of a Premarket Approval Application, or PMA, clearance under Section 510(k), or be granted a De Novo classification, in accordance with the FDCA. For additional information on the PMA or the De Novo classification processes, see “Business—FDA and Other Government Regulation.”

The FDA can delay, limit or deny clearance or approval of a medical device for many reasons, including:

- we may not be able to demonstrate to the FDA’s satisfaction that our products are safe and effective for its intended use;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- the manufacturing process or facilities we use or contract to use may not meet applicable requirements; and
- disruptions at the FDA caused by funding shortages or global health concerns, including the COVID-19 pandemic.

We previously submitted an FDA De Novo classification request in December 2019 and, following feedback and communications with the FDA during and since that submission, we have been making modifications to our device, including our proprietary algorithm. We have finished the patient recruitment and core lab work for our FDA validation study and have been undertaking device and algorithm development testing for a revised FDA submission. We had been planning a revised submission under the De Novo pathway, however, in December 2023 the FDA confirmed that we could submit the MyoVista *wav*ECG for clearance under the 510(k) pathway following the grant by the FDA in August 2023, of an industry first De Novo clearance which created a new Class II product code for cardiovascular machine learning-based notification software. This was in respect of a hypertrophic cardiomyopathy algorithm and in late September 2023, the FDA cleared an algorithm for low ejection fraction (less than 40%) under the 510(k) pathway using this new product code. Accordingly, we are now preparing for a 510(k) FDA submission and are aiming for a submission in the first calendar quarter of 2025. Despite the time, effort and cost, we may not ultimately be successful in completing the review process and our 510(k) application may not be granted by the FDA

in a timely manner or at all. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for our products, which may limit the market for the device in the United States.

In order to sell the device in member countries of the EEA, our device must comply with the essential requirements of the EU Medical Device Regulation (EU) 2017/745, or EU MDR. Compliance with these requirements is a prerequisite to be able to affix the Conformité Européene, or CE, mark to our device, without which it cannot be sold or marketed in the EEA. For additional information on the PMA or the De Novo classification processes, see "Business—FDA and Other Government Regulation."

The Company previously achieved a CE Mark under the MDD in February 2017. The Medical Device Directive was established on June 14, 1993 but the MDD regulatory framework, has since been replaced by EU MDR. In order to sell in member countries of the EEA, our devices must now comply with the essential requirements of the EU MDR. Our CE Mark issued under the MDD lapsed in February 2022 and we will need to establish compliance under EU MDR. An updated CE mark certificate under EU MDR, which we have not yet obtained, would entitle the Company to market the MyoVista *wav*ECG in the European Economic Area as well as other countries for which CE Mark represents an appropriate regulatory standard.

Sales of our products outside of the United States and the EEA are also subject to foreign regulatory requirements that vary widely from country to country. Approval procedures vary among countries and can involve additional testing. Complying with foreign regulatory requirements, including obtaining registrations, clearances or approvals, can be expensive and time-consuming, and we may not receive regulatory clearances or approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. If we modify our devices, we may need to apply for additional regulatory clearances or approvals before we are permitted to sell the modified device. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable device in that country.

Regulatory clearance or approval by the FDA does not ensure registration, clearance or approval by regulatory authorities in other countries, and registration, clearance or approval by one or more foreign regulatory authorities does not ensure registration, clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining registration or regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

Our success will be dependent upon physician acceptance.

Our future growth and profitability largely depend on our ability to increase physician awareness of the MyoVista *wav*ECG device and the MyoVista Insights Cloud Platform as well as the willingness of hospitals, physicians, patients and/or third-party payors to use it. These parties may not use our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products are safe, effective and cost-effective, on a stand-alone basis and relative to our competitors' products. If we fail to deliver products that physicians want to use, our revenue potential, financial results and business may be significantly harmed. Even if we are able to deliver a superior device and are able to raise physician awareness of our products through effective marketing, physicians tend to be slow in making changes to their medical treatment practices and may be hesitant to select one of our devices as their preferred diagnostic device for a variety of reasons, including:

- long-standing relationships with competing companies and distributors that sell competing devices;
- lack of experience with our products and concerns that we are new to market;
- lack or perceived lack of sufficient clinical evidence, including long-term data, supporting safety or clinical benefits; and
- time commitment and skill development that may be required to gain familiarity and proficiency with our products.

Physicians play a significant role in determining the course of a patient's treatment and, as a result, the type of treatment that will be utilized and provided to a patient. We intend to focus our sales, marketing and education efforts on educating cardiologists and any other potential referring physicians. However, if physicians do not perceive our products to be useful and reliable, we may not be able to attract or retain customers.

If third-party payors do not provide adequate coverage and reimbursement for the use of the MyoVista wav*ECG*, MyoVista Insights Cloud Platform and associated AI-*ECG *algorithms our revenue will be negatively impacted.

Our products do not currently have coverage and reimbursement approved for third-party payor coverage or reimbursement. Such reimbursement, if and when approved, will vary based on the identity of the third-party.

Our ability to successfully launch sales of our products into the U.S. and achieve market acceptance of our products depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors (such as the Medicare and Medicaid programs in the U.S.), managed care organizations and private health insurers. Third-party payors decide which treatments they will cover and then establish reimbursement rates for those treatments. If approved and successfully marketed, we expect that our products may be used by hospitals and other providers who will then seek reimbursement from third-party payors for the use of our products and, in many cases, the decision whether or not to purchase our products will be dependent upon whether or not such purchaser will be able to seek reimbursement.

Increasingly, third-party payors are also examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Third-party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices before they will reimburse healthcare providers who use such devices. Additionally, there is no uniform policy for coverage and reimbursement in the U.S., and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from the Medicare coverage determination process. It is uncertain whether our products will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels for use in any given jurisdiction.

We expect to engage with the American Medical Association, or AMA, and American College of Cardiology to gain approval for use of the standard ECG reimbursement coding for the conventional ECG functions of the MyoVista *wav*ECG device. We will also seek to have private third-party payors provide reimbursement for the use of our proprietary AI-ECG algorithms. We cannot assure you that these efforts will be successful in obtaining third-party payor reimbursement. The lack of reimbursement from third-party payors would have an adverse effect on our revenues, which could have an adverse effect on our business, financial condition and results of operations.

Reimbursement systems in international markets vary significantly by country and, within some countries, by region and reimbursement approvals must be obtained on a country-by-country or a region-by-region basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Furthermore, many international markets have government-managed healthcare systems that control reimbursement for new devices. In most markets, there are private insurance systems as well as government-managed systems. For more information regarding the process of receiving reimbursement approval, please see "Business—Market Strategy—Reimbursement."

We will be dependent upon third-party manufacturers and suppliers, making us vulnerable to supply shortages and problems, increased costs and quality or compliance issues, any of which could harm our business.

The MyoVista *wav*ECG device consists mostly of off-the-shelf components and once we are able to sell the MyoVista *wav*ECG, we will need to rely on third parties to supply components and assemble the components into a completed device. Any third-party supplier that we work with, and may eventually depend on, could encounter problems during sourcing and manufacturing that could delay or impede such supplier's ability to meet our

requirements. Any reliance on these third-party suppliers will also subjects us to other risks that could harm our business, including:

- we are not currently a major customer of any of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- we may not be able to obtain an adequate supply in a timely manner or on commercially reasonable terms;
- our suppliers may make errors in manufacturing that could negatively affect the efficacy or safety of our devices or cause delays in shipment;
- we may have difficulty locating and qualifying alternative suppliers;
- switching components or suppliers may require product redesign and possibly additional future submission(s) to the FDA or other similar foreign regulatory agencies, which could impede or delay our commercial activities;
- one or more of our suppliers may be unwilling or unable to supply components of our device;
- the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner; and
- our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

We may not be able to quickly establish additional or alternative suppliers if necessary, in part because we may need to undertake additional activities and incur additional expenses to establish such suppliers as required by the regulatory approval process. Any interruption or delay in obtaining products from our third-party suppliers, or our inability to obtain products from qualified alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to switch to competing products. Given our reliance on certain suppliers, we may be susceptible to supply shortages while looking for alternate suppliers.

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

The success of our products and services will be dependent upon our ability to perform computing functions associated with our cardiac focused AI-ECG algorithms and data management. The diagnostic processing 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 the 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.

Our proprietary data analytics engine may not operate properly, which could damage our reputation, give rise to claims against us or divert application of our resources from other purposes, any of which could harm our business and operating results.

The ECG data that is gathered through our products is evaluated using AI-based ECG algorithms that are part of our service. The continuous development, maintenance and operation of our deep-learned backend data analytics engine is expensive and complex, and may involve unforeseen difficulties including material performance problems, undetected defects or errors. We may encounter technical obstacles, and it is possible that we may discover additional problems that prevent our proprietary algorithms from operating properly. We may also attempt to develop new capabilities and incorporate new technologies, including AI, which could impact our data analytics platform's performance. If our data analytics platform does not function reliably or fails to meet physician or payor expectations

in terms of performance, physicians may stop prescribing our service and payors may attempt to deny coverage or payment for our products.

Any unforeseen difficulties we encounter in our existing or new software, cloud-based applications, telecommunication service providers, and analytics services, and any failure by us to identify and address them could result in loss of revenue or market share, diversion of development resources, injury to our reputation, increased service and maintenance costs, a recall of our products, modification of allowed indications, or a loss of regulatory approval of our products. Correction of defects or errors could prove to be impossible or impracticable. The costs incurred in correcting any defects or errors may be substantial and could adversely affect our operating results.

Medical device development is costly and involves continual technological change in order to remain competitive which may render our products obsolete.

Even if we are successful in obtaining regulatory clearance or approval for our products and are able to launch sales of our products into the U.S., our future success will depend on our ability to enhance our products as well as develop or acquire new technologies to keep pace with technological developments, evolving industry standards, as well as responses to changes in customer needs and expectations. The market for medical devices is unique due to factors such as: rapid technological change, medical advances, short device lifecycles, changing regulatory requirements and evolving industry standards.

Any one of these factors could either reduce potential demand for our products or require substantial resources and expenditures for, among other things, research, design and development, to avoid technological or market obsolescence. A failure to adequately develop enhancements and improvements to our products or acquire new devices that will address changing technologies and customer requirements adequately, or to introduce such devices on a timely basis, may have a material adverse effect on our business, financial condition and results of operations. We might have insufficient financial resources to improve our products at a competitive rate, if at all. Technological advances by one or more competitors or future entrants into the field may result in our products becoming non-competitive or obsolete, which may adversely affect our business and results of operations.

We face intense competition in the market and, as a result, we may be unable to effectively compete in our industry.

Many of our competitors, such as GE Healthcare, Philips and Baxter, have long histories and strong reputations within the industry. These competitors have significantly greater brand recognition, and financial and human resources than we do. They also have more experience and capabilities in researching and developing diagnostic devices, obtaining and maintaining regulatory clearances and other requirements, manufacturing and marketing those products than we do. There is a significant risk that we may be unable to overcome the advantages held by our competition, and our inability to do so could lead to the failure of our business and the loss of your investment. In addition, we may be unable to develop additional products in the future or to keep pace with developments and innovations in the market and lose market share to our competitors.

Medical device markets, and more specifically ECG technologies and solutions markets, are competitive, which can lead to, among other things, price reductions, longer selling cycles, lower product margins, loss of market share and additional working capital requirements. To succeed, we must, among other critical matters, gain consumer acceptance for our products as compared to other solutions currently available in the cardiac screening market or advanced cardiac screening offering. For more information regarding risks related to our dependence on physician acceptance, see “— Our success will be dependent upon physician acceptance.”

If our competitors offer significant discounts on certain products and solutions, we may need to lower our prices or offer other favorable terms in order to compete successfully. Any broad-based changes to our prices and pricing policies could make it difficult to generate revenues or cause our revenues to decline. Moreover, if our competitors develop and market products and solutions that are more effective or desirable than products and solutions than we may develop, we may not convince our customers to use our products and solutions. Any such changes would likely reduce our commercial opportunity and revenue potential and could materially adversely impact our operating results.

If we are not able to attract and retain highly skilled managerial, scientific, technical and marketing personnel, we may not be able to implement our business model successfully.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management as well as clinical and scientific personnel to implement our business strategy. We are highly dependent upon our senior management, our employees, consultants and scientific and medical collaborators. Our management team must be able to act decisively to apply and adapt our business model in the rapidly changing markets in which we will compete. In addition, we rely upon technical and scientific employees or third-party contractors to effectively establish, manage and grow our business. In order to attract and retain highly skilled managerial, sales, scientific and technical personnel, we may need to pay them higher compensation or fees than currently expected and such higher compensation may have a negative effect on our operating results. Competition for experienced, high-quality personnel in the medical device field is intense. Our failure to hire and retain quality personnel on acceptable terms could impair our ability to develop new products and services and manage our business effectively.

We may need to expand our organization and we may experience difficulties in recruiting additional employees and consultants, which could disrupt our operations.

As our development and marketing plans and strategies develop, we will likely need additional managerial, operational, sales, marketing, financial, legal and other resources. The competition for qualified personnel in the medical device industry is intense. Due to this intense competition, we may be unable to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Our management may need to divert its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require capital expenditures and may divert financial resources from other projects, such as the development of additional medical device products. If our management is unable to effectively manage our growth, our expenses may increase more than expected. Our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to market and sell medical device products and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our management team has limited experience managing a public company.

Some members of our management team have limited experience managing a publicly traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies in the United States. Our management team may not successfully or efficiently manage our recent transition to being a public company due to significant regulatory oversight and reporting obligations under the U.S. federal securities laws and the continuous scrutiny of securities analysts and investors. These new obligations and constituents will require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, any committees of our Board of Directors, or as executive officers and/or adversely affect our business, financial condition, results of operations and prospects.

We manage our business through a small number of employees and key consultants.

As of July 26, 2024, we had 15 full-time employees and several independent consultants. Our future growth and success depend, to a large extent, on the continued service of members of our current management. Any of our employees and contractors may leave our Company or discontinue services at any time. Our operational success will substantially depend on the continued employment of our management, including our executive officers, technical staff and other key personnel. We do not currently maintain key person life insurance policies on any of our employees. The loss of key personnel may have an adverse effect on our operations and financial performance and adversely affect our ability to execute our business plan.

We expect to conduct business outside of the U.S. and doing so exposes us to additional business, regulatory, political, operational, financial and economic risks.

We plan to conduct business outside of the U.S. which will therefore subject us to a number of risks, including, but not limited to, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses.

Since we anticipate conducting business outside of the U.S., we anticipate that we will be subject to rules and regulations in non-U.S. jurisdictions. In some countries, pricing may be subject to governmental control under certain circumstances. In these countries, pricing negotiations with governmental agencies can take considerable time after the receipt of marketing approval for a medical device. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We could face serious consequences for any violations of such laws and regulations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

We could become subject to product liability, warranty or similar claims and product recalls that could be expensive, divert management's attention and harm our business reputation and financial results.

Our business exposes us to an inherent risk of potential product liability, warranty or similar claims and product recalls. The medical device industry has historically been litigious, and we face financial exposure to product liability, warranty or similar claims if the use of our products were to cause or contribute to injury or death. There is also the possibility that defects in the design or manufacture of the MyoVista *wav*ECG device may necessitate a product recall. Although we plan to maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. In the future, we may be unable to maintain product liability insurance on acceptable terms or at reasonable costs and such insurance may not provide us with adequate coverage against potential liabilities. A product liability claim, regardless of merit or ultimate outcome, or any product recall could result in substantial costs to us, damage to our reputation, customer dissatisfaction and frustration and a substantial diversion of management attention. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cybersecurity.

Despite the implementation of security measures and safeguards intended to secure our data against impermissible access and to preserve the integrity and confidentiality of our data, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The

risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, including under data privacy and protection laws, damage to our reputation, disruption to our operations, and the further development of our products. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology, or IT, and infrastructure, we may be vulnerable to cyber-attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. We rely extensively on IT systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever- increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber- attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third- party providers. Although the aggregate impact on our operations and financial condition has not been material to date, we may become the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems that could materially and adversely affect our business, financial condition and results of operations. For a discussion of our management of cybersecurity risks, see Item 1C, "Cybersecurity".

Our business may be impacted by changes in general economic conditions.

Our business is subject to risks arising from changes in domestic and global economic conditions, including adverse economic conditions in the markets in which we operate, which may harm our business. If our future customers significantly reduce spending in areas in which our technology and products are utilized, or prioritize other expenditures over our technology and products, our business, financial condition, results of operations and prospects would be materially adversely affected.

Disruption to the global economy could also result in a number of follow-on effects on our business, including a possible slow-down resulting from lower customer expenditures; inability of customers to pay for products on time, if at all; more restrictive export regulations which could limit our potential customer base; negative impact on our liquidity, financial condition and share price, which may impact our ability to raise capital in the market, obtain financing and secure other sources of funding in the future on terms favorable to us.

In addition, the occurrence of catastrophic events, such as war, hurricanes, storms, earthquakes, tsunamis, floods, medical epidemics and other catastrophes that adversely affect the business climate in any of our markets could have a material adverse effect on our business, financial condition and results of operations. Some of our operations are located in areas that may be in the future, susceptible to such occurrences.

Our business and operations, and the operations of our suppliers and customers, have been in the past, and may in the future be adversely affected by epidemics, pandemic 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 outbreak of COVID-19 evolved into a global pandemic as COVID-19 spread to many regions of the world. The pandemic caused states of emergency to be declared in various countries, travel restrictions to be imposed globally and quarantines established in certain jurisdictions. The extent to which COVID-19 impacts our business and operating results may continue to depend on future developments that are uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, including variants, and the actions to contain COVID-19 or treat its impact, among others.

The spread of an infectious disease, such as COVID-19, may also result in the inability of our manufacturers to deliver components or finished products on a timely basis and may also result in the inability of our suppliers to deliver the parts required by our manufacturers to complete manufacturing of components or finished products. In addition, governments may divert spending from other budgeted resources as they seek to reduce and/or stop the spread of COVID-19. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. While the potential economic impact brought by the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from COVID-19 could materially and adversely affect our business and the value of our Common Stock.

Risks Related to Product Development and Regulatory Approval

Our products and operations are subject to extensive government regulation and oversight both in the U.S. and abroad, and our failure to comply with applicable requirements could harm our business.

Our products are subject to extensive regulation in the U.S. and elsewhere, including by the FDA and its foreign counterparts, the U.S. Department of Justice, or the DOJ, and the HHS. The FDA and foreign regulatory agencies regulate, among other things, with respect to our device: design, development and manufacturing; non-clinical and clinical testing, safety, efficacy, labeling, content and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, sales and distribution; pre-market clearance and approval; conformity assessment procedures; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to occur, could lead to death or serious injury; post-market approval studies; and product import and export.

The regulations our product is subject to are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales for any approved, cleared or authorized product. FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future regulatory inspections. Moreover, the FDA and state authorities have broad enforcement powers. Failure to comply with applicable regulations could jeopardize our ability to sell our future products, if cleared or approved, and result in enforcement actions such as: adverse publicity; warning, untitled letters, or it has come to our attention letters; fines; injunctions; consent decrees; civil penalties; customer notifications; repair, replacement, or refunds; termination of distribution; recalls or seizures of products; administrative detention of medical devices believed to be adulterated or misbranded; delays in the introduction of products into the market; operating restrictions; total or partial suspension of production; refusal to grant future clearances or approvals for new products, new intended uses or modifications to our device; withdrawals or suspensions of regulatory clearances or approvals in place, resulting in prohibitions on sales of our device; and in the most serious cases, criminal prosecution or penalties. The occurrence of any of these events would have a material adverse effect on our business, financial condition and results of operations and could result in shareholders losing their entire investment.

If and when our products are ready for sales launch into the U.S., modifications to our marketed products may require new 510(k) clearances or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

If a 510(k) classification is granted, any future modifications to the devices may require us to obtain FDA approval prior to implementing the change. The FDA requires every manufacturer to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new clearance or approval is necessary. The FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We may make modifications or add additional features in the future that we believe, based on FDA's regulatory framework, do not require a new 510(k) clearance or PMA. If the FDA disagrees with our determination and requires

us to submit new 510(k) notifications or even a PMA for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant enforcement actions. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or cancelled, which could adversely affect our ability to grow our business.

Clinical studies may be necessary to support future product submissions to the FDA. The clinical trial process is lengthy and expensive with uncertain outcomes, and often requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical studies will prevent us from launching sales of modified or new products into the U.S. and will adversely affect our business, operating results and prospects.

Initiating and completing clinical studies necessary to support any future PMA or De Novo applications, and additional safety and efficacy data beyond that typically required for a 510(k) clearance, for our possible future product candidates, will be time-consuming and expensive and the outcome uncertain. Moreover, the results of early clinical studies are not necessarily predictive of future results, and any product we advance into clinical studies may not have favorable results in later clinical studies. The results of preclinical studies and clinical studies of our devices conducted to date and ongoing or future studies and studies of our current, planned or future products may not be predictive of the results of later clinical studies, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical studies do not ensure that we will achieve similar results in future clinical studies. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical studies have nonetheless failed to replicate results in later clinical studies. Products in later stages of clinical studies may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical studies. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

The initiation and completion of any clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in our ongoing clinical studies for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical studies, including related to the following:

- we may be required to submit an IDE application to the FDA, which must become effective prior to commencing certain human clinical studies of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical studies;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical studies;
- regulators and/or an Institutional Review Board, or IRB, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of subjects or patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical studies at a higher rate than we anticipate;

- our third-party contractors, including those manufacturing products or conducting clinical studies on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical studies may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical studies may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- approval policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates.

Clinical studies must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical studies are conducted. Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical studies and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and able to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical studies if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts.

We depend on our collaborators and on medical institutions and CROs to conduct our clinical studies in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical studies, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of studies, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical studies that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical studies. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted sales launch of our products in the U.S. or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical studies, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

Medical device development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent advanced clinical studies. There is a high failure rate for medical devices proceeding through clinical studies, and product candidates in later stages of clinical studies may fail to show the desired sensitivity and specificity parameters despite having progressed satisfactorily through preclinical studies and initial clinical studies. A number of companies in the medical device industry have suffered significant setbacks in advanced clinical studies due to insufficient sensitivity and specificity or adverse safety profiles, notwithstanding promising results in earlier studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. We do not know whether any pivotal studies we may conduct will demonstrate consistent or adequate sensitivity and specificity sufficient to obtain regulatory approval to market our product candidates.

If the third parties on which we rely to conduct our clinical studies and to assist us with pre-clinical development do not perform as required or expected, we may be delayed or unable to obtain regulatory clearance or approval for sales launch of our products in the U.S.

We may not have the ability to independently conduct our pre-clinical and clinical studies for our future products and we may need to rely on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories to conduct such studies. We would depend on our collaborators and on medical institutions and CROs to conduct our clinical studies in compliance with GCP requirements and other regulatory requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical studies, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of studies, including achieving full enrollment, including on account of the outbreak of infectious disease, such as the COVID-19 pandemic, or otherwise, we may be affected by increased costs, program delays or both, any resulting data may be unreliable or unusable for regulatory purposes, and we may be subject to enforcement action.

If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully launch sales of, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected.

We may encounter substantial delays in our clinical studies, or we may fail to demonstrate specificity and sensitivity to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for sales launch of our products into the U.S., we must conduct extensive clinical studies to demonstrate its specificity and sensitivity. Clinical testing is expensive, time consuming and uncertain as to the outcome. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. Our clinical studies involve adults and, before we are permitted to enroll them in clinical studies, we must demonstrate that although the research may pose a risk to the subjects, there is a

prospect of direct benefit to each patient. We must do so to the satisfaction of each research site's IRB. If we fail to adequately demonstrate this to the satisfaction of the relevant IRB, it will decline to approve the research, which could have significant adverse consequences for us.

A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required IRB approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an IDE application, or equivalent application, or an inspection of our clinical study operations or study sites;
- delays in recruiting suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's GCP requirements, or applicable regulatory guidelines in other countries;
- delays in having patients complete participation in a study;
- patients dropping out of a study;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. We may also be required to conduct additional safety, efficacy and comparability studies before we will be allowed to start clinical studies. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to market products in the U.S. before we do, which could impair our ability to successfully launch sales of and market our product candidates and may harm our business and results of operations.

The results of future clinical studies may not support additional or new claims for future products or may result in the discovery of adverse side effects.

We cannot be certain that the results of our future clinical studies will support our claims for our current products or any future product claims or that the FDA will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the later studies will replicate the results of prior studies and pre-clinical studies. The clinical trial process may

fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical studies will delay the filing of our product submissions and, ultimately, our ability to launch sales of our product candidates and generate revenues. It is also possible that patients enrolled in clinical studies will experience adverse side effects that are not currently part of the future product's profile.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

If and when we receive regulatory clearance or approval of our product, we will remain subject to ongoing and pervasive regulatory requirements governing, among other things:

- the manufacture—as set forth in the FDA's Quality System Regulation, or QSR, requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provides adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;;
- medical device reporting, sale, promotion, import, export, registration, and listing of devices.
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared products;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with the new federal law and regulations requiring Unique Device Identifiers, or UDI, on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database, or GUDID;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory clearance or approval to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- adverse publicity;
- "it has come to our attention" letters, untitled letters or warning letters;

- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our device;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future clearances or approvals or foreign marketing authorizations of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of product clearances or approvals, resulting in prohibitions on sales of our device;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

In addition, the FDA or state or foreign authorities may change their clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may require, prevent or delay clearance or approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new clearances or approvals, increase the costs of compliance or restrict our ability to maintain any approvals we are able to obtain.

The MyoVista wavECG device must be manufactured in accordance with federal, state and foreign regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our device must comply with the FDA's Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. As manufacturers of electron radiation-emitting products, we are also responsible for compliance with the radiological health regulations and certain radiation safety performance standards.

Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which include the facilities of subcontractors. Our device is also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our device. In addition, failure to comply with applicable FDA or state or foreign requirements or later discovery of previously unknown problems with our device or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; seizures or recalls of our device; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our device; clinical holds; refusal to permit the import or export of our device; and criminal prosecution of us, our suppliers or our employees.

Any of these actions could significantly and negatively affect supply of our device. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

The misuse or off-label use of our products may harm our reputation in the marketplace, could potentially cause harm to the patient and lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Advertising and promotion of our future products that obtains approval in the United States may be heavily scrutinized by the FDA, the DOJ, HHS, state attorneys general, members of Congress, and the public. In addition, advertising and promotion of any future product that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities.

We expect that, if cleared or approved, our products will also be cleared by the requisite regulatory authorities for specific indications. We expect to train our marketing personnel and direct sales force to not promote our products for uses outside of the FDA-approved indications for use, known as "off-label uses." Physicians may use our devices off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. There may be increased risk of injury to patients if physicians attempt to use our devices off-label. Furthermore, the use of our devices for indications other than those approved by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among healthcare providers and patients.

If the FDA or any state or foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of a warning letter, an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties, which could have an adverse impact on our reputation and financial results. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations. We may become subject to such actions and, if we are not successful in defending against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations. Equivalent laws and potential consequences exist in foreign jurisdictions.

In addition, if our devices are cleared or approved, healthcare providers may misuse our devices or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Our devices may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our device, or a recall of our devices either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

If our products receive clearance, authorization, or approval, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA or other regulatory bodies could take action, including warning letters, untitled letters, administrative actions, criminal prosecution,

imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our device or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of marketed products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our device in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

The MyoVista wavECG device may in the future be subject to product recalls that could harm our reputation, business and financial results.

Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, software errors, design defects or labeling inadequacies affecting a medical device could lead to a government-mandated or voluntary recall by the device manufacturer, in particular when such deficiencies may endanger health. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our device in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Product recalls may divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers and adversely impact our business, financial condition and results of operations.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Many federal, state and foreign healthcare laws and regulations apply to medical devices. We may be subject to certain federal and state regulations, including the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, offering, receiving, or paying any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, ordering or arranging for or recommending the purchase or order of any item or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; the federal Civil Monetary Penalties Law, which authorizes the imposition

of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program; (3) violations of the federal Anti- Kickback Statute; or (4) failing to report and return a known overpayment; the federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services; the federal civil False Claims Act, or the FCA, which prohibits, among other things, knowingly presenting, or causing to be presented claims for payment of government funds that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to such a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government; and other federal and state false claims laws. The FCA prohibits anyone from knowingly presenting, conspiring to present, making a false statement in order to present, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. This law also prohibits anyone from knowingly underpaying an obligation owed to a federal program. Increasingly, U.S. federal agencies are requiring nonmonetary remedial measures, such as corporate integrity agreements in FCA settlements. The DOJ announced in 2016 its intent to follow the “Yates Memo,” taking a far more aggressive approach in pursuing individuals as FCA defendants in addition to corporations.

The majority of states also have statutes similar to the federal Anti-Kickback Statute and false claims laws that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, that apply regardless of whether the payor is a government entity or a private commercial entity. The Federal Open Payments, or Physician Payments Sunshine Act, program requires manufacturers of drugs, medical devices, and biologics for which payment is available under Medicare, Medicaid or the State Children’s Health Insurance Program, to track and report annually to the federal government (for disclosure to the public) certain payments and other transfers of value made to physicians and teaching hospitals as well as disclosure of payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests in the manufacturer held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations. Our failure to appropriately track and report Sunshine Act covered payments to the government could result in civil fines and penalties, which could adversely affect the results of our operations. In addition, several U.S. states and localities have enacted legislation requiring medical device companies to establish marketing compliance programs, file periodic reports with the state, and/or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Other state laws prohibit certain marketing-related activities including the provision of gifts, meals or other items to certain healthcare providers. Many of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

The medical device industry has been under heightened scrutiny as the subject of government investigations and enforcement actions involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including arrangements with physician consultants. If our operations or arrangements are found to be in violation of such governmental regulations, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment of our operations. All of these penalties could adversely affect our ability to operate our business and our financial results.

Legislative or regulatory reforms in the United States or the European Union may make it more difficult and costly for us to obtain regulatory clearances or approvals for our devices or to manufacture, market or distribute our devices after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Any new regulations or revisions or reinterpretations of existing regulations may impose

additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our device. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance for or approval of, manufacture, market or distribute our device. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our device; or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our future products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, certain forthcoming policies of the Biden administration could impact our business and industry. It is difficult to predict what policies may be implemented or how any such executive actions will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If executive actions or new policies impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval or clearance that we may have obtained and we may not achieve or sustain profitability.

The European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. Among other things, the Medical Devices Regulation:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for follow-up regarding the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthened rules for the assessment of certain high-risk devices, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an effect on the way we conduct our business in the EEA.

Healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. In the United States and some foreign jurisdictions, there have been, and continue to be, legislative and regulatory changes and proposed changes regarding the healthcare system and how its costs should be controlled or managed. Certain of these proposals could limit the prices we are able to charge for our devices or the coverage and reimbursement available for our devices and could limit the acceptance and availability of our products. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that are directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or

their full impact. Additionally, it remains unclear how any new legislation or regulation might affect the prices we may obtain for any of our products for which regulatory approval is obtained. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or market our device.

Recently, there has been heightened governmental scrutiny over the manner in which companies set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase, and which suppliers will be included in their healthcare programs. Adoption of price controls and other measures designed to restrict spending or purchasing power may prevent or limit our ability to generate revenue and attain profitability.

In addition, the delivery of healthcare in the European Union, including the establishment and operation of health services, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval, restrict or regulate post-approval activities and affect our ability to launch sales of any products for which we obtain marketing approval.

We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry may be enacted in the future or what effect recently enacted federal legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in the price of our Common Stock or limit our ability to raise capital or to enter into collaboration agreements for the further development and potential marketing of our device.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared or approved or launched for sale into the U.S. in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices or modifications to cleared or approved medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in response to the COVID-19 pandemic, in March of 2020 the FDA postponed most inspections of foreign manufacturing and domestic facilities. Although limited inspections were again initiated in 2021, FDA also utilized alternative methods for inspections and could continue to exercise discretion on a case-by-case basis to approve products based on a desk review, particularly for foreign inspections. If a prolonged government shutdown occurs, or if global health concerns continue to prevent or temporarily restrict the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns

continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Changes in laws or regulations relating to data protection, or any actual or perceived failure by us to comply with such laws and regulations or our privacy policies, could materially and adversely affect our business or could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

In the normal course of business, we will receive health information and other highly sensitive or confidential information and data of patients and other third parties, which we compile and analyze. Our collection and use of this data, including that of our vendors, might raise privacy and data protection concerns, which could negatively impact our business. There are numerous federal, state and international laws and regulations regarding privacy, data protection, information security, and the collection, storing, sharing, use, processing, transfer, disclosure, and protection of personal information and other data, and the scope of such laws and regulations may change, be subject to differing interpretations, and may be inconsistent among countries and regions we intend to operate in (e.g., the United States and the European Union),or conflict with other laws and regulations. The regulatory framework for privacy and data protection worldwide is, and is likely to remain for the foreseeable future, uncertain and complex, and this or other actual or alleged obligations may be interpreted and applied in a manner that we may not anticipate or that is inconsistent from one jurisdiction to another. Further, any significant change to applicable laws, regulations, or industry practices regarding the collection, use, retention, security, or disclosure of data, or any changes regarding the manner in which the consent of relevant users for the collection, use, retention, or disclosure of such data must be obtained, could increase our costs and require us to modify our services and products, possibly in a material manner, which we may be unable to complete, and may limit our ability to store and process patients' data or develop new services and features.

In particular, we are subject to U.S. data protection laws and regulations (i.e., laws and regulations that address privacy and data security of personal information) at both the federal and state levels. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. Numerous federal and state laws, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, and disclosure of health-related and other personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant civil or criminal penalties), private litigation and/or adverse publicity that could negatively affect our business.

In addition, we expect to obtain health information that is subject to privacy and security requirements under HIPAA and its implementing regulations. The Privacy Standards and Security Standards under HIPAA establish a set of standards for the protection of individually identifiable health information by health plans, health care clearing houses and certain health care providers, referred to as Covered Entities, and the business associates with whom Covered Entities enter into service relationships pursuant to which individually identifiable health information may be exchanged. Notably, whereas HIPAA previously directly regulated only Covered Entities, HITECH makes certain of HIPAA's privacy and security standards also directly applicable to Covered Entities' business associates. As a result, both Covered Entities and business associates are now subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards. As part of our normal operations, we expect to collect, process and retain personal identifying information regarding patients, including as a business associate of Covered Entities, so we expect to be subject to HIPAA, including changes implemented through HITECH, and we could be subject to criminal penalties if we improperly handle or knowingly obtain or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA. A data breach affecting sensitive personal information, including health information, also could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. HIPAA requires Covered Entities (like many of our potential customers) and business associates (like us) to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. HITECH expands the notification requirement for breaches of patient-identifiable health information, restricts certain disclosures and sales of patient-identifiable health information, and provides for civil monetary penalties for HIPAA violations. HITECH also increased the civil and criminal penalties that may be imposed against Covered Entities and business associates and

gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and its implementing regulations and seek attorney's fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA.

In addition, certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, thus, complicating compliance efforts. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California enacted the California Consumer Privacy Act, or CCPA, which creates individual privacy rights for California consumers (as defined in the law), including the right to opt out of certain disclosures of their information, and places increased privacy and security obligations on entities handling certain personal data of consumers or households and may apply to us in the future. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Further, the California Privacy Rights Act, or CPRA, was recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for sensitive data such as health information, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions have gone into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CCPA and CPRA are reflective of a trend toward more stringent privacy legislation in the United States, as other states or the federal government have followed or may follow California's lead and increase protections for U.S. residents. For example, on March 2, 2021, the Virginia Consumer Data Protection Act, which went into effect on January 1, 2023, was signed into law, and on July 8, 2021 the Colorado Privacy Act, which took effect on July 1, 2023, was also signed into law. The CCPA has already prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, add layers of complexity to compliance in the U.S. market, increase our compliance costs and adversely affect our business.

Internationally, many jurisdictions have or are considering enacting privacy or data protection laws or regulations relating to the collection, use, storage, transfer, disclosure and/or other processing of personal data, as well as certification requirements for the hosting of health data specifically. Such laws and regulations may include data hosting, data residency or data localization requirements (which generally require that certain types of data collected within a certain country be stored and processed within that country), data export restrictions, international transfer laws (which prohibitor impose conditions upon the transfer of such data from one country to another), or may require companies to implement privacy or data protection and security policies, enable users to access, correct and delete personal data stored or maintained by such companies, inform individuals of security breaches that affect their personal data or obtain individuals' consent to use their personal data.

The General Data Protection Regulation (the "GDPR"), which went into effect in May 2018, imposes stringent requirements for controllers and processors of personal data of individuals within the EEA. As Switzerland and the United Kingdom are not part of the European Union they enforce separate laws governing personal data, which are derived from or directly based on the GDPR. The GDPR applies to any company established in the EEA as well as to those outside the EEA if they collect, process, and use personal data in connection with the offering of goods or services to individuals in the EEA or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA countries governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions involve the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA to jurisdictions deemed to have inadequate data protection laws, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the European Union, or EU, and the United States remains uncertain. In 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union, (the "CJEU"). While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. The European Commission has published revised standard contractual clauses for data transfers from the EEA: the revised clauses must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must have been migrated to the revised clauses by December 27, 2022. If applicable, we would be required to implement the revised standard contractual clauses, in relation to relevant existing contracts and certain additional contracts and arrangements, within the relevant time frames. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR.

While we implement various measures intended to enable us to comply with applicable privacy or data protection laws, regulations and contractual obligations, these measures may not always be effective and do not guarantee compliance. Any failure or perceived failure by us to comply with our contractual or legal obligations or regulatory requirements relating to privacy, data protection, or information security may result in governmental investigations or enforcement actions, litigation, claims, or public statements against us by consumer advocacy groups or others and could result in significant liability, cause our customers, partners or patients to lose trust in us, and otherwise materially and adversely affect our reputation and business. Furthermore, the costs of compliance with, and other burdens imposed by, the laws, regulations, and policies that are applicable to the businesses of our customers or partners may limit the adoption and use of, and reduce the overall demand for, our device. Additionally, if third parties we work with violate applicable laws, regulations, or agreements or suffer data breaches such violations or data breaches may put the data we have received at risk, could result in governmental investigations or enforcement actions, fines, litigation, claims, or public statements against us by consumer advocacy groups or others and could result in significant liability, cause our customers, partners or patients to lose trust in us, and otherwise materially and adversely affect our reputation and business. Further, public scrutiny of, or complaints about, technology companies or their data handling or data protection practices, even if unrelated to our business, industry or operations, may lead to increased scrutiny of technology companies, including us, and may cause government agencies to enact additional regulatory requirements, or to modify their enforcement or investigation activities, which may increase our costs and risks.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain effective patent rights for our products, we may not be able to compete effectively in our markets. If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

Our success and future revenue growth will depend, in part, on our ability to protect our patent rights. In addition to the protection afforded by any patents that may be granted, historically, we have relied on trade secret protection and confidentiality agreements with our employees, consultants, and contractors to protect proprietary know-how that is not patentable or that we elect not to patent, processes that are not easily known, knowable, or easily ascertainable, and for which patent infringement is difficult to monitor and enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, agreements may be breached, trade secrets may be difficult to protect, and we may not receive

adequate remedies for any breach. In addition, our trade secrets and intellectual property may otherwise become known or be independently discovered by competitors or other unauthorized third parties.

There is no guarantee that the patent applications that we submitted with regards to our technologies will result in patent grants. In the event of failure to obtain patent registration, our developments will not be proprietary, which might allow other entities to manufacture our device and compete with them.

Further, there is no assurance that all potentially relevant prior art relating to our patent applications has been found, which can invalidate a patent or prevent a patent from being issued from a pending patent application. Even if patents are successfully issued, and even if such patents cover our products, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patent applications and any future patents may not adequately protect our intellectual property, products and provide exclusivity for our new products or future services or prevent others from designing around our claims. Furthermore, there is no guarantee that third parties will not infringe or misappropriate our patents or similar proprietary rights. In addition, there can be no assurance that we will not have to pursue litigation against other parties to assert its rights.

Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If we cannot obtain and maintain effective patent rights for our products, we may not be able to compete effectively, and our business and results of operations would be harmed.

We cannot provide any assurances that our trade secrets and other confidential proprietary information will not be disclosed in violation of our confidentiality agreements or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Also, misappropriation or unauthorized and unavoidable disclosure of our trade secrets and intellectual property could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets and intellectual property are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret.

The patent position of medical device companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation within our industry. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Further, the issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and in-licensed patents may be challenged, invalidated or legally circumvented by third parties, or may expire. We cannot be certain that our patents will be upheld as valid and enforceable or will prevent the development of competitive products by third parties. For example, we may become involved in opposition, interference, derivation, *inter partes* review or other proceedings challenging our patent rights, and the outcome of any proceedings are highly uncertain. Such challenges may result in the patent claims of our owned or in-licensed patents being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or marketing similar or identical technology and products, or limit the duration of the patent protection of our products and technology. Consequently, competitors could develop, manufacture and sell products that directly compete with our products, which could decrease our sales and affect our ability to compete. In addition, competitors could attempt to reverse engineer our device to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology, or develop their own competitive technologies that fall outside the scope of our patents. If our intellectual property does not adequately protect us from our competitors' products and methods, our business and competitive position could be adversely affected. We may in the future become involved in litigation to protect the patents associated with our products, which could result in substantial costs and distraction to management and other employees.

Intellectual property rights of third-parties could adversely affect our ability to market our products, and we might be required to litigate or obtain licenses from third parties in order to develop or market our products. Such litigation or licenses could be costly or not available on commercially reasonable terms.

It is inherently difficult to conclusively assess our freedom to operate without infringing on third-party rights. Our competitive position may be adversely affected if existing patents or patents resulting from patent applications issued to third parties in the future or other third-party intellectual property rights are held to cover our products or elements thereof, or our manufacturing or uses relevant to our development plans. In such cases, we may not be in a position to develop or market products or services unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may also be pending patent applications that if they result in issued patents, could be alleged to be infringed by our new products or services. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, be forced to abandon our new products or services or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our new products could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our services, our new products or the use of our new products. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in pursuing the development of and/or marketing our new products or services. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from selling or marketing our new products or services that are held to be infringing. We might, if possible, also be forced to redesign our new products so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may be subject to claims challenging the inventorship of our intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in, or right to compensation, with respect to our current patent and patent applications, future patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our device. Litigation may be necessary to defend against these and other claims challenging inventorship or claiming the right to compensation. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Such litigation or proceedings could increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Some of our competitors may be able to devote significantly more resources to intellectual property proceedings, and may have significantly broader intellectual property portfolios to assert against us if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised leading to others making, using, importing or selling products that are the same or substantially the same as ours, which could adversely affect our ability to compete in the market.

We may be involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our intellectual property. If we were to initiate legal proceedings against a third- party to enforce a patent covering one of our new products or services, the defendant could counter claim that the patent covering our product is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are common place. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or USPTO, or made a misleading statement, during prosecution. Under the Leahy-Smith Act, the validity of U.S. patents may also be challenged in post-grant proceedings before the USPTO. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Derivation proceedings initiated by third parties or brought by us may be necessary to determine the priority of inventions and/or their scope with respect to our patent or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us launch sales of new products or services into the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our Common Stock.

Third-party claims of intellectual property infringement may prevent or delay our development and marketing efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing new products and services. As our industries expand and more patents are issued, the risk increases that our products may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There maybe third-party patents or patent applications with claims to materials, designs or methods of manufacture related to the use or manufacture of our products. There may be currently pending patent applications or continued patent applications that may later result in issued patents that our products may infringe. In addition, third parties may obtain patents or services in the future and claim that use of our technologies infringes upon these patents.

If any third-party patents were held by a court of competent jurisdiction to cover aspects of our processes for designs, or methods of use, the holders of any such patents may be able to block our ability to develop and market the applicable product unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and market our device. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or services, or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of any patents that may issue from our patent applications or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we were the first to file the invention claimed in our owned and licensed patent or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming all other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention without undue delay in filing, is entitled to the patent, while generally outside the United States, the first to file a patent application is entitled to the patent.

After March 15, 2013, under the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could have a material adverse effect on our business and financial condition.

The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of the patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Further, because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on products and services, as well as monitoring their infringement in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States.

Competitors may use our technologies develop their own products or services in jurisdictions where we have not obtained patent protection to and may export infringing products or services to territories where we have patent protection, but where patents are not enforced as strictly as they are in the United States. These products or services may compete with our devices or services. Future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor

the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to stop the marketing of competing products or services in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly, put the issuance of our patent applications at risk, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and any damages or other remedies that we may be awarded, may not be commercially meaningful. Accordingly, our efforts to monitor and enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Our License Agreements with Mount Sinai

We are highly dependent on the Licenses, the termination of which may prevent us from commercializing our products, and which imposes significant obligations on us.

We are highly dependent on the intellectual property licensed from Mount Sinai, pursuant to which we aim to incorporate the licensed technology for use and development in our MyoVista products. Other products or services we may develop also may rely on the same technology. In the event that we fail to uphold development obligations under our Licenses with Mount Sinai, Mount Sinai could terminate our Licenses. Any termination of the Licenses resulting in the loss of the licensed rights would prevent us from marketing and selling our anticipated MyoVista products and any other products or services we may develop based on such underlying licensed technology. Any termination of the exclusivity of the license, in those cases where applicable, could damage our competitive position within the marketplace.

Furthermore, the License Agreements impose significant obligations on us. We will be required to pay Mount Sinai royalties in low-single digit percentages of annual net sales of licensed products sold by us and a share of any sublicense revenue received by us from sublicensees of the licensed products as well as achieve the milestones prescribed by the License Agreements and Securities Purchase Agreement.

Our future financial performance will depend in part on the successful integration, improvement and software updates from the Mount Sinai algorithms.

Our future financial performance will depend in part on our ability to influence, anticipate, identify and respond to changing consumer preferences and needs and the technologies relating to the care and treatment of heart disease. We can provide no assurances that the Mount Sinai algorithms and products will be successfully integrated, achieve significant commercial success and gain meaningful market share. We may not correctly anticipate or identify trends in consumer preferences or needs or may identify them later than competitors do. In addition, difficulties in manufacturing or in obtaining regulatory approvals due to integrating the Mount Sinai algorithms or providing a cloud-based environment to host the algorithms may delay or prohibit our algorithm-based product offerings from completing the development process. Further, we may not be able to develop improvements and software updates to our “EKG” product at a cost that allows us to meet our goals for profitability. Service costs relating to our product may be greater than anticipated and we may be required to devote significant resources to address any quality issues associated with our product.

Failure to successfully introduce, improve or update our products on a cost-effective basis, or delays in customer decisions related to the evaluation of our products could cause us to lose market acceptance and could materially adversely affect our business, financial condition and results of operations.

Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce the algorithms underlying the Mount Sinai Licenses to the market in a timely manner. If we do not obtain and maintain the regulatory registrations and clearances for the algorithms, we will be unable to market and sell our products utilizing the Licenses in the United States, Europe or other regions.

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to, an existing product, we must first receive either approval of a Premarket Approval Application, or PMA, clearance under Section 510(k), or be granted a De Novo classification, in accordance with the FDCA. For

additional information on the PMA or the De Novo classification processes, see “Business — FDA and Other Government Regulation.”

The FDA can delay, limit or deny clearance or approval of a medical device for many reasons, including:

- we may not be able to demonstrate to the FDA’s satisfaction that the algorithms underlying the Mount Sinai Licenses are safe and effective for its intended use;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use or contract to use may not meet applicable requirements.

Sales of our products outside of the United States and the EEA are also subject to foreign regulatory requirements that vary widely from country to country. Approval procedures vary among countries and can involve additional testing. Complying with foreign regulatory requirements, including obtaining registrations, clearances or approvals, can be expensive and time-consuming, and we may not receive regulatory clearances or approvals in each country in which we plan to market our device, or we may be unable to do so on a timely basis. If we modify our device, we may need to apply for additional regulatory clearances or approvals before we are permitted to sell the modified device. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable device in that country.

Regulatory clearance or approval by the FDA does not ensure registration, clearance or approval by regulatory authorities in other countries, and registration, clearance or approval by one or more foreign regulatory authorities does not ensure registration, clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining registration or regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

Risks Related to the Ownership of our Securities

The market price of our Common Stock may be highly volatile, and you could lose all or part of your investment.

The market price of our Common Stock 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. This volatility could be the result of a variety of factors, which include:

- whether we achieve our anticipated corporate objectives;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in our financial or operational estimates or projections;
- our ability to implement our operational plans;
- termination of lock-up agreements or other restrictions on the ability of our shareholders to sell shares after the IPO;
- changes in the economic performance or market valuations of companies similar to ours;
- general economic or political conditions in the U.S. or elsewhere; and
- other events or factors, including those resulting from war, incidents of terrorism or responses to these events.

In addition, the stock market in general, and the stock of publicly-traded medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of such companies. Broad market and industry factors may negatively affect the market price

of our Common Stock and IPO Warrants, regardless of our actual operating performance, and we have little or no control over these factors.

Future sales and issuances of our Common Stock or rights to purchase our Common Stock, including pursuant to our Equity Incentive Plan 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. As of July 26, 2024, there were 855,966 shares of our Common Stock outstanding. In addition, as of July 26, 2024 there were 380,440 shares of Series C Preferred Stock outstanding that, as of such date, were convertible into 72,546 shares of Common Stock and options and warrants exercisable for 84,170 shares of our Common Stock.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they publish negative reports regarding our business or our securities, our share price and trading volume could decline.

The trading market for the Common Stock and the IPO Warrants will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding the Common Stock or IPO Warrants, or provide more favorable relative recommendations about our competitors, the price of our Common Stock and IPO Warrants would likely decline. If any analyst who may cover us were to cease coverage of our Company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our Common Stock and IPO Warrants or trading volume to decline.

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.

Prior to the completion of the IPO, we had been a private company with limited accounting personnel to adequately execute our accounting processes and limited supervisory resources with which to address our internal control over financial reporting. While a private company, we had not designed or maintained an effective control environment as required of public companies under the rules and regulations of the SEC. Management and our independent registered public accounting firm, Haskell & White LLP, identified several material weaknesses in our internal control over financial reporting in connection with our preparation and the audits of our financial statements for Fiscal 2024.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financing reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses we and our independent registered public accounting firms identified are listed below:

- lack of proper approval processes and review processes and documentation for such reviews;
- we did not maintain sufficient U.S. GAAP and SEC accounting resources commensurate with those required of a public company; and
- insufficient number of staff to maintain optimal segregation of duties and levels of oversight.

These material weaknesses resulted in adjustments to our prior year financial statements primarily related to equity accounts, accruals, and inventory and could result in a misstatement of any account balances or disclosures that

would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

During Fiscal 2024, we have taken and continue to take remedial steps to improve our internal controls over financial reporting, which includes establishing a more robust process related to review of complex accounting transactions, preparation of account reconciliations, and review of journal entries. Our Chief Financial Officer frequently attends continuing education for updates on accounting policies and procedures. We cannot assure you that these measures will significantly improve or remediate the material weaknesses described above. Management is monitoring the effectiveness of these and other processes, procedures and controls and will make any further changes deemed appropriate. Management believes the foregoing actions will effectively remediate the material weaknesses, however, our material weaknesses will not be considered remediated until controls are in place for a period of time, the controls are tested, and management concludes that the controls are properly designed and operating effectively. As a result, the timing of when we will be able to fully remediate the material weaknesses is uncertain. If the steps we take do not remediate the material weaknesses in a timely manner, there could continue to be a reasonable possibility that these control deficiencies or others would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected on a timely basis. This, in turn, could jeopardize our ability to comply with our reporting obligations, limit our ability to access the capital markets and adversely impact our stock price.

Our independent registered public accounting firm was not required to perform an evaluation of our internal control over financial reporting as of either April 30, 2024 or April 30, 2023 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting in the future as required by reporting requirements under Section 404 of the Sarbanes-Oxley Act.

If we are unable to successfully remediate the existing material weaknesses in our internal control over financial reporting, the accuracy and timing of our financial reporting, and our stock price, may be adversely affected and we may be unable to maintain compliance with the applicable stock exchange listing requirements. Implementing any appropriate changes to our internal controls may divert the attention of our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are adequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our services to new and existing customers.

Our Board of Directors is authorized to issue and designate shares of our preferred stock in additional series without shareholder approval.

Our amended and restated certificate of formation authorizes our Board of Directors, without the approval of our shareholders, to issue shares of our preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of formation, as shares of preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences, privileges and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of preferred stock may be senior to or on parity with our Common Stock, which may reduce its value.

As of July 26, 2024 our principal shareholders, officers and directors beneficially own approximately 14.3% of our Common Stock. They will therefore be able to exert significant control over matters submitted to our shareholders for approval.

As of July 26, 2024, our principal shareholders, officers and directors beneficially owned approximately 14.3% of the outstanding shares of our Common Stock, including shares issuable pursuant to antidilution provisions set forth in the Series C Preferred Stock. This significant concentration of share ownership may adversely affect the trading price for our Common Stock because investors often perceive disadvantages in owning shares in companies with

controlling shareholders. As a result, these shareholders, if they acted together, could significantly influence or even unilaterally approve matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these shareholders may not always coincide with our interests or the interests of other shareholders. For more information regarding the beneficial ownership of such principal shareholders, officers and directors, see "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters."

We have incurred and will continue to incur significant costs as a result of the listing of our securities for trading on Nasdaq. As a public company in the U.S., our management is required to devote substantial time to new compliance initiatives as well as compliance with ongoing U.S. requirements.

Upon the listing of securities on Nasdaq, we became a publicly traded company in the United States and as such, we are incurring significant accounting, legal and other expenses that we did not incur before the IPO. We also are incurring costs associated with corporate governance requirements of the SEC, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act. We expect these rules and regulations to continue to increase our legal and financial compliance costs, introduce new costs such as investor relations, stock exchange listing fees and shareholder reporting, and to make some activities more time consuming and costly. The implementation and testing of such processes and systems may require us to hire outside consultants and incur other significant costs. Any future changes in the laws and regulations affecting public companies in the United States, including Section 404 and other provisions of the Sarbanes-Oxley Act, and the rules and regulations adopted by the SEC, for so long as they apply to us, will result in increased costs to us as we respond to such changes. These laws, rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, any committees of our Board of Directors, or as executive officers.

We may be subject to securities litigation, which is expensive and could divert management attention.

In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could seriously hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

We have never paid cash dividends on our Common Stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have neither declared nor paid cash dividends, and we do not anticipate paying cash dividends in the foreseeable future. Therefore, you should not rely on an investment in Common Stock as a source for any future dividend income. Our Board of Directors has complete discretion as to when or whether to distribute dividends. Even if our Board of Directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board of Directors.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to "emerging growth companies" will make our Common Stock or IPO Warrants less attractive to investors.

We are an "emerging growth company," as defined in Section 2(a)(19) of the Securities Act, and for as long as we continue to be an emerging growth company, we may choose to take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company," among other exemptions, we will:

- not be required to engage an independent registered public accounting firm to report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;

- not be required to comply with the requirement in Public Company Accounting Oversight Board Auditing Standard 3101, The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion, to communicate critical audit matters in the auditor's report;
- be permitted to present only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our periodic reports and registration statements, including in this prospectus;
- not be required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation; or
- not be required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay,""say-on-frequency," and "say-on-golden parachutes."

In addition, the JOBS Act also permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies, meaning that we can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period and, as a result, our financial statements may not be comparable with similarly situated public companies.

We will remain an "emerging growth company" until the earliest to occur of (1) our reporting of $1.235 billion or more in annual gross revenue; (2) our becoming a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (3) our issuance, in any three-year period, of more than $1.0 billion in non-convertible debt; and (4) 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.

We cannot predict if investors may find our Common Stock or IPO Warrants less attractive if we rely on the exemptions and relief granted by the JOBS Act. For example, if we do not adopt a new or revised accounting standard, our future results of operations may not be as comparable to the results of operations of certain other companies in our industry that adopted such standards. If some investors find our Common Stock or IPO Warrants less attractive as a result, there may be a less active trading market for our Common Stock or IPO Warrants and our stock price may decline and/or become more volatile.

Anti-takeover provisions could make a third party acquisition of us difficult.

Our amended and restated certificate of formation and amended and restated bylaws eliminate the ability of shareholders to take action by less than unanimous written consent. This provision could make it more difficult for a third party to acquire us without the approval of our board. In addition, the Texas Business Organizations Code (the "TBOC") also contains certain provisions that could make an acquisition by a third party more difficult.

Provisions of the IPO Warrants, the Remaining Bridge Warrants and our Series C Preferred Stock could discourage an acquisition of us by a third party.

In addition to the provisions of our Certificate of Formation and Bylaws, certain provisions of the IPO Warrants, the Remaining Bridge Warrants and the Series C Preferred Stock could make it more difficult or expensive for a third party to acquire us. The terms of the IPO Warrants, the Remaining Bridge Warrants and the Series C Preferred Stock prohibit us from engaging in certain transactions constituting "fundamental transactions" or a "Deemed Liquidation Event", unless, among other things, the surviving entity assumes our obligations under the IPO Warrants, the Remaining Bridge Warrants or the Series C Preferred Stock. These and other provisions of the IPO Warrants, the Remaining Bridge Warrants or the Series C Preferred Stock could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to investors.

Financial Industry Regulatory Authority, Inc. ("FINRA") sales practice requirements may limit a stockholder's ability to buy and sell our shares Common Stock.

FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for certain customers. FINRA requirements will likely make it more difficult for broker-dealers to recommend that their customers buy our shares of Common Stock, which may have the effect of reducing the level of trading activity in our Common Stock. As a result, fewer broker- dealers may be willing to make a market in our Common Stock, reducing a stockholder's ability to resell shares of our Common Stock.

If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on Nasdaq and if the price of our Common Stock is less than $5.00, our Common Stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our Common Stock or IPO Warrants, and therefore shareholders may have difficulty selling their shares of Common Stock or IPO Warrants.

Item 1B. Unresolved Staff Comments.

None

Item 1C. Cybersecurity

Risk Management and Strategy

We utilize a combination of manual processes, specialized software and automated tools, and third-party assessments to assist with our cybersecurity efforts. We engage third-party service providers, with significant information technology and cybersecurity experience, to assist with designing, implementing and managing our information technology infrastructure and cybersecurity program. We consider the cybersecurity practices of our third-party service providers, including through a general security assessment and contractual requirements, as appropriate, before engaging them in order to help protect us from any related vulnerabilities.

Governance

Our third party service provider, alongside our senior management leads the operational oversight of the company-wide cybersecurity strategy, policy, standards and processes. As a smaller reporting Company, we do not have an employee who has significant and demonstrated professional IT management experience and possesses the requisite education, skills and experience expected to perform such a duty. The audit committee of the board of directors intends to provide oversight of our cybersecurity risk as part of its periodic review of enterprise risk management. Additionally, the board of directors intends to review our enterprise risk management processes and will be notified by management between management updates regarding significant new cybersecurity threats or incidents.

As of the date of this Annual Report on Form 10-K, we are not aware of any cybersecurity threats that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. No matter how well designed or implemented our internal controls are, we will not be able to

anticipate all cybersecurity threats, and we may not be able to implement effective preventive or detective measures against such security breaches in a timely manner. While we maintain insurance that may cover certain liabilities in connection with certain disruptions, security breaches, and incidents, there can be no guarantee that our insurance coverage will be adequate to compensate us for the potential losses.

Item 2. Properties.

The Company leases a 4,634 square foot suite located at 550 Reserve Street, Suite 360, Southlake, Texas 76092, pursuant to an Office Lease, dated May 2, 2017, by and between the Company and GPI-MT, LP. The lease was a 64-month lease and was amended on September 27, 2022, extending the lease term for an additional 64 months, commencing on February 1, 2023 and expiring on May 31, 2028. We consider our current office space sufficient to meet our anticipated needs for the foreseeable future and believe it is suitable for the conduct of our business.

Item 3. Legal Proceedings.

There are no actions, suits, proceedings, inquiries or investigations before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the executive officers of the Company, threatened against or affecting the 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 Shareholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our Common Stock and IPO Warrants are traded on Nasdaq under the symbols "HSCS" and "HSCSW," respectively. The closing price of our Common Stock and IPO Warrants on Nasdaq on July 26, 2024 was $4.58 and $0.03, respectively.

Holders

As of July 26, 2024, there were approximately 292 holders of record of our Common Stock. As many of our shares of Common Stock are held by brokers and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders 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 revenue and earnings, if any, capital requirements and general financial condition, and will be within the discretion of our then-existing board of directors.

Recent Sales of Unregistered Securities

The following sets for information regarding all unregistered securities sold by the registrant in the three years preceding the date of this Annual Report on Form 10-K. All Common Stock share and per share data, and exercise price data for applicable Common Stock equivalents, included below have been retroactively adjusted to give effect to the Reverse Stock Split.

- In July 2021 and November 2021, the Company issued warrants to purchase 231 shares of Common Stock in exchange for consulting services and extensions of the $1M Loan and Security Agreement and $1.5M Notes. See "Description of Securities—$1M Lender Warrants and $1.5M Lender Warrants" for a description of these warrants. These warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act.

- In August 2021, the Company issued 101 shares of Common Stock as a facility fee in connection with debt for non-cash consideration amounting to $35,000. These shares were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act.

- From October 2021 to February 2022, in connection with the 2021 Bridge Securities, the Company issued Bridge Warrants to purchase 13,677 shares of Common Stock (as adjusted following consummation of the IPO, as required under the terms of the Bridge Warrants). See "Description of Securities—Warrants issued in connection with the 2021 Bridge Financing" for a description of the Bridge Warrants. Upon consummation of the IPO, and as required under the terms of the Bridge Notes, the Company issued 16,061 shares of Common Stock and Pre-Funded Warrants to purchase 775 shares of Common Stock from the conversion of the Bridge Notes. See "Description of Securities—Warrants issued in connection with the 2021 Bridge Financing" for a description of the Pre-Funded Warrants. The Bridge Warrants and the Pre-Funded Warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act. The Benchmark Company, LLC served as the underwriter for the 2021 Bridge Securities and was paid $94,500 in compensation.

- In June 2022, as a result of the IPO, as required under the terms of the $1.5M Notes, the Company issued 9,091 shares of Common Stock from the conversion of the $1.5M Notes. These shares were issued in reliance on the exemption from registration provided by Section 4(a)(2) and/or Section 3(a)(9) of the Securities Act.

• In June 2022, as a result of IPO, the Series B convertible preferred stock, par value $0.001 per share, was cancelled and we issued 7,033 shares of Common Stock to certain officers, prior directors and employees in connection with the conversion of the Series A convertible preferred stock, par value $0.001 per share.

• In July 2022, August 2022, October 2022, February 2023, and July 2023 we issued an aggregate of 2,426 shares of Common Stock without the payment of additional consideration upon the conversion of 88,025 shares of Series C Preferred Stock by holders. Such shares of Common Stock were issued in reliance on the exemption from registration provided by Section 4(a)(2)and/or Section 3(a)(9)of the Securities Act. In accordance with Section 3(a)(9)of the Securities Act, the securities were exchanged by the Company with existing security holders in a transaction where no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange.

• In September 2022, we issued warrants (the "Pre-Funded Bridge Warrants") to purchase 619 shares of Common Stock to an accredited investor in connection with the cancellation of 619 shares of Common Stock (with the issuance of such cancelled shares being deemed null and void, *ab initio*) pursuant to provisions in the Bridge Notes limiting the number of shares of Common Stock into which the Bridge Notes were convertible.

• In September 2022, as a result of the Amendment No. 1 to Bridge Warrant by and between Heart Test Laboratories, Inc. and the lead investor under the Bridge SPA, dated September 8, 2022 (the "Bridge Warrant Amendment No. 1"), the number of shares of Common Stock for which the Bridge Warrants are exercisable increased by 3,172 shares. The Bridge Warrant Amendment No. 1, including the issuance of the shares of Common Stock underlying the Bridge Warrants and of the amended and restated Bridge Warrants to accredited investors, was completed in accordance with Section 3(a)(9) of the Securities Act, as securities exchanged by the Company with its existing security holders in a transaction where no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange, and/or Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

• In January 2023, the lead investor under the Securities Purchase Agreement we entered into with the Bridge Purchasers in connection with the 2021 Bridge Financing (the "Bridge SPA"), exercised its Pre-Funded Bridge Warrants in full to acquire 1,394 shares of Common Stock at an exercise price of $0.01 per share, for a total price of $13.94.

• In February 2023, we entered into Amendment No. 2 to Bridge Warrant by and between the Company and the lead investor under the Bridge SPA, dated February 3, 2023 (the "Bridge Warrant Amendment No. 2"), which included the issuance of the shares of Common Stock underlying the Bridge Warrants and the amended and restated Bridge Warrants to accredited investors, was completed in accordance with Section 3(a)(9) of the Securities Act, as securities exchanged by the Company with its existing security holders in a transaction where no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange, and/or Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering. During a period of ten business days beginning February 3, 2023 and ending February 16, 2023, the Company issued 11,736 shares of Common Stock and a pre-funded warrant to purchase 1,500 shares of Common Stock (the "Remaining Pre-Funded Bridge Warrant") pursuant to exercises of the Bridge Warrants. The issuance of the shares of Common Stock upon the exercises of the Bridge Warrants were completed in accordance with Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering. The issuance of the Remaining Pre-Funded Bridge Warrant was completed in accordance with Section 3(a)(9) of the Securities Act. In accordance with Section 3(a)(9) of the Securities Act, the Remaining Pre-Funded Bridge Warrant was issued by the Company to its existing security holder in exchange for existing Bridge Warrants in a transaction where no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange. The Remaining Pre-Funded Bridge Warrant will take on the registered characteristics of the existing Bridge Warrants as in effect prior to the Bridge Warrant Amendment No. 2.

• In March 2023, we issued warrants to purchase an aggregate amount of 2,500 shares of our Common Stock at an exercise price of $104.00 per share as consideration, in lieu of cash, for approximately $203,000 billed in respect of research and development services rendered by a third-party to the Company.

• In March 2023, we issued 5 shares of our Common Stock to a certain unrelated third party for consideration of $20,000.

- In July 2023, we issued 1,087 shares of Common Stock as consideration for consulting services.
- In September 2023, we issued warrants to purchase an aggregate amount of 150 shares of our Common Stock at an exercise price of $73.00 per share as consideration for consulting services.
- In November 2023, we issued warrants to purchase an aggregate amount of 2,400 shares of our Common Stock at an exercise price of $17.00 per share as consideration, in lieu of cash, for approximately $102,000 billed in respect of research and development services rendered by a third-party to the Company.
- In June 2024, we issued warrants to purchase an aggregate amount of 2,000 shares of our Common Stock at an exercise price of $5.15 per share as consideration for consulting services.

Except as disclosed above with respect to the 2021 Bridge Securities, no underwriters were involved in the foregoing sales of securities described above under “Issuances of Unregistered Securities.” All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Neither the Company nor any affiliated purchaser (as defined in Rule 10b-18(a)(3) under the Exchange Act) repurchased any equity securities of the Company during the year ended April 30, 2024.

Equity Incentive Plan

See “Executive Compensation — 2023 Equity Incentive Plan” section in Part III.

Transfer agent and registrar

The transfer agent and registrar for our Common Stock and IPO Warrants is Equiniti Trust Company, LLC.

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 the related notes included elsewhere in this Annual Report on Form 10-K. The discussion below contains forward-looking statements that are based upon our current expectations and are subject to uncertainty and changes in circumstances. Actual results may differ materially from these expectations due to inaccurate assumptions and known or unknown risks and uncertainties, including those identified in "Cautionary Note Regarding Forward-Looking Statements" and under "Risk Factors" elsewhere in this Annual Report on Form 10-K.

Overview

We are a medical technology company focused on applying innovative AI-based technology to an ECG, also known as an "EKG," to expand and improve an ECG's clinical usefulness. Our objective is to make an ECG a far more valuable cardiac screening tool by expanding its clinical capability to detect a broader range of heart disease conditions through the development of AI-ECG. We are seeking to provide AI-ECG solutions in any care setting worldwide in a manner that best suits different providers, either via our cloud-based application that can receive an upload from one of the millions of ECG devices currently in clinical use or via our proprietary MyoVista *wav*ECG device. The MyoVista *wav*ECG, is a resting 12-lead ECG that will incorporate HeartSciences' proprietary AI-ECG algorithm designed to provide diagnostic information related to cardiac dysfunction as well as conventional ECG information in the same test. We are also developing a cloud-based platform to host AI-ECG algorithms on an ECG hardware agnostic basis (the "MyoVista Insights Cloud Platform"). In the future, we intend to offer a range of AI-ECG algorithms, via each product. Neither the MyoVista *wav*ECG device, MyoVista Insights Cloud Platform nor any of our AI-ECG algorithms are yet cleared for marketing by the FDA.

The AI-ECG algorithms are intended to provide diagnostic information which has traditionally required cardiac imaging. We believe, the combination of a device agnostic cloud platform and MyoVista *wav*ECG device would allow us to offer AI-ECG solutions across a wide range of healthcare settings from large heath systems to frontline or point of care environments such as primary care. The initial revenue model for the MyoVista *wav*ECG device, which involves the use of the MyoVista hardware, associated software and consumables for each test, is expected to be "razor-razorblade" as the cable connection to the electrodes used with the MyoVista *wav*ECG are proprietary to HeartSciences, and new electrodes are used for every test performed. As further algorithms are made commercially available via the MyoVista *wav*ECG or the MyoVista Insights Cloud Platform, we would expect to adopt revenue models based on algorithm usage and/or recurring subscriptions. Our MyoVista Insights Cloud Platform is being designed to fit simply into existing clinical workflows and be available to host third party AI-ECG algorithms, which increases its clinical value and our speed to market as well as reducing R&D costs associated with internal algorithm development.

On September 20, 2023, we entered into the License Agreements with Mount Sinai to commercialize a range of AI-ECG algorithms covering a range of cardiovascular conditions developed by Mount Sinai as well as a memorandum of understanding for ongoing cooperation encompassing de-identified data access, on-going research, and the evaluation of the MyoVista *wav*ECG device.

Our future success is dependent upon receiving FDA clearances for our products and additional funding may be required as part of achieving FDA clearance and thereafter would be required to support the sales launch, provide working capital and support further R&D.

We believe that there is currently no low-cost, front-line, medical device that is effective at screening broadly for many types of heart disease. As a result, we believe that frontline physicians face a significant challenge in determining if a patient has heart disease. Although many think of the ECG as the frontline test for heart disease, in 2012, the United States Preventive Services Task Force conducted an evaluation of conventional ECG testing and stated: "There is no good evidence the test, called an ECG, helps doctors predict heart risks any better than traditional considerations such as smoking, blood pressure and cholesterol levels in people with no symptoms."

ECG devices record the electrical signals of a patient's heart. The ECG is a ubiquitous, relatively low-cost, simple and quick test; it is portable and can be performed in a wide range of clinical settings by a non-specialist clinician or clinical aide. There are three basic categories of heart disease: electrical (such as an arrhythmia), structural (such as valvular disease) and ischemic (such as coronary artery disease, or CAD). Conventional resting ECGs have limited sensitivity in detecting structural and ischemic disease and are typically used for diagnosing cardiac rhythm abnormalities, such as atrial fibrillation, or acute coronary syndrome, such as a myocardial infarction which is also known as a heart attack. However, traditional ECGs have a limited role in identifying cardiac dysfunction associated with structural and ischemic disease.

HeartSciences has designed or licensed algorithms designed to help address these limitations and extend the clinical capability of an ECG to detect cardiac dysfunction and other heart disease types.

Our first AI-ECG algorithm to be incorporated into the MyoVista *wav*ECG device has been designed by the Company and applies AI-machine learning to the signal processed ECG signal to develop a proprietary algorithm designed to detect impaired cardiac relaxation, or cardiac dysfunction caused by heart disease and/or age-related cardiac dysfunction. We have been adjusting the algorithm to reflect updated echo measurement thresholds in respect of ≥60 year old patients. The change was made, and agreed with the FDA, to reflect recent clinical findings which we believe will further increase the clinical value of this algorithm.

We expect the first AI-ECG algorithm to be submitted as part of the MyoVista Insights Cloud Platform will be for detection of low ejection fraction, or systolic dysfunction, and based on one of those licensed from Mount Sinai.

The editorial comment associated with the study titled "Prediction of Abnormal Myocardial Relaxation from Signal Processed Surface ECG" presented below discusses recent applications of machine learning to data derived from surface 12-lead ECGs in relation to cardiac dysfunction:

> "These represent some of the most significant advances in electrocardiography since its inception, which has historically had a limited, if any, role in the evaluation of cardiac dysfunction. In the past, our cardiovascular community was resigned to the fact that surface ECGs are poor indicators for cardiac dysfunction."
>
> Khurram Nasir, MD, MPH, MSC, Department of Cardiology, Houston Methodist DeBakey Heart & Vascular Center, Houston, Texas, et. al., *Journal of American College of Cardiology Editorial Comment Volume 76 Number 8 2020.*

Almost all forms of heart disease, including CAD and structural disease, affect heart muscle, or cardiac function prior to symptoms. Impaired cardiac function is first observed as impaired cardiac relaxation which is an early indicator of diastolic dysfunction and usually continues to increase in severity as heart disease progresses. The diastolic phase of the cardiac cycle occurs when the heart muscle relaxes (following contraction). Diastolic dysfunction may also be related to age-related cardiac dysfunction. Low ejection fraction, or systolic dysfunction, is a later stage of cardiac dysfunction and occurs when the heart pumps a reduced level of blood from the ventricles during contraction.

If we receive FDA clearances for our product candidates, our main target markets would be frontline healthcare environments in the U.S., to assist physician decision making in the cardiology referral process. Currently, cardiology referral decisions are often based on a patient's risk factors and/or a conventional ECG test. Accordingly, many patients with heart disease are left undetected while no current treatment or intervention is required for most patients referred for cardiac imaging. We believe that adding the capability to detect a broader range of cardiac conditions to the standard 12-lead resting ECG could help improve cardiac referral pathways and be valuable for patients, physicians, health systems and third-party payors.

New Class II devices, such as our products, require FDA premarket review. The MyoVista *wav*ECG device along with its proprietary software and hardware is classified as a Class II medical device by the FDA. Premarket review and clearance by the FDA for these devices is generally accomplished through the 510(k) premarket notification process or De Novo classification request, or petition process. We previously submitted an FDA De Novo classification request in December 2019 and, following feedback and communications with the FDA during and since that submission, we have been making modifications to our device, including our proprietary algorithm. We have

finished the patient recruitment and core lab work for our FDA validation study and have been undertaking device and algorithm development testing for a revised FDA submission. We had been planning a revised submission under the De Novo pathway, however, in December 2023 the FDA confirmed that we could submit the MyoVista *wav*ECG device for clearance under the 510(k) pathway following the grant by the FDA in August 2023 of an industry-first De Novo clearance which created a new Class II product code for cardiovascular machine learning-based notification software. This was in respect of a hypertrophic cardiomyopathy algorithm and in late September 2023, the FDA cleared an algorithm for low ejection fraction (less than 40%) under the 510(k) pathway using this new product code. Accordingly, we are now preparing for a 510(k) FDA submission and are aiming for a submission in the first calendar quarter of 2025. If successful, FDA clearance would provide us the ability to market and sell the MyoVista *wav*ECG device in the U.S. and additional funding would be required to support the sales launch of the MyoVista *wav*ECG device in the U.S., provide working capital and support further R&D.

To date we have not yet entered into a discussion with the FDA regarding the MyoVista Insights Cloud Platform or Mount Sinai licensed AI-ECG algorithms but are aiming to start that process in the current calendar year. We expect these products to fall under the 510(k) pathway and are aiming for an FDA submission of our MyoVista Insights Cloud Platform and low ejection fraction algorithm in the middle of 2025.

Recent Developments during Fiscal 2024

Going Concern

On July 29, 2024, our independent registered public accounting firm issued an opinion on our audited financial statements, included in our Annual Report on Form 10-K for the year ended April 30, 2024, that contained an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern because we have experienced recurring losses, negative cash flows from operations, and limited capital resources. These events and conditions raise substantial doubt about our ability to continue as a going concern.

Compliance with Nasdaq Listing Requirements

On December 21, 2022, we received notice from the Listing Qualifications Staff of Nasdaq indicating that we were not in compliance with the Minimum Stockholders' Equity Requirement, because our stockholders' equity of $1,082,676 as reported in our Quarterly Report on Form 10-Q for the period ended October 31, 2022 was below the required minimum of $2.5 million, and because, as of October 31, 2022, we did not meet the alternative compliance standards, relating to the market value of listed securities of $35 million or net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years.

On August 2, 2023, we received a letter from the Staff indicating that, based upon the closing bid price of the Company's Common Stock for the last 30 consecutive business days, the Company no longer met the Minimum Bid Price Requirement. In accordance with Nasdaq listing rules, we had until January 29, 2024 to regain compliance with the Minimum Bid Price Requirement. In the event we did not regain compliance during this period, we were eligible to seek an additional 180 calendar day compliance period if we met the Nasdaq continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the Minimum Bid Price Requirement, and provide written notice to Nasdaq of our intent to cure the deficiency during this second compliance period.

We attended an August 17, 2023 hearing before the Nasdaq Hearing Panel (the "Panel"), and requested the continued listing of its securities on the Nasdaq Capital Market pending our return to compliance with the Minimum Stockholder's Equity Requirement and Minimum Bid Price Requirement.

On November 22, 2023, we were formally notified by the Panel that we have demonstrated compliance with the Minimum Stockholders' Equity Requirement. Pursuant to Nasdaq Listing Rule 5815(d)(4)(B), we are subject to a Mandatory Panel Monitor through November 22, 2024.

On January 30, 2024, we received a letter from the Panel advising that we have been granted an additional 180-day extension to July 29, 2024, to regain compliance with the Minimum Bid Price Requirement.

On May 9, 2024, the Company received a Staff Determination from Nasdaq to delist the Company's securities from the Nasdaq Capital Market. The Staff Determination was issued because, as of May 8, 2024, the Company's Common Stock had a closing bid price of $0.10 or less for at least ten consecutive trading days. Accordingly, the Company is subject to the provisions contemplated under Nasdaq Listing Rule 5810(c)(3)(A)(iii) (the "Low Priced Stocks Rule").

On May 17, 2024, the Company effected the Reverse Stock Split, such that as a result of the Reverse Stock Split, every 100 shares of the Company's issued and outstanding pre-reverse split common stock were combined into one share of Common Stock.

On June 3, 2024, the Company received a letter from Nasdaq informing the Company that the Nasdaq Listing Qualifications staff has confirmed that the Company has regained compliance with the $1.00 per share minimum bid price requirement pursuant to the Minimum Bid Price Requirement, and that the Company is therefore in compliance with Nasdaq's listing requirements. The Company's common stock and public warrants continue to be listed on Nasdaq.

Senior Unsecured Promissory Drawdown Loan Note

On September 7, 2023, we entered into the MSW Note with MSW for an unsecured drawdown loan of up to $1,000,000, drawn in installments consisting of (i) $250,000 on or prior to September 8, 2023, (ii) $250,000 on or prior to September 20, 2023, and (iii) further drawdowns of up to $500,000 in such amounts and such times to be mutually agreed upon between the Company and MSW. In September 2023, we drew down $0.5 million pursuant to the terms of the note and issued 10,000 warrants to purchase shares of Common Stock in lieu of a facility fee.

On November 16, 2023, we entered into the MSW Note Conversion Letter Agreement with MSW. Pursuant to the MSW Note Conversion Letter Agreement, in consideration for the conversion of the aggregate principal and interest amount due under the MSW Note, on November 16, 2023, we (i) issued to MSW 31,250 shares of Common Stock at a conversion price of $16.00 per share; and (ii) entered into the MSW Warrant Amendment with MSW, amending the Existing MSW Warrants to reduce the exercise price of an aggregate of 10,000 Existing MSW Warrants to $16.00 per share. Except as expressly set forth in the MSW Warrant Amendment, the terms and provisions of the warrants held by MSW shall remain in full force and effect.

Equity Distribution Agreement

On September 18, 2023, we entered into an EDA with Maxim Group LLC as sales agent ("Maxim") pursuant to which we may offer and sell up to $3.25 million of our shares of Common Stock in an at-the-market offering. The shares may be issued and sold from time to time through or to the placement agent acting as sales agent or principal pursuant to our shelf registration statement on Form S-3 (the "Shelf S-3"), as filed with the SEC on September 18, 2023. Pursuant to General Instruction I.B.6 of Form S-3, we may not sell the shelf securities in a public primary offering with a value exceeding more than one of the aggregate market value of its voting and non-voting ordinary shares held by non-affiliates in any 12 month period as long as the aggregate market value of our outstanding ordinary shares held by non-affiliates is less than $75 million. The $3.25 million shares comprised of Common Stock that may be offered, issued and sold under the at-the-market offering prospectus is included in the $50.0 million of securities that may be offered, issued, and sold by us under the base prospectus of the Shelf S-3. The Shelf S-3 was declared effective by the SEC on September 28, 2023. On November 9, 2023, we entered into Amendment No.1 of the EDA with Maxim pursuant to which, we may issue and sell up to $10.0 million worth of shares of Common Stock from time to time through the sales agent. On November 11, 2023, we entered into Amendment No. 2 of the EDA with Maxim pursuant to which, we may issue and sell up to $15.0 million shares of Common Stock through the sales agent. To date, we have sold 418,568 shares of Common Stock under the ATM Facility, receiving net proceeds of approximately $9.3 million after Maxim fees, legal fees and other costs.

Debt Conversion

On January 24, 2023, we entered into Amendment No. 4 to the Loan and Security Agreement dated April 24, 2020 (the "Loan and Security Agreement") with Front Range Ventures LLC ("FRV") and Adams. Pursuant to the Loan and Security Agreement, a secured promissory note in the original principal amount of $500,000 was issued to

FRV (the "FRV Note") and a secured promissory note in the original principal amount of $500,000 was issued to Adams (the "Adams Note"). The Loan and Security Agreement was further amended on September 29, 2023 to amend the dates on which principal and accrued interest is due under the Adams Note. As consideration for such extension, we issued FRV and Adams warrants (the "$1M Lender Warrants") to purchase an aggregate of 2,000 shares of Common Stock at an exercise price of $44.00 per share.

On November 16, 2023, we entered into the note conversion letter agreement, dated November 16, 2023, between us and Adams (the "Adams Note Conversion Letter Agreement"). Pursuant to the Adams Note Conversion Letter Agreement, in consideration for the conversion of the principal and interest amounts due under the Adams Note, on November 16, 2023, we: (1) issued 36,563 shares of Common Stock to Adams; and (2) entered into a Warrant Amendment Agreement with Adams, amending the $1M Lender Warrants owned by Adams to reduce the exercise price of an aggregate of 1,076 $1M Lender Warrants to $16.00 per share (the "Adams Warrant Amendment"). Except as expressly set forth in the Adams Warrant Amendment, the terms and provisions of the warrants held by Adams shall remain in full force and effect.

Mount Sinai Licenses

On September 20, 2023, we entered into the License Agreements with Mount Sinai to commercialize a range of AI cardiovascular algorithms developed by Mount Sinai as well as a memorandum of understanding for ongoing cooperation encompassing de-identified data access, on research, and the evaluation of the MyoVista *wav*ECG. The License Agreements, of which there are eleven in total, cover rights to thirteen AI cardiovascular algorithms, two data science methods for use with ECG waveforms and three filed patents.

On November 15, 2023, we closed the transactions contemplated under the Mount Sinai Securities Purchase Agreement and the licenses under the License Agreements, which became effective on that date. On November 16, 2023 and pursuant to the Mount Sinai Securities Purchase Agreement, we issued to Mount Sinai the following:

- 48,549 shares of Common Stock (the "Consideration Shares");
- pre-funded warrants to purchase up to 7,107 shares of Common Stock, with an exercise price per share of $0.001, which warrants were issued in lieu of shares of Common Stock issuable to Mount Sinai to ensure that the number of shares of Common Stock held by Mount Sinai does not exceed the Beneficial Ownership Limitation (the "MTS Pre-Funded Warrants"); and
- Common stock warrants to purchase up to 9,142 shares of Common Stock, having an exercise price per share equal to $50.60, (the "MTS Warrants" and collectively with the Consideration Shares and the MTS Pre-Funded Warrants, the "MTS Securities").

On December 1, 2023, the Company satisfied all material closing conditions of the Mount Sinai Securities Purchase Agreement and the MTS Warrants thereafter became fully exercisable by Mount Sinai. Registration rights related to the MTS Securities provide that on or prior to the date of one hundred and fifty days (150) days after the closing date, the Company shall prepare and file with the SEC a Registration Statement on Form S-1 (or such other form as applicable) covering the resale under the Securities Act of the MTS Securities issued to Mount Sinai, subject to any limitations imposed by the Nasdaq Rules. On March 5, 2024, the Company filed with the SEC a Registration Statement on Form S-1 registering the resale of the MTS Securities issued to Mount Sinai and the Registration Statement on Form S-1 was declared effective on March 13, 2024.

Patents

In January 2024, we were issued a notice of patent allowance from the European Patent Office covering quantification by an ECG of key echocardiographic measures of heart function using AI methods.

In March 2024, we were granted a patent from the Canadian Intellectual Property Office covering MyoVista wavelet technology.

In May 2024, we were granted a patent from the Indian Patent Office covering MyoVista wavelet technology.

Reverse Stock Split

On May 6, 2024, the Company filed a Certificate of Amendment to the Amended and Restated Certificate of Formation with the Secretary of the State of Texas to effect the Reverse Stock Split of its outstanding shares of Common Stock, with an effective date of May 17, 2024. As a result of the Reverse Stock Split, equitable adjustments corresponding to the Reverse Stock Split ratio were made to the Company's outstanding warrants and its other convertible instruments and upon the exercise or vesting of all stock options such that every 100 shares of Common Stock that may be issued upon the exercise of the Company's warrants and stock options and conversion of its other convertible instruments held immediately prior to the Reverse Stock Split represent one share of Common Stock that may be issued upon exercise of such warrants and stock options and conversion of the other convertible instruments immediately following the Reverse Stock Split. Correspondingly, the exercise price per share of Common Stock attributable to the Company's warrants and stock options and the conversion price of its other convertible instruments immediately prior to the Reverse Stock Split was proportionately increased by a multiple of 100 following the Reverse Stock Split.

Unless noted otherwise, all shares of Common Stock and per share amounts contained in our audited financial statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations," have been retroactively adjusted to reflect the Reverse Stock Split.

Results of Operations

Revenues

Revenues, which have been minimal to date, consist mainly of sales of devices, electrodes and other supplies in the establishment of distributor relationships outside the U.S. during the approval, development and improvement of the MyoVista *wav*ECG.

Cost of Sales

Cost of sales consists primarily of costs related to materials, components and subassemblies. Cost of sales also includes certain direct costs such as those incurred for shipping and freight.

Operating Expenses

Our operating expenses have consisted solely of research and development expenses and selling, general and administrative expenses.

Research and Development Expenses

Our research and development activities primarily consist of clinical, regulatory, engineering and research work associated with our MyoVista *wav*ECG device. Research and development expenses include payroll and personnel-related costs for our research and development, clinical and regulatory personnel, including expenses related to stock-based compensation for such employees, consulting services, clinical trial expenses, regulatory expenses, prototyping and testing. Research and development expenses also include costs attributable to clinical trial expenses including clinical trial design, site development and study costs, data, related travel expenses, the cost of products used for clinical activities, internal and external costs associated with regulatory compliance and patent costs. We have expensed research and development costs as they have been incurred.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist of payroll and personnel-related costs for field support personnel, business development, consulting, stock-based compensation, and for administrative personnel that support our general operations such as executive management and financial accounting. Selling, general and administrative expenses also include costs attributable to professional fees for legal and accounting services, premises costs, IT, insurance, consulting, recruiting fees, travel expenses and depreciation.

Interest Expense

Interest expense relates to our loan facilities and convertible notes. For more information, see "—Description of Indebtedness."

Other Income (Expense), Net

Other income (expense), net primarily consists of forgiveness of loans issued under the CARES Act.

The following table summarizes our results of operations for the periods presented and as a percentage of our total revenue for those periods based 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.

Summary of Statements of Operations for Fiscal 2024 and Fiscal 2023:

	For the year ended April 30,			
	2024	2023	$ Change	% Change
	(In thousands, except percentages)			
Revenue	$ 19	$ 5	$ 14	280%
Cost of sales	6	3	3	100%
Gross margin	13	2	11	550%
Operating expenses:				
Research and development	2,879	2,461	418	17%
Selling, general and administrative	3,440	3,654	(214)	(6)%
Total operating expenses	6,319	6,115	204	3%
Loss from operations	(6,306)	(6,113)	(193)	3%
Other income (expense)				
Interest expense	(354)	(243)	(111)	46%
Other income	55	2	53	2,650%
Other income (expense), net	(299)	(241)	(58)	24%
Net loss	$ (6,605)	$ (6,354)	$ (251)	4%

Revenues were $19,000 and cost of sales were $6,000 for the year ended April 30, 2024, compared to revenues of $5,000 and costs of sales of $3,000 for the year ended April 30, 2023. Our revenues to date have been mainly generated in the establishment of distributor relationships outside the United States as part of obtaining feedback during product development and improvement of the MyoVista *wav*ECG. The increase in revenue and cost of sales in the year ended April 30, 2024, is due to electrode sales during the year.

Research and development expenses are primarily from software consulting and hardware development and clinical trial studies which is consistent with work being performed for device development and ongoing clinical validation studies in preparation for a 510(k) submission. Research and development expenses were $2.9 million for the year ended April 30, 2024, representing an increase of $418,000, or 17%, when compared to the year ended April 30, 2023. Increase is primarily due to consulting costs incurred for development of our Cloud Platform and increase in headcount and professional services supporting the FDA submission process.

Selling, general, and administrative expenses are primarily related to personnel and professional services. Selling, general, and administrative expenses were $3.4 million for the year ended April 30, 2024, representing a decrease of $214,000, or 6%, when compared to the year ended April 30, 2023. Decrease in selling, general, and administrative expenses is primarily related to reduced D&O insurance premiums and reduced professional fees relating to the IPO in the prior year.

Interest expense was $355,000 for the year ended April 30, 2024, representing an increase of $112,000, or 46%, when compared to the year ended April 30, 2023. Interest expense in Fiscal 2024 is primarily related to interest on the $1M Loan and Security Agreement, warrants issued as consideration for extension of the JQA interest maturity date

in October 2023, interest and debt service amortization related to MSW Note, and warrants issued pursuant to the JQA Note and MSW Note conversions. The JQA Note and related accrued interest and the MSW Note converted to equity in November 2023.

Liquidity and Capital Resources

As of April 30, 2024, we had approximately $5.8 million in cash, an increase of $4.1 million from $1.7 million as of April 30, 2023. We incurred a net loss of $6.6 million for the year ended April 30, 2024. As of April 30, 2024, we had an accumulated deficit of $67.4 million and working capital of $5.6 million.

During the year ended April 30, 2023, we raised approximately $5.2 million in net proceeds from the sale of Common Stock and Warrants in our IPO and raised approximately $1.3 million from warrant exercises.

On March 10, 2023, we entered into the Lincoln Park Purchase Agreement providing for the purchase, from time to time at our discretion, of up to $15.0 million of our Common Stock, over the 36-month term of the agreement. Actual sales of shares of Common Stock will depend on a variety of factors to be determined by us from time to time. The net proceeds received from these purchases will depend on the frequency and prices at which we sell shares of our Common Stock to Lincoln Park. As of the date of this Annual Report, we have received approximately $1.6 million from the sale of Common Stock pursuant to the Lincoln Park Purchase Agreement. We expect that any proceeds received from such sales to Lincoln Park will be used for working capital and general corporate purposes.

On September 18, 2023, we entered into an EDA with Maxim Group LLC as sales agent pursuant to which we may offer and sell up to $3.25 million of our shares of Common Stock in at-the-market offerings. The EDA was further amended on November 9, 2023 and again on November 17, 2023, to increase the number of shares of Common Stock we may sell to up to $15.0 million. The shares of Common Stock may be issued and sold from time to time through or to the placement agent acting as sales agent or principal pursuant to our shelf registration statement on the Shelf S-3, as filed with the SEC on September 18, 2023. As of the date of this Annual Report, we have received approximately $9.7 million in net proceeds, after Maxim fees, legal fees and other costs, from the sale of Common Stock pursuant to the amended EDA. We expect that any proceeds received from such sales under the ATM Facility will be used for working capital and general corporate purposes.

In September 2023, we entered into the MSW Note for up to $1.0 million, drawn in installments consisting of (i) $0.25 million on or prior to September 8, 2023, (ii)) $0.25 million on or prior to September 20, 2023, and (iii) further drawdowns of up to $0.5 million in such amounts and such times to be mutually agreed upon between the Company and MSW. In September 2023, the Company drew $0.5 million under the MSW Note and in November 2023, the MSW Note was converted into shares of Common Stock.

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, clinical studies and go-to-market strategies. Our principal sources of capital are cash on hand and the proceeds of future offerings of equity and debt securities. We cannot assure you that we will be able to consummate the sale of any such securities on terms acceptable to us, if at all.

Our independent registered public accounting firm has issued an opinion on our audited financial statements included in this Annual Report on Form 10-K that contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern because we have experienced recurring losses, negative cash flows from operations, and limited capital resources. The events and conditions described in this paragraph, along with other matters, indicate that a material uncertainty exists that may cast significant doubt on our ability to continue as a going concern. Additionally, financial statements for future fiscal years may continue to include this explanatory paragraph with respect to our ability to continue as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. This going concern opinion could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through debt or equity financing. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans for, or efforts with respect to launch of sales of, our device. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in

our financial statements. Our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into critical contractual relations with third parties and otherwise execute our business objectives.

The table below presents our cash flows for the periods indicated:

U.S. dollars, in thousands	For the year ended April 30, 2024	2023
	(In thousands)	
Net cash used in operating activities	$ (6,070)	$ (5,774)
Net cash used in investing activities	$ (125)	$ (18)
Net cash provided by financing activities	$ 10,343	$ 6,534
Net change in cash and cash equivalents during the period	$ 4,147	$ 742

Operating Activities

Net cash used by our operating activities of $6.1 million during Fiscal 2024 was primarily due to our net loss of $6.6 million plus net non-cash operating expense items of $0.9 million less $0.4 million of net changes in operating assets and liabilities.

Net cash used by our operating activities of $5.8 million during Fiscal 2023 was primarily due to our net loss of $6.4 million plus net non-cash operating expense items of $0.4 million and $0.2 million of net changes in operating assets and liabilities.

Financing Activities

Net cash provided by financing activities of $10.3 million during Fiscal 2024 is primarily from the issuance of Common Stock under the ATM Facility and Equity Line.

Net cash provided by financing activities of $6.5 million during Fiscal 2023 is primarily from the issuance of Common Stock in the IPO and to Lincoln Park, and exercise of Bridge Warrants.

Current Outlook

We have financed our operations to date primarily through the issuance of Common Stock, preferred stock, warrants and debt securities. We have incurred losses and generated negative cash flows from operations since inception. Since inception, we have generated limited revenues from the sale of products through establishment of distributor relationships outside the U.S. during the development of the MyoVista *wav*ECG. We require FDA clearance to market our products in the U.S. and do not expect to generate significant revenues from the sale of our devices in the near future or prior to FDA clearance.

As of April 30, 2024, our cash and cash equivalents were $5.8 million. We will need to seek additional financing to fund our future operations. Our future capital requirements will depend on many factors, including:

- the progress and costs of our research and development activities;
- the costs of manufacturing our device;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally; and
- the magnitude of our general and administrative expenses.

Until we can generate sufficient cash flow from operations, we expect to satisfy our future cash needs through equity financings. Additional funding will be required to support the sales launch of our products into the U.S., provide working capital and support further R&D. We cannot be certain that additional funding will be available to us when

needed on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans for, or efforts with respect to launch of sales of our products. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. Our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into critical contractual relations with third parties and otherwise execute our business objectives.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of these financial statements in accordance with U.S. 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. Our estimates are based on our knowledge of current events and actions we may undertake in the future and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may materially differ from these estimates under different assumptions or conditions. We believe the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgements and estimates. For additional details regarding our critical accounting policies, see the "Financial Statements—Notes to the Financial Statements, Note 3 - Summary of Significant Accounting Policies".

Stock-Based Compensation

The Company accounts for employee and non-employee share-based compensation in accordance with the provisions of ASC 718, *Compensation—Stock Compensation*. Under ASC 718, share-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the requisite service period (generally the vesting period of the equity grant).

The estimated fair value of common stock option awards is calculated using the Black-Scholes option pricing model, based on key assumptions such as 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 rate and (iv) expected dividend yields. These assumptions are primarily based on historical data, peer company data and the judgment of management regarding future trends and other factors.

Management has estimated the expected term of its Common 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 expected volatility is derived from the historical volatilities of comparable publicly traded companies over a period approximately equal to the expected term for the options. 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 that commensurate with the expected term of the associated award. There is no expected dividend yield since the Company has never paid cash dividends and does not expect to pay cash dividends in the foreseeable future.

For stock options issued to employees and non-employees, the fair value of stock-based awards is recognized as compensation expense over the requisite service period, which is defined as the period during which an employee is required to provide service in exchange for an award. The Company uses a straight-line attribution method for all grants that include only a service condition. The Company accounts for forfeitures when they occur. Stock-based compensation expense recognized in the financial statements is reduced by actual awards forfeited.

Pricing and Valuation of Inventories

Inventory consists of finished goods, work in progress, sub-assemblies and raw materials and is stated at the lower of cost or net realizable value. Net realizable value is the estimated sales price, which is derived from similar marketable devices, less standard costs approximating the purchase costs on a first-in, first-out basis. Reserves for slow-moving, excess, or obsolete inventories are recorded when required to reduce inventory values to their estimated net realizable values based on product life cycle, development plans, production expiration or quality issues. Inventory that is used for research and development are expensed as consumed.

Inventory consists mainly of raw materials and components used in the current hardware build of the MyoVista *wav*ECG devices and components are used for research and development purposes and device sales, which to date have been in international markets as sale of the MyoVista *wav*ECG in the U.S. is subject to FDA clearance. The Company believes that its hardware platform is in final form, however, prior to FDA clearance and market acceptance of the MyoVista *wav*ECG devices, further hardware changes could be necessary which could have an impact on net realizable values. The majority of the Company's current inventory is intended for use to build finished products following regulatory clearance. Finished products do not contain materials that would degrade significantly over the useable life of the device and are considered to have a useable life of over seven years. Existing inventory related to finished devices are planned to be updated to the latest hardware revision and specifically allocated to a limited distribution for field reliability studies and are not slated for general purpose sales. The Company periodically evaluates inventory and makes specific write-offs and provides an allowance for inventory that is considered obsolete due to hardware and or software related changes. If the Company does not receive FDA clearance and/or obtain market acceptance of the MyoVista *wav*ECG, the Company could have further material write-downs of inventory due to obsolescence in excess of the amount currently reserved.

Recent Accounting Pronouncements

See Note 3 - Summary of Significant Accounting Policies to our audited financial statements included elsewhere in this Annual Report on Form 10-K.

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

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

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of
Heart Test Laboratories, Inc. dba HeartSciences
Southlake, Texas

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Heart Test Laboratories, Inc. dba HeartSciences (the "Company") as of April 30, 2024 and 2023, the related statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended April 30, 2024, 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 April 30, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended April 30, 2024, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has experienced recurring losses, negative cash flows from operations, and limited capital resources. These matters 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.

HASKELL & WHITE LLP

We have served as the Company's auditor since 2021.

Irvine, California
July 29, 2024

HEART TEST LABORATORIES, INC.
D/B/A HEARTSCIENCES
Balance Sheets

	April 30, 2024	April 30, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,807,648	$ 1,660,467
Inventory, net	629,179	676,359
Prepaid expenses	183,704	143,460
Other current assets	40,374	40,374
Deferred offering costs	692,988	175,921
Total current assets	7,353,893	2,696,581
Property and equipment, net	97,991	61,428
Intangible assets, net	1,589,246	—
Right-of-use assets, net	461,983	529,224
TOTAL ASSETS	$ 9,503,113	$ 3,287,233
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 448,183	$ 631,369
Accrued expenses	398,331	385,857
Accrued interest expense	268,813	237,534
Operating lease liabilities, current portion	102,293	29,535
Current portion of notes payable	500,000	500,000
Other current liabilities	34,147	48,596

Total current liabilities	1,751,767	1,832,891
LONG-TERM LIABILITIES		
Notes payable	—	500,000
Accrued expenses	—	187,450
Operating lease liabilities, long-term portion	434,045	536,335
Total long-term liabilities	434,045	1,223,785
TOTAL LIABILITIES	2,185,812	3,056,676
COMMITMENTS AND CONTINGENCIES (NOTE 2, 4-6, and 8)		
STOCKHOLDERS EQUITY		
Series A, B, and C convertible preferred stock, $ 0.001 par value, 20,000,000 shares authorized and 620,000 designated; 380,440 shares issued and outstanding as of April 30, 2024 and 380,871 shares issued and outstanding as of April 30, 2023.	380	381
Common Stock, $ 0.001 par value, 500,000,000 shares authorized; 676,598 shares issued and outstanding as of April 30, 2024 and 101,332 shares issued and outstanding as of April 30, 2023.	677	101
Additional paid-in capital	74,678,650	60,987,273
Accumulated deficit	(67,362,406)	(60,757,198)

TOTAL STOCKHOLDERS EQUITY	7,317,301	230,557
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 9,503,113	$ 3,287,233

The accompanying notes are an integral part of these financial statements.

HEART TEST LABORATORIES, INC.
D/B/A HEARTSCIENCES
Statement of Operations

	Year ended April 30, 2024	2023
Revenue	$ 18,600	$ 5,150
Cost of sales	6,081	2,796
Gross margin	12,519	2,354
Operating expenses:		
Research and development	2,878,554	2,460,868
Selling, general and administrative	3,439,735	3,654,450
Total operating expenses	6,318,289	6,115,318
Loss from operations	(6,305,770)	(6,112,964)
Other income (expense)		
Interest expense	(354,080)	(243,174)
Other income	54,642	1,848
Total other income (expense)	(299,438)	(241,326)
Net loss	(6,605,208)	(6,354,290)
Net loss per share, basic and diluted	(19)	(80)
Weighted average common shares outstanding, basic and diluted	352,520	79,506

The accompanying notes are an integral part of these financial statements.

HEART TEST LABORATORIES, INC.
D/B/A HEARTSCIENCES
Statements of Stockholders' Equity
for the Year ended April 30, 2023

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Total Convertible Preferred Stock	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholder's Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount		Shares	Amount			
BALANCE AT APRIL 30, 2022	10,000	$ 10	10,000	$ 10	463,265	$ 463	$ 483	33,383	$ 34	$ 48,346,596	$ (54,402,908)	$ (6,055,795)
Sale of Common Stock, net of fees	—	—	—	—	—	—	—	19,786	20	5,624,045	—	5,624,065
Issuance of Common Stock upon conversion of $ 1.5 M Notes	—	—	—	—	—	—	—	9,091	9	1,499,991	—	1,500,000
Issuance of Common Stock upon conversion of Bridge Notes and accrued interest	—	—	—	—	—	—	—	15,442	15	3,618,689	—	3,618,704
Issuance of Common Stock upon conversion of Series A and B Convertible Preferred Stock	(10,000)	(10)	(10,000)	(10)	—	—	(20)	7,033	7	13	—	—
Issuance of Common Stock upon conversion of Series C Convertible Preferred Stock	—	—	—	—	(87,594)	(87)	(87)	3,479	3	84	—	—
Issuance of Series C Preferred Stock upon conversion of $ 130 K Note	—	—	—	—	5,200	5	5	—	—	129,995	—	130,000
Issuance of Common Stock upon exercise of pre-funded warrants	—	—	—	—	—	—	—	1,394	1	13		14
Issuance of Common Stock upon exercise of Bridge Warrants	—	—	—	—	—	—	—	11,724	12	1,141,011	—	1,141,023
Stock based compensation - management and other employees	—	—	—	—	—	—	—	—	—	248,307	—	248,307
Warrants issued in IPO	—	—	—	—	—	—	—	—	—	17,250	—	17,250

Issuance of pre-funded Bridge Warrants	—	—	—	—	—	—	—	—	—	150,000	—	150,000
Warrants issued to non-employees	—	—	—	—	—	—	—	—	—	211,279	—	211,279
Net loss	—	—	—	—	—	—	—	—	—	—	(6,354,290)	(6,354,290)
BALANCE AT APRIL 30, 2023	—	—	—	—	380,871	$ 381	381	101,332	$ 101	$ 60,987,273	$ (60,757,198)	$ 230,557

The accompanying notes are an integral part of these financial statements.

HEART TEST LABORATORIES, INC.
D/B/A HEARTSCIENCES
Statements of Stockholders' Equity
for the Year ended April 30, 2024

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Total Convertible Preferred Stock	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholder's Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount		Shares	Amount			
BALANCE AT APRIL 30, 2023	—	—	—	—	380,871	$ 381	381	101,332	$ 101	$ 60,987,273	$ (60,757,198)	$ 230,557
Sale of Common Stock, net of fees	—	—	—	—	—	—	—	457,797	458	10,299,555	—	10,300,013
Issuance of Common Stock upon conversion of debt	—	—	—	—	—	—	—	67,813	68	1,022,782	—	1,022,850
Issuance of Common Stock for acquired assets	—	—	—	—	—	—	—	48,549	49	1,528,382	—	1,528,431
Issuance of Common Stock for consulting services	—	—	—	—	—	—	—	1,087	1	99,999	—	100,000
Issuance of Common Stock upon conversion of Series C Convertible Preferred Stock	—	—	—	—	(431)	(1)	(1)	20	—	1		—
Warrants issued to non-employees	—	—	—	—	—	—	—	—	—	335,633	—	335,633
Stock based compensation - management and other employees	—	—	—	—	—	—	—	—	—	405,025	—	405,025
Net loss	—	—	—	—	—	—	—	—	—	—	(6,605,208)	(6,605,208)
BALANCE AT APRIL 30, 2024	—	—	—	—	380,440	$ 380	380	676,598	$ 677	$ 74,678,650	$ (67,362,406)	$ 7,317,301

The accompanying notes are an integral part of these financial statements.

HEART TEST LABORATORIES, INC.
D/B/A HEARTSCIENCES
Statements of Cash Flows

	Year ended April 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,605,208)	$ (6,354,290)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	27,892	26,915
Amortization of debt discounts and deferred financing costs	103,595	61,381
Amortization - Right-of-use assets, operating lease	67,241	108,538
Stock-based compensation	405,025	248,307
Warrants issued to non-employees	335,633	171,326
Issuance of Common Stock for consulting services	100,000	—
Gain on settled accounts payable	—	(101,200)
Changes in current assets and liabilities:		
Accounts receivable	—	2,321
Inventory	47,180	(2,220)
Prepaid and other current assets	236,932	385,773
Deferred offering costs	(517,067)	60,432
Accounts payable	(183,186)	37,824
Accrued liabilities	(58,690)	(310,146)
Lease liability, operating lease	(29,532)	(108,538)
Net cash used in operating activities	(6,070,185)	(5,773,577)

CASH FLOWS FROM INVESTING ACTIVITIES:

Purchase of property and equipment	(64,455)	(18,308)
Acquisition of intellectual property - intangibles	(60,816)	—
Net cash used in investing activities	(125,271)	(18,308)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of Common Stock in IPO, net of fees	—	5,194,740
Issuance of warrants in IPO	—	17,250
Issuance of Common Stock for exercise of pre-funded warrants	—	14
Issuance of Common Stock for bridge warrant exercises	—	1,141,023
Issuance of Common Stock under equity line, net of offering costs	—	429,325
Issuance of pre-funded warrants for bridge warrant exercises	—	150,000
Issuance of Common Stock, net of fees	10,300,013	—
Proceeds from shareholder note, net	334,249	—
Principal repayments of finance lease obligations	(291,625)	(398,260)
Net cash provided by investing activities	10,342,637	6,534,092
Net change in cash and cash equivalents during the period	4,147,181	742,207
Cash and cash equivalents, beginning of period	1,660,467	918,260
Cash and cash equivalents, end of period	$ 5,807,648	$ 1,660,467

The accompanying notes are an integral part of these financial statements.

HEART TEST LABORATORIES, INC.
D/B/A HEARTSCIENCES

SUPPLEMENTAL DISCLOSURES OF NON-CASH TRANSACTIONS:	Year ended April 30, 2024	2023
Issuance of Common Stock for $1.5M Note conversions	$ —	$ 1,500,000
Issuance of Common Stock for Bridge Note and accrued interest conversions	$ —	$ 3,618,704
Issuance of Common Stock for Series A and B Preferred Stock conversions	$ —	$ 703
Issuance of Common Stock for Series C Preferred Stock conversions	$ —	$ 348
Issuance of Series C Preferred Stock for $130K Note conversion	$ —	$ 130,000
Issuance of Common Stock for cashless bridge warrant exercises	$ —	$ 31
Issuance of Common Stock warrants in payment of payables	$ —	$ 171,326
Issuance of Common Stock as consideration for note conversions	$ 1,022,850	$ —
Issuance of Common Stock as consideration for acquired intangible assets	$ 1,528,431	$ —
Warrants issued as underwriter compensation	$ —	$ 39,953
Financed insurance premiums	$ 277,176	$ 445,636
Operating lease assets obtained in exchange for lease obligations	$ —	$ 549,227

The accompanying notes are an integral part of these financial statements.

Note 1 – **Organization and Operations**

Heart Test Laboratories, Inc. d/b/a HeartSciences (“HeartSciences” or the “Company”) is a medical technology company specializing in cardiovascular diagnostic technology. The Company is a Texas C-Corporation and is headquartered in Southlake, Texas.

HeartSciences’ focus is on applying AI-based technology to an electrocardiograph (“ECG”) device, to expand and improve an ECG's clinical usefulness. The Company's objective is to make an ECG a far more valuable cardiac screening tool by expanding its clinical capability to detect a broader range of cardiac indications through the development of AI-based ECG cardiovascular algorithms (“AI-ECG”). The Company is seeking to provide AI-ECG solutions in any care setting worldwide in a manner that best suits different providers, either via one of the millions of ECG’s currently in clinical use or via its proprietary MyoVista *wav*ECG device. The MyoVista *wav*ECG, is a resting 12-lead ECG that will incorporate HeartSciences’ proprietary AI-ECG algorithm designed to provide diagnostic information related to cardiac dysfunction as well as conventional ECG information in the same test. Additionally, the Company is developing a cloud-based platform to provide access to AI-ECG algorithms, both HeartSciences developed and third-party algorithms, (the “MyoVista Insights Cloud Platform”). In the future, the Company intends to deliver a range of AI-ECG algorithms for each product. The Company is preparing to seek U.S. Food and Drug Administration (“FDA”) submission in the first calendar quarter of 2025.

On May 6, 2024, the Company filed a Certificate of Amendment to the Amended and Restated Certificate of Formation with the Secretary of the State of Texas to effect a 1-for-100 reverse stock split of its outstanding shares of Common Stock, with an effective date of May 17, 2024. As a result of the reverse stock split, every

100

shares of the Company's issued and outstanding pre-reverse split common stock were combined into one share of Common Stock, except to the extent that the reverse stock split resulted in any of the Company's shareholders owning a fractional share, which was rounded up to the next highest whole share. In connection with the reverse stock split, there was no change in the par value per share of $

0.001

. As a result of the reverse stock split, equitable adjustments corresponding to the reverse stock split ratio will be made to the Company’s outstanding warrants and upon the exercise or vesting of all stock options such that every one hundred (

100

) shares of Common Stock that may be issued upon the exercise of the warrants and stock options held immediately prior to the reverse stock split will represent one share of Common Stock that may be issued upon exercise of such warrants and stock options immediately following the reverse stock split. Correspondingly, the exercise price per share of Common Stock attributable to the warrants and stock options immediately prior to the reverse stock split will be proportionately increased by a multiple of 100 following the reverse stock split.

All Common Stock share and per share data, and exercise price data for applicable Common Stock equivalents, included in these financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented, unless otherwise indicated.

Note 2 – **Liquidity, 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 need to obtain additional capital, competition from larger 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 April 30, 2024, the Company had an accumulated deficit of $

67.4

million. These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

In March 2023, the Company entered into a purchase agreement and a registration rights agreement with an institutional investor, providing for the sale, from time to time at the discretion of the Company, of up to $

15.0

million of the Company’s Common Stock, over the thirty-six (36) month term of the purchase agreement (the “Equity Line”). As of April 30, 2024, the Company has issued and sold an aggregate

53,378

shares of Common Stock, including

1,000

commitment shares, under the Equity Line and received proceeds of approximately $

1.5

million (see Note 5). Subsequent to April 30, 2024 and through the date of this filing, the Company sold

14,500

shares of Common Stock under the Equity Line, receiving proceeds of approximately $

72,000

(see Note 9).

In September 2023, the Company entered into an Equity Distribution Agreement (“EDA”) with an institutional investor, pursuant to which the Company may offer and sell an aggregate of up to $

3.25
million of its shares of Common Stock in at-the-market offerings (“ATM Facility”). In November 2023, the EDA was further amended increasing the aggregate amount of Common Stock that may be sold under the ATM Facility from $

3.25
million to up to $

15.0
million. The Company is eligible to sell up to approximately $

11.0
million worth of shares of Common Stock as the aggregate market value of the Company's shares of Common Stock eligible for sale under the EDA is subject to limitations of General Instruction I.B.6 of Form S-3 until such time that the Company's public float equals or exceeds $

75.0
million. In the event the aggregate market value of the Company’s outstanding Common Stock held by non-affiliates equals or exceeds $

75.0
million, then the one-third limitation on sales set forth in General Instruction I.B.6 of Form S-3 shall not apply to additional sales made pursuant to the EDA. From inception through April 30, 2024, the Company has issued and sold an aggregate

409,200
shares of Common Stock and received net proceeds of approximately $

9.2
million, after banker fees, legal fees and other costs (see Note 5). Subsequent to April 30, 2024 and through the date of this filing, the Company sold

70,407
shares of Common Stock under the ATM Facility, receiving net proceeds of approximately $

369,000
(see Note 9).

Based on the Company’s forecasts and cashflow projections, the Company believes that current resources would be insufficient to fund operations for the next twelve months following the issuance of these financial statements. Additionally, the FDA can delay, limit or deny clearance of a medical device for many reasons outside the Company’s control which may involve substantial unforeseen costs.

Management’s plans include raising capital through the sale of additional equity securities, debt, or capital inflows from strategic partnerships. 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 recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern for a reasonable period.

Note 3 - Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("US GAAP") 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 the disclosure of contingent assets and liabilities as of the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. As of April 30, 2024 the Company had $

5.8
million held as cash equivalents and as of April 30, 2023 there were $

1.7
million had as cash equivalents. The fair value of cash and cash equivalents approximates carrying value. At times, the Company’s cash balances may exceed the current insured amounts under the Federal Deposit Insurance Corporation (“FDIC”).

Inventory

All inventories are stated at lower of cost or net realizable value, with cost determined substantially on a “first-in, first-out” basis. Selling, general, and administrative expenses are not inventoried, but are charged to expense when incurred. The following is a summary of the Company’s inventories at April 30, 2024 and April 30, 2023:

	April 30, 2024	April 30, 2023
Raw materials	$ 322,996	$ 322,996
Sub-assemblies	347,436	347,436
Work in progress	21,741	21,741
Finished goods	22,581	28,662
Reserve for obsolescence	(85,575)	(44,476)
Total Inventory	$ 629,179	$ 676,359

Inventory consists mainly of raw materials and components used in the current hardware build of the MyoVista *wav*ECG devices and components are used for research and development purposes and device sales, which to date have been in international markets as sale of the MyoVista *wav*ECG in the U.S. is subject to FDA clearance. Management believes that its hardware platform is in final form, however, prior to FDA clearance and market acceptance of the MyoVista *wav*ECG, further hardware changes could be necessary which could have an impact on net realizable values. The majority of the Company’s current inventory is intended for use to build finished products following regulatory clearance. Finished products do not contain materials that would degrade significantly over the useable life of the device and are considered to have a useable life of over seven years . Existing inventory related to finished devices are planned to be updated to the latest hardware revision and specifically allocated to a limited distribution for field reliability studies and are not slated for general purpose sales. The Company periodically evaluates inventory and makes specific write-offs and provides an allowance for inventory that is considered obsolete due to hardware and or software related changes. If the Company does not receive FDA clearance and/or obtain market acceptance of the MyoVista *wav*ECG, the Company could have further material write-downs of inventory due to obsolescence in excess of the amount currently reserved.

Research and Development Expenses

The Company accounts for research and development expenditures, including payments to collaborative research partners and regulatory filing costs, as research and development expenses. Accordingly, all research and development costs are charged to expense as incurred.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives. The range of estimated useful lives used to calculate depreciation is generally 3 to 5 years. Ordinary maintenance and repairs are charged to expense as incurred, and replacements and betterments are capitalized. When items are retired or otherwise disposed, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in other income (expense).

The following is a summary of the Company's property and equipment at April 30, 2024 and 2023:

	April 30, 2024	April 30, 2023
Equipment	$ 462,375	$ 397,920
Furniture & fixtures	102,563	102,563
Leasehold improvements	32,812	32,812
Total	597,750	533,295

	(	(
	499,759	471,867
Less: Accumulated depreciation	)	)
Property and equipment, net	$ 97,991	$ 61,428

Depreciation expense for the years ended April 30, 2024 and 2023, was $ 27,892 and $ 26,915 , respectively.

Deferred Offering Costs

The Company capitalizes certain legal, professional, and other-third party charges related to its efforts to raise capital and other ongoing equity financings as deferred offering costs until fully consummated. These costs are deferred until the completion of the offerings at which time they are reclassified to additional paid-in-capital as a reduction of the offering proceeds. If the Company terminates the planned offering, all of the deferred offering costs will be immediately written off to operating expenses.

In March, 2023, the Company entered into the Equity Line. Deferred offering costs associated with the Equity Line are reclassified to additional paid in capital on a pro-rata basis over the term of the agreement.

In September 2023, the Company entered into an EDA to sell its Common Stock under the ATM Facility. Deferred offering costs associated with the ATM Facility are reclassified to additional paid in capital on a pro-rata basis.

In October 2023, the Company filed an S-1/A registration statement which has not yet been declared effective by the SEC. These costs are deferred until the completion of the offerings at which time they are reclassified to additional paid-in-capital as a reduction of the offering proceeds.

As of April 30, 2024 and April 30, 2023, $

692,988
and $

175,921
of deferred offering costs were capitalized on the balance sheet, respectively.

Fair Value Measurements

The accounting guidance establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. 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. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- 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 judgement and considers factors specific to the asset or liability. The carrying amounts of the Company's financial instruments, which primarily include cash and cash equivalents, accounts payable and accrued expenses, approximate their fair values due to their short-term nature. The carrying amounts of the Company's existing notes payable approximate their fair values at the stated interest rates and are reflective of the prevailing market rates.

Long-Lived Assets

Long-lived assets, such as equipment and intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances

require a long-lived asset or asset group be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying amount. If the carrying amount of the long-lived asset or asset group is determined to not be recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent the carrying amount exceeds its fair value.

Leases

The Company determines if a contract is or contains a lease at inception or modification of a contract. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period in exchange for consideration. Control over the use of the identified asset means the lessee has both (a) the right to obtain substantially all of the economic benefits from the use of the asset and (b) the right to direct the use of the asset. Right-of-use assets and liabilities are recognized based on the present value of future minimum lease payments over the expected lease term at commencement date. The Company measures and records a right-of-use asset and lease liability based on the discount rate implicit in the lease, if known. In cases where the discount rate implicit in the lease is not known, the Company measures the right-of-use assets and lease liabilities using a discount rate equal to the Company's estimated incremental borrowing rate for loans with similar collateral and duration.

The Company elected to not apply the recognition requirements to leases of all classes of underlying assets that, at the commencement date, have a lease term of 12 months or less and do not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise. Instead, lease payments for such short-term leases are recognized in operations on a straight-line basis over the lease term and variable lease payments in the period in which the obligation for those payments is incurred.

Stock-Based Compensation

The Company accounts for employee and non-employee share-based compensation in accordance with the provisions of ASC 718, *Compensation – Stock Compensation*. Under ASC 718, share-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the requisite service period (generally the vesting period of the equity grant).

The estimated fair value of common stock option awards is calculated using the Black-Scholes option pricing model, based on key assumptions such as 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 rate and (iv) expected dividend yields. These assumptions are primarily based on historical data, peer company data and the judgment of management regarding future trends and other factors.

Management has estimated the expected term of its Common 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 that commensurate with the expected term of the associated award. There is no expected dividend yield since the Company has never paid cash dividends and does not expect to pay cash dividends in the foreseeable future.

For stock options issued to employees and non-employees, the fair value of stock-based awards is recognized as compensation expense over the requisite service period, which is defined as the period during which an employee is required to provide service in exchange for an award. The Company uses a straight-line attribution method for all grants that include only a service condition. The Company accounts for forfeitures when they occur. Stock-based compensation expense recognized in the financial statements is reduced by actual awards forfeited.

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 shareholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities.

Diluted net loss per share is computed by dividing the net loss attributable to common shareholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, convertible preferred stock, stock options, common stock subject to repurchase related to early exercise of stock options, convertible stock warrants and convertible notes are considered to be potentially dilutive securities. As the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Common Stock Warrants

The Company grants warrants to purchase common stock in connection with financing transactions. Warrants are valued based on Black-Scholes models and the fair value is recorded to additional paid-in-capital.

Revenue Recognition

In accordance with ASC 606, *Revenue from Contracts with Customers,* revenue is recognized when a customer obtains control of promised goods or services. The guidance focuses on the core principle for revenue recognition, which is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company recognizes revenue in accordance with ASC 606, which provides a five-step model for recognizing revenue from contracts with customers as follows:

- Step 1: Identify the contract(s) with a customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation

A contract with a customer exists when (i) the Company enters into a legally enforceable contract with a customer, through a purchase order, that defines each party's rights regarding the products to be transferred and identifies the payment terms related to these products, (ii) the contract has commercial substance and, (iii) the Company determines that collection of substantially all consideration for products that are transferred is probable based on the customer's intent and ability to pay the promised consideration. The only performance obligation is to create and ship the product and each product has separate, distinct pricing. Performance obligations are met and revenue is recognized at a point in time when the order for its goods are shipped FOB manufacturer and control is transferred.

The transaction price is determined based on the amount expected to be entitled to in exchange for transferring the product to the customer net of any transaction price adjustments. The Company's payment terms to customers generally range from 30 to 60 days.

Payment terms fall within the one-year guidance for the practical expedient which allows the Company to forgo adjustment of the promised amount of consideration for the effects of a significant financing component. The Company accepts product returns at its discretion or if the product is defective as manufactured. Historically, the actual product returns have been immaterial to the Company's financial statements. The Company elected to treat shipping and handling costs as a fulfillment cost and included them in the cost of goods sold as incurred. Costs associated with product sales include commissions. The Company applies the practical expedient and recognizes commissions as expense when incurred because the expense is incurred at a point in time and the amortization period is less than one year. Commissions are recorded as selling expense.

As of April 30, 2024 and April 30, 2023, the Company did

no

t have any contract assets or liabilities from contracts with customers and there were

no

remaining performance obligations that the Company had not satisfied.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires recognition of deferred tax assets, subject to valuation allowances, and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting and income tax purposes. Management considers many factors when assessing the likelihood of future realization of deferred tax assets, including recent cumulative experience by taxing jurisdiction, expectations of future taxable income or loss, the carry-forward periods available to the Company for tax reporting purposes, and other relevant factors.

A valuation allowance is established if it is more likely than not that all or a portion of the net deferred tax assets will not be realized.

Accruals for uncertain tax positions are provided for in accordance with applicable accounting standards. The Company may recognize the tax benefits from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. Judgment is required in assessing the future tax consequences of events that have been recognized in the financial statements or tax returns.

Based on its analysis, the Company has determined that it has not incurred any liability for unrecognized tax benefits as of April 30, 2024 and April 30, 2023.

The Company may be subject to potential examination by U.S. federal, U.S. states or foreign jurisdiction authorities in the areas of income taxes. These potential examinations may include questioning the timing and amount of deductions, the nexus of income among various tax jurisdictions and compliance with U.S. federal, U.S. state and foreign tax laws.

The Company is subject to income taxes in the U.S. federal jurisdiction and franchise taxes in the State of Texas. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. Generally, the Company is no longer subject to income tax examinations by major taxing authorities for years before 2018.

Recent Accounting Standards

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 annual periods beginning January 1, 2024, and for interim periods beginning January 1, 2025, with early adoption permitted. The Company does not expect that the updated standard will have a significant impact on its 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 annual periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the potential effect that the updated standard will have on its financial statement disclosures.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist primarily of cash. The Company maintains its cash with high-credit quality financial institutions. At April 30, 2024 and April 30, 2023, the Company had cash balances in excess of federally insured limits of $

5.6
million and $

1.4
million, respectively. The Company does not anticipate non-performance by its financial institution.

Note 4 – Debt

Debt consists of the following:

	April 30, 2024	April 30, 2023
$1M Notes	$ 500,000	$ 1,000,000
Less: current maturities	(500,000)	(500,000)
Notes payable, long-term	$ —	$ 500,000

$1M Notes and Loan and Security Agreement

In April 2020, the Company entered into a loan and security agreement (the "$1M Loan and Security Agreement") pursuant to which a secured promissory note in the original principal amount of $

500,000

was issued to each of FRV (the "FRV Note") and John Q. Adams (the "JQA Note"), who were both shareholders of the Company at the time of issuance. John Q. Adams was also a Director of the Company at the time of entering into the $1M Loan and Security Agreement. Each party committed to lend a principal amount of $

500,000

, totaling $

1,000,000

, and the loan was drawn in three installments of $

300,000

upon execution of the loan agreement, $

350,000

on or about July 2, 2020 and $

350,000

on or about September 4, 2020. The loan accrued interest at a rate of

12

% per annum, compounded annually, payable at maturity. The Company is also required to pay default interest at a rate of

18

% per annum, compounded annually, on any unpaid amounts after the applicable due date until the loan amounts are fully re-paid. The loan is collateralized by substantially all of the Company's assets and intellectual property, except for the secured interest on the covered technology as discussed in Note 8.

The loan had an original maturity date of September 30, 2021 , which was amended in September 2021 making the note repayable on demand. The loan was amended in November 2021, extending the maturity to September 30, 2022 ; further amended in May 2022 to extend the maturity to September 30, 2023 ; amended again in January 2023 to (i) further extend the maturity date of the FRV Note to September 30, 2024 , on which date the principal amount and all accrued interest thereon would be due and payable; and (ii) amend the dates on which principal and accrued interest was due under the JQA Note, such that interest accrued since June 28, 2022 would be due and payable on September 30, 2023 , and the principal amount together with all accrued interest after September 30, 2023 would be due and payable on March 31, 2024 .

In connection with the amendment in May 2022, the Company agreed to pay Mr. Adams all accrued but unpaid interest on his note prior to September 30, 2022.

In October 2023, the Company issued to FRV and Mr. Adams warrants ("$1M Lender Warrants") to purchase an aggregate of

2,000

shares of Common Stock as consideration for the extension of the interest maturity date to one lender.

On November 16, 2023, the Company entered into a note conversion letter agreement with John Q. Adams (the "Adams Note Conversion Letter Agreement"). Pursuant to the Adams Note Conversion Letter Agreement, in consideration for the conversion of the principal and interest in the amounts of $

585,006

due under the JQA Note, on November 16, 2023, the Company: (1) issued

36,563

shares of Common Stock to Mr. Adams; and (2) entered into a Warrant Amendment Agreement with Mr. Adams, amending the $1M Lender Warrants owned by Mr. Adams to reduce the exercise price of an aggregate of

1,076

$1M Lender Warrants to $

16.00
per share (the “Adams Warrant Amendment”). See further discussion in Note 5.

As of April 30, 2024 and April 30, 2023, accrued interest was approximately $

269,000
and $

238,000
, respectively, and is included in accrued expenses in the accompanying balance sheets.

MSW Note

On September 6, 2023, the Company entered into the MSW Note with Matthews Holdings Southwest, Inc., (the “Lender”). The MSW Note provided for an unsecured drawdown loan of up to $

1.0
million, drawn in installments consisting of (i) $

250,000
on or prior to September 8, 2023, (ii) $

250,000
on or prior to September 20, 2023, and (iii)

further drawdowns of up to $

500,000
in such amounts and such times to be mutually agreed upon between the Company and Lender.

In September 2023, the Company drew $

0.5
million under the MSW Note and issued warrants in lieu of a facility fee to purchase

5,000
shares of Common Stock exercisable at $

100.00
per share, warrants to purchase

2,500
shares of Common Stock exercisable at $

125.00
per share, and warrants to purchase

2,500
shares of Common Stock exercisable at $

150.00
per share.

On November 16, 2023, the Company entered into a note conversion letter agreement with the Lender (the “MSW Note Conversion Letter Agreement”). Pursuant to the MSW Note Conversion Letter Agreement, in consideration for the conversion of the aggregate amount of $

500,000
due under the MSW Note, on November 16, 2023, the Company (i) issued to the Lender

31,250
shares of Common Stock at a conversion price of $

16.00
per share; and (ii) entered into a Warrant Amendment Agreement with the Lender, amending the warrants to reduce the exercise price of an aggregate of

10,000
warrants to $

16.00
per share (the “MSW Warrant Amendment”). See further discussion in Note 5. In accordance with the terms, no interest was payable as the note converted prior to maturity.

$130K Unsecured Drawdown Convertible Promissory Note

On August 12, 2019, the Company entered into an unsecured drawdown convertible promissory note with Front Range Ventures, LLC (“FRV”) for an aggregate amount not to exceed $

130,000
(“$130K Note”). FRV is a shareholder of the Company and the Company entered into an agreement with FRV where FRV is entitled to appoint a member of the Board of Directors and a board observer so long as it holds at least

71,000
shares of Series C Preferred Stock.

In April 2023, the $130K Note was converted into

5,200
shares of Series C Preferred Stock pursuant to a notice of conversion to FRV (see Note 5).

$1.5M Secured Convertible Promissory Notes

In December 2020, the Board of Directors approved the offering of a series of secured convertible promissory notes in the amount of $

1,500,000
(“$1.5M Notes”). The $1.5M Notes were sold as a series to a number of different investors with $

1,490,000
of the notes being sold to shareholders of the Company of which members of the Board of Directors of the Company subscribed for $

30,000
. In June 2022, the entire amount of the $1.5M Notes converted upon the IPO into

9,091

shares of Common Stock. In accordance with their terms, no interest was payable as the notes converted prior to maturity (see Note 5).

2021 Bridge Securities

In December 2021 the Board approved the sale of Senior Subordinated Convertible Loan Notes (the “Bridge Notes”) and associated warrants (the “Bridge Warrants” and, together with the Bridge Notes, the “2021 Bridge Securities”). The Company sold $

4,695,555
principal value of the Bridge Notes which were issued with a

10
% original issue discount (OID), and accrued interest at

8
% per annum and had a maturity date of December 22, 2024 . During the year ended April 30, 2023, the Bridge Notes, including $

165,516
of accrued interest, converted into

15,442
shares of Common Stock (see Note 5).

Note 5 – Stockholders’ Equity

Preferred Stock

The Company authorized

20,000,000
shares of preferred stock, par value $

0.001
per share (“Preferred Stock”), of which

10,000
shares have been designated as Series A Convertible Preferred Stock (“Series A Preferred Stock”),

10,000
shares have been designated as Series B Convertible Preferred Stock (“Series B Preferred Stock”), and

600,000
shares have been designated as Series C Preferred Stock with a liquidation preference to Common Stock. During the year ended April 30, 2024, there were

no
issuances of Preferred Stock by the Company. During the year ended April 30, 2023, the Company issued

5,200
shares of Series C Preferred Stock for the conversion of the $130K Note (See Note 4).

On June 2, 2022, the Company filed amendments to the Amended and Restated Certification of Designations of Series A Convertible Preferred Stock and the Amended and Restated Certification of Designations of Series B Convertible Preferred Stock, which amended certain provisions in the agreements including to provide that on completion of an IPO by the Company, each share of Series A Preferred Stock and Series B Preferred Stock would automatically be converted into shares of Common Stock and all shares of Series A Preferred Stock and Series B Preferred Stock would be deemed converted and canceled. Upon consummation of the IPO in June 2022, all the outstanding shares of Series A Preferred Stock were converted into

7,033
shares of Common Stock at a conversion ratio of

0.7033
shares of Common Stock for each share of Series A Preferred Stock and all outstanding shares of Series B Preferred Stock were canceled.

Series C Preferred Stock

The Series C Preferred Stock was originally issued at $

25.00
per share. An amendment to, or waiver of rights in, the Series C Preferred Stock certificate of designation requires the approval of holders of a majority of the outstanding shares of Series C Preferred Stock and FRV (so long as FRV holds at least

71,000
shares of Series C Preferred Stock).

At April 30, 2024 and April 30, 2023, there were

380,440
and

380,871
shares of Series C Preferred Stock outstanding, respectively.

Holders of the Series C Preferred Stock are entitled to receive dividends at an annual rate of $

1.50
per share of Series C Preferred Stock, shall accrue and are payable out of funds legally available, are payable only when and if declared by the board of directors, and are noncumulative.

No
dividends have been declared to date. The holders of the shares of Series C Preferred Stock have voting rights equal to an equivalent number of shares of Common Stock into which it is convertible and vote together as one class with Common Stock.

Each share of Series C Preferred Stock is convertible, at the option of the holder at any time, into such number of fully paid and non-assessable shares of Common Stock determined by dividing the original issue price of $

25.00
by the conversion price for such series in effect at the time of conversion for the Series C Preferred Stock. The conversion price for the Series C Preferred Stock is subject to adjustment in accordance with conversion provisions contained in the Company's certificate of formation, as amended.

During the year ended April 30, 2024,

431
shares of Series C Preferred Stock converted into

20
shares of Common Stock at a conversion ratio of

0.0464
shares of Common Stock for each shares of Series C Preferred Stock.

During the year ended April 30, 2023,

87,594
shares of Series C Preferred Stock converted into

3,479
shares of Common Stock at a conversion ratio of approximately

0.0397
shares of Common Stock for each share of Series C Preferred Stock. At April 30, 2024, the Series C Preferred Stock were convertible into

66,663
shares of Common Stock at a conversion price of $

142.61
per share.

At July 26, 2024, the outstanding Series C Preferred Stock were convertible into

72,546
shares of Common Stock at a conversion price of $

131.04
per share.

Common Stock

The Company's Certificate of Formation, as amended, authorizes

500,000,000
shares of common stock with a par value of $

0.001
per share. As of April 30, 2024 and April 30, 2023 the Company had issued

676,598
and

101,332
shares of common stock, respectively.

During the years ended April 30, 2024 and April 30, 2023, the Company issued

575,266
and

67,949
shares of Common Stock, respectively, as set forth in the below table:

	Number of Shares
Issuance of Common Stock in IPO	15,000
Issuance of Common Stock under Equity Line	4,781
Issuance of Common Stock	5
Conversion of $1.5M notes to Common Stock (see Note 4)	9,091
Conversion of Bridge Notes and accrued interest to Common Stock (see Note 4)	15,442
Conversion of Series A Preferred Stock to Common Stock	7,033
Conversion of Series C Preferred Stock to Common Stock	3,479
Common Stock issued upon exercise of Bridge Warrants	11,724
Common stock issued up exercise of Pre-Funded Warrants	1,394
Total Common Stock issued during twelve months ended April 30, 2023	67,949
Issuance of Common Stock under Equity Line	48,597
Issuance of Common Stock under ATM Facility	409,200
Issuance of Common Stock for note conversions (see Note 4)	67,813
Issuance of Common Stock pursuant to MTS Transaction (see Note 8)	48,549
Issuance of Common Stock as payment for consulting services rendered	1,087
Conversion of Series C Preferred Stock to Common Stock	20
Total Common Stock issued during twelve months ended April 30, 2024	575,266

Summary table of Common Stock share transactions:

Balance at April 30, 2022	33,383

Issued in Fiscal 2023	67,949
Balance at April 30, 2023	101,332
Issued in Fiscal 2024	575,266
Balance at April 30, 2024	676,598

In June 2022, the Company closed on the sale of

15,000
units in the IPO (the “Units”), with each Unit consisting of one share of Common Stock, par value $

0.001
per share, and one warrant to purchase one share of Common Stock at a combined public offering price of $

425.00
per Unit. The Company received approximately $

5.2
million in net proceeds from the IPO after deducting the underwriting discount and commission and other IPO expenses payable by the Company of approximately $

1.2
million.

On March 10, 2023, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC (“Lincoln Park”) providing for the purchase, from time to time at the Company’s discretion, of up to $

15.0
million of the Company’s Common Stock, over the thirty-six (36) month term of the purchase agreement. The agreement allows the Company, at its sole discretion, to direct Lincoln Park to purchase shares of Common Stock, subject to limitations in both volume and dollar amount. The purchase price of the shares that may be sold to Lincoln Park under the agreement is the lower of (i) the lowest sale price on the date of purchase, or (ii) the average of the three lowest closing prices in the prior ten business days. Concurrently with the purchase agreement, the Company entered into a registration rights agreement, pursuant to which the Company filed a registration statement on Form S-1 with the SEC on March 22, 2023. This registration statement was declared effective on April 10, 20 23 . At the annual shareholder meeting held on January 17, 2024, the Company’s shareholders approved the full issuance of shares of Common Stock issuable by the Company pursuant to the Company’s Equity Line, for purposes of complying with Nasdaq Listing Rule 5635(d). The Company filed a registration statement on Form S-1 with the SEC on March 5, 2024 and the registration statement was declared effective on March 13, 2024. During the year ended April 30, 2024, the Company issued

48,597
shares of Common Stock to Lincoln Park receiving approximately $

1.1
million in proceeds. During the year ended April 30, 2023, the Company issued

4,781
shares of Common Stock, including

1,000
commitment shares, receiving proceeds of approximately $

370,000
.

On September 18, 2023, the Company entered into an EDA with Maxim Group LLC as sales agent pursuant to which the Company may offer and sell up to $

3.25
million shares of Common Stock in an ATM Facility. The shares may be issued and sold from time to time through or to the placement agent acting as sales agent or principal pursuant to our shelf registration statement on Form S-3 (the “Shelf S-3”), as filed with the SEC on September 18, 2023. The $

3.25
million shares comprised of Common Stock that may be offered, issued and sold under the at-the-market

offering prospectus is included in the $

50.0
million of securities that may be offered, issued, and sold by the Company under the base prospectus of the Shelf S-3. The Shelf S-3 was declared effective by the SEC on September 28, 2023.

On November 9, 2023, the Company entered into Amendment No. 1 to the EDA with Maxim, pursuant to which the Company may sell up to $

10.0
million shares of Common Stock from time to time through the sales agent. On November 17, 2023, the Company entered into Amendment No. 2 to the EDA with Maxim, pursuant to which the Company may sell up to $

15.0
million shares of Common Stock from time to time through the sales agent.

During the year ended April 30, 2024, the Company issued

409,200
shares of Common Stock under the ATM Facility, receiving net proceeds of approximately $

9.2
million after Maxim fees, legal fees and other costs.

During the year ended April 30, 2024, the Company issued

1,087
shares of Common Stock as consideration for consulting services.

During the year ended April 30, 2024, the Company issued

67,813
shares of Common Stock as consideration for the conversion of the MSW Note and the JQA Note (see Note 4).

During the year ended April 30,2024, the Company issued

48,549
shares of Common Stock as consideration for certain license agreements with Icahn School of Medicine at Mount Sinai (“Mount Sinai”) (see Note 8).

The holders of Common Stock are entitled to receive dividends whenever funds and assets are legally available and when declared by the board of directors, subject to the rights of holders of Preferred Stock outstanding.

No

dividends were declared as of the years ended April 30, 2024 and 2023.

Common Stock Warrants

The Company has issued warrants to investors in connection with funding or for services rendered and these warrants are convertible into a fixed number of shares of the Company’s common stock for a period of 5 years from the date of issuance.

The following is a summary of warrant activity during the years ended April 30, 2024 and 2023:

	Warrants Outstanding and Exercisable	Exercise Price Per Share	Weighted Average Strike Price per Share
Balance, April 30, 2022	14,477	$ 347.00 -$ 1,518.00	$ 900.00
Issued	40,543	$ 1.00 -$ 425.00	$ 375.00
Exercised	(15,254)	$ 1.00 -$ 425	$ 386.00

Forfeited	(146)	$ 1,221.00 -$ 1,518.00	$ 1,396.00
Cancelled	(13,677)	$ 516.00	$ 516.00
Balance, April 30, 2023	25,943	$ 1.00 -$ 1,518.00	$ 373.00
Issued	30,799	$ 1.00 -$ 73.00	$ 24.00
Forfeited	(187)	$ 347.00 -$ 1,518.00	$ 545.00
Balance, April 30, 2024	56,555	$ 1.00 -$ 825.00	$ 182.00

The risk-free interest rate is based on U.S. Treasury yields in effect at the time of grant. Expected volatilities are derived from third party valuations. The expected life in years is based on the contract term of the warrant.

IPO Warrants and Underwriter's Warrants

In June 2022, the Company issued warrants to purchase

15,000
shares of Common Stock (“IPO Warrants”) with a per share exercise price of $

425.00
and exercisable immediately. The IPO Warrants expire five years from the date of issuance. In June 2022, the Company issued

2,250
warrants to purchase shares of Common Stock as an

over-allotment option to the underwriter. The Company also issued warrants to purchase an aggregate of

1,050

shares of Common Stock as compensation payable in connection with the IPO (the “Underwriter’s Warrants”). These Underwriter’s Warrants are exercisable at a per share price equal to $

425.00

per share, expire five years from the date of issuance, and are subject to a 180-day lock-up period.

Bridge Warrants

In connection with the 2021 Bridge Securities, as discussed in Note 4, the Company issued Bridge Warrants to note holders which were subject to antidilution provisions and price adjustments. On September 8, 2022, the Company entered into an amendment to the Bridge Warrants, which is referred to as the Bridge Warrant Amendment No. 1. The amendment simplified the Bridge Warrants and made their terms more consistent with the IPO Warrants and amended the Bridge Warrants by (i) increasing the number of shares of Common Stock for which the Bridge Warrants were exercisable from a total of

13,677

shares to a total of

16,849

shares, (ii) lowered the exercise price to $

425.00

per share, and (iii) shortened the period for which the exercise price protection provisions applied.

Following the Bridge Warrant Amendment, the Company cancelled

13,677

warrants that were issued previously to purchase Common Stock and re-issued

16,849

warrants to purchase shares of Common Stock per the terms of the amendment.

In January 2023,

1,394

pre-funded warrants were exercised into

1,394

shares of Common Stock at an exercise price of $

0.01

for cash consideration of $

14

.

On February 3, 2023, the Company entered into a second written amendment to the Bridge Warrants with the lead investor in the private placement of the 2021 Bridge Securities. The Bridge Warrant Amendment No. 2 amended the Bridge Warrants by (i) lowering the exercise price of $

425.00

for a period of ten business days beginning February 3, 2023 and ending February 16, 2023 (the “Limited Period”), during which period the exercise price was set at $

100.00

, subject to adjustments set forth in the Bridge Warrant, (ii) provided that during the Limited Period, the holder, in its sole discretion, could elect a cashless exercise of the Bridge Warrant in whole or in part, pursuant to which the holder would receive a net number of shares of Common Stock equal to one-third of the total number of shares with respect to which the Bridge Warrant then being exercised, and (iii) removed the exercise price adjustment provisions of the Bridge Warrants with limited exceptions for transactions such as stock dividends, stock splits, stock combinations and reverse stock splits. In the event that the aggregate number of shares of Common Stock to be received by a holder upon an exercise of its Bridge Warrant during the Limited Period would result in such holder’s receiving shares of Common Stock in excess of is applicable Maximum Percentage (as defined in the Bridge Warrant), in lieu of delivery of shares of Common Stock in excess of the Maximum Percentage, the holder shall receive such excess shares as pre-funded warrants with certain exercise price adjustment provisions removed.

During the Limited Period, the Company issued

11,736

shares of Common Stock and a pre-funded warrant to purchase

1,500

shares of Common Stock pursuant to the exercise of the Bridge Warrants and received approximately $

1.3

million in proceeds from these exercises. Immediately after the end of the Limited Period, Bridge Warrants to purchase

2,989

shares of Common Stock remained outstanding, with a fixed exercise price of $

425.00
, subject to adjustments as set forth in the Bridge Warrants.

In September 2023, the Company issued warrants in lieu of a facility fee under the MSW Note to purchase

5,000
shares of Common Stock exercisable at $

100.00
per share, warrants to purchase

2,500
shares of Common Stock exercisable at $

125.00
per share, and warrants to purchase

2,500
shares of Common Stock exercisable at $

150.00
per share. On November 16, 2023, pursuant to the MSW Warrant Amendment Agreement, the exercise price of the warrants were reduced to $

16.00
per share. See further discussion in Note 4.

In September 2023, the Company issued warrants to purchase up to

150
shares of Common Stock, at an exercise price of $

73.00
per share, to a consultant of the Company as consideration for services rendered to the Company.

In October 2023, the Company issued $

1
M Lender Warrants to FRV and John Q. Adams to purchase an aggregate of

2,000
shares of Common Stock at an exercise price of $

44.00
. On November 16, 2023, pursuant to the Adams Warrant Amendment Agreement, the exercise price of the warrants issued to Mr. Adams were reduced to $

16.00
per share. See further discussion in Note 4.

In November 2023, the Company issued warrants to purchase up to

2,400
shares of Common Stock, at an exercise price of $

17.00
per share, to consultants of the Company as consideration for services rendered to the Company.

In November 2023, the Company issued pre-funded warrants to purchase up to

7,107
shares of Common Stock, with an exercise price per share of $

0.001
and warrants to purchase up to

9,142
shares of Common Stock, having an exercise price per share equal to $

50.60
to Mount Sinai. See further discussion in Note 8.

Note 6 – Stock-based Compensation

The Company grants certain employees and board members stock option awards where vesting is contingent upon a service period, as it believes that such awards better align the interests of its employees with those of its shareholders. Stock option awards are granted with an exercise price equal to or above the market price of the Company's stock at the date of grant. Certain stock option awards provide for accelerated vesting if there is a change in control, as defined in the Nonstatutory Stock Option Agreement. Unvested stock options forfeit when an employee leaves the Company.

Time-based grants generally vest quarterly based on 3 years continuous service for executive directors and employees, or 12 months continuous service for directors and have 10-year contractual terms. The Company also grants stock option awards where vesting is contingent upon meeting various departmental and company-wide performance goals, including FDA and CE Mark regulatory approval and certain EBITDA and funding thresholds. Such performance-based stock options are expected to vest when the performance criteria and metrics have been met. These stock options have contractual lives of ten years .

2023 Equity Incentive Plan

On March 15, 2023, the Company's Board of Directors adopted the 2023 Equity Incentive Plan (the "Equity Incentive Plan"), subject to shareholder approval. The Equity Incentive Plan provides for the grant of nonstatutory stock options, incentive stock options, restricted stock, restricted stock units, performance units, performance shares, and other share-based awards. Pursuant to the Equity Incentive Plan, the Company is authorized to issue up to

25,000
shares of Common Stock plus (i) any shares of our Common Stock subject to options that expire or otherwise terminate without having been exercised in full, are tendered to or withheld by us for payment of an exercise price or for tax withholding obligations, or are forfeited to or repurchased by us due to failure to vest, with the maximum number of shares of our Common Stock to be added to the Equity Incentive Plan under this clause (ii) equal to

8,322
shares of our Common Stock.

On November 27, 2023, the Company's Board of Directors approved and entered into Amendment No. 1 to the Equity Incentive Plan, subject to shareholder approval, to increase the initial number of shares currently issuable under the Plan from

25,000
shares to

85,000
shares.

The Company's shareholders approved the Equity Incentive Plan at the annual shareholder meeting held on January 17, 2024.

During the year ended April 30, 2024 and 2023, the Company granted

8,000
and

9,315
shares of time-based stock option awards to employees and non-employee directors under the Equity Incentive Plan, subject to shareholder approval.

The following table summarizes the Company's time-based stock options:

	Number of Options Outstanding	Weighted Average Exercise Price	Average Remaining Contractual Life (in years)
Outstanding - April 30, 2022	2,649	$ 1,179.00	4.6
Options granted	9,315	$ 97.00	9.9
Options forfeited	(29)	$ 381.00	—
Outstanding - April 30, 2023	11,935	$ 329.00	8.6
Options granted	8,000	$ 12.00	9.9
Options forfeited	(1,276)	1,323.00	—
Outstanding - April 30, 2024	18,659	$ 131.00	8.9
Non-vested at April 30, 2024	12,838	$ 47.00	9.5
Vested at April 30, 2024	5,821	$ 316.00	7.2

The following summarizes the Company's performance-based stock options:

	Number of Options Outstanding	Weighted Average Exercise Price	Average Remaining Contractual Life (in years)
Outstanding - April 30, 2022	5,852	$ 517.00	7.8
Options forfeited	(39)	$ 334.00	—
Outstanding - April 30, 2023	5,813	$ 517.00	6.8
Options forfeited	(357)	$ 760.00	—
Outstanding - April 30, 2024	5,456	$ 502.00	5.9

Non-vested at April 30, 2024	3,565	$ 626.00	5.7
Vested at April 30, 2024	1,891	$ 268.00	6.3

As of April 30, 2024 and as of April 30, 2023, there was approximately $ 1.5 million and $ 1.7 million of unrecognized compensation costs related to non-vested performance-based common stock options and approximately $ 0.2 million and $ 0.5 million of unrecognized compensation costs related to non-vested service-based common stock options.

The Company estimates fair values of time-based stock options using the Black-Scholes option-pricing model on grant date. For the years ended April 30, 2024 and 2023, the principal assumptions used in applying this model were as follows:

	April 30, 2024	April 30, 2023
Risk free interest rate	4.10 %	3.56 %
Volatility	85.8 %	79.6 %
Weighted average expected term (in years)	5.0	5.0

Note 7 – Income Taxes

The tax effects of temporary differences and carry-forwards that give rise to significant portions of the deferred tax assets and liabilities are presented below:

	April 30, 2024	April 30, 2023
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 11,378,409	$ 9,701,650
Start-up costs	833,918	934,999
Stock option and warrant payments	694,206	538,669
Accumulated depreciation	(3,339)	(3,111)
Research and development credits	255,600	255,600
Research and development warrants	21,488	21,488
Total deferred tax assets, net	13,180,282	11,449,295
Valuation Allowance	(13,180,282)	(11,449,295)
Net Deferred Tax Assets	$ —	$ —

For the years ended April 30, 2024 and April 30, 2023, the Company's cumulative net operating loss for federal income tax purposes was approximately $

54
million and $

46
million, respectively. The net operating loss, subject to limitations, may be available in future tax years to offset taxable income. The net operating loss carry-forward will begin to expire in year 2028 .

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based upon the projections for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences, and therefore, a full valuation allowance has been recorded at April 30, 2024 and April 30, 2023, respectively.

Note 8 – Commitments and Contingencies

Operating Leases

The Company has a long-term operating lease for office, industrial, and laboratory space which was entered into in May 2017. On September 27, 2022, the Company entered into the First Amendment to Lease (the "Lease Amendment"), which amended the Lease Agreement to document the exercise of its option to extend the term of the lease for an additional 64 months , commencing February 1, 2023 , and expiring on May 31, 2028 (the "Extension Term"). Pursuant to the amendment, the Company will pay initial monthly payments of $

13,129
, beginning February 2023, subject to

3
% annual increases. Rent expense for the years ended April 30, 204 and 2023 were $

187,517
and

167,309
, respectively.

The Company records right-of-use assets and liabilities at the present value of the fixed lease payments over the term at the commencement date. The Company uses its incremental borrowing rate of

12
% to determine the present value of the lease as the rate implicit in the lease is typically not readily available.

Information related to the Company's right-of-use assets and lease liabilities consist of the following:

	April 30, 2024
Right-of-use assets	$ 461,983
Lease liabilities, current	102,293
Lease liabilities, net of current portion	434,045
Total lease liabilities	$ 536,338
Weighted average remaining term (in years)	4.1
Weighted average discount rate	12 %

As of April 30, 2024, future maturities of lease liabilities due under lease agreements for the fiscal year ended are as follows:

April 30, 2025	161,167
April 30, 2026	165,190
April 30, 2027	169,307
April 30, 2028	173,559
April 30, 2029	14,493
Total lease payments	683,716
Less imputed interest	(147,378)
Total operating lease liabilities	$ 536,338

Litigation

From time to time, the Company may be subject to legal proceedings and claims that arise in the ordinary course of business. The Company does not believe that the outcome of those matters will have a material adverse effect to the financial position, operating results or cash flows. However, there can be no assurance such legal proceedings will not have a material impact.

Management is not aware of any material claims outstanding or pending against the Company as April 30, 2024 and April 30, 2023.

Royalty Agreements

In 2013, the Company entered into an agreement (“Technology Agreement”) with its founder, conveying ownership of all intellectual property and rights to the Company. As part of that agreement, the Company will make royalty payments, based upon paid MyoVista *wav*ECG device unit sales, as follows:

a) $

500
on each of the first 2,400 MyoVista *wav*ECG devices

b) $

200
on each MyoVista *wav*ECG device thereafter until royalties total $

3,500,000
.

The royalty obligation has a first priority security interest and pledge on the covered technology (as defined in the Technology Agreement, which essentially is comprised of the intellectual property of the MyoVista *wav*ECG device) in priority to the debt holders of the $

1
M Loan and Security Agreement as discussed further in Note 4.

Upon (i) the aggregate payment of $

3,000,000
of royalties; (ii) the Common Stock having a closing quoted share price of $

6,875.00
per share or more; or (iii) receipt by the Company of a bona fide offer valuing the Common Stock at $

6,875.00
or more, then the secured interest and pledge shall be released.

In the event of a bankruptcy of the Company, any balance of the $

3,500,000
royalty not paid at that point would accelerate and become an immediately due debt obligation of the Company with the benefit of the secured interest and pledge (if it remained at such time).

In December 2015, the Company entered into an agreement with The University Court of The University of Glasgow (“Glasgow”) for a non-exclusive license of the Glasgow algorithm interpretive analysis for the conventional

ECG trace. The agreement was amended in March 2023 and as part of the agreement, the Company is required to make royalty payments, based upon MyoVista *wav*ECG device unit sales dependent on sale volumes per year, subject to minimum annual fees. To date, such amounts have been expensed to research and development as the Glasgow algorithm has been part of the device development and will form part of the submission for FDA clearance of the MyoVista *wav*ECG device.

Collaboration Agreements

Rutgers Collaboration Agreement

On November 29, 2022, the Company entered into a multi-year Collaboration Agreement with Rutgers, The State University of New Jersey, to research and develop AI-based ECG algorithms for new or improved ECG indications, which is expected to accelerate our product development pipeline and further expand the clinical value of an ECG for low-cost detection of heart disease.

Mount Sinai Collaboration Agreement

On September 20, 2023, the Company entered into multiple definitive license agreements (each a "License Agreement" and collectively, the "License Agreements") with Mount Sinai to commercialize a range of AI cardiovascular algorithms developed by Mount Sinai as well as a memorandum of understanding for ongoing cooperation encompassing de-identified data access, on-going research, and the evaluation of the MyoVista *wav*ECG. The License Agreements, of which there are eleven in total, cover rights to thirteen AI cardiovascular algorithms, two data science methods for use with ECG waveforms and three filed patents.

The closing of the transactions contemplated under the Securities Purchase Agreement (the "MTS Transaction"), dated as of September 20, 2023 (the "Securities Purchase Agreement"), by and between the Company and Mount Sinai, and the effectiveness of the licenses under the License Agreements, were subject to the satisfaction or waiver of certain closing conditions.

On November 16, 2023, and pursuant to the Securities Purchase agreement, the Company issued to Mount Sinai the following:

- 48,549 shares of Common Stock (the "Consideration Shares");
- pre-funded warrants to purchase up to 7,107 shares of Common Stock, with an exercise price per share of $ 0.001, which warrants were issued in lieu of shares of Common Stock issuable to Mount Sinai to ensure that the number of shares of Common Stock held by Mount Sinai does not exceed the Beneficial Ownership Limitation (the "MTS Pre-Funded Warrants"); and
- Common stock warrants to purchase up to 9,142 shares of Common Stock, having an exercise price per share equal to $ 50.60, (the "MTS Warrants" and collectively with the Consideration Shares and the MTS Pre-Funded Warrants, the "MTS Securities").

On December 1, 2023, the Company satisfied all material closing conditions of the Mount Sinai Securities Purchase Agreement and the MTS Warrants thereafter became fully exercisable by Mount Sinai. Registration rights related to the MTS Securities provide that on or prior to the date of one hundred and fifty days (150) days after the closing date, the Company shall prepare and file with the SEC a Registration Statement on Form S-1 (or such other form as applicable) covering the resale under the Securities Act of the MTS Securities issued to Mount Sinai, subject to any limitations imposed by the Nasdaq Rules. On March 5, 2024, the Company filed with the SEC a Registration Statement on Form S-1 registering the resale of the MTS Securities issued to Mount Sinai and the Registration Statement on Form S-1 was declared effective on March 13, 2024.

Note 9 - Subsequent Events

Management has evaluated subsequent events after the balance sheet date of April 30, 2024 through the date of filing.

During June and July 2024, the Company sold 14,500 shares of Common Stock under the Equity Line, receiving proceeds of approximately $72,000.

During June and July 2024, the Company sold 70,407 shares of Common Stock under the ATM Facility, receiving proceeds of approximately $369,000.

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

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We adopt 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 3a-15(f) and 15d-15(f), our management, including our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer), after evaluating the effectiveness of disclosure controls and procedures, determined that the Company's disclosure controls and procedures were not effective as of April 30, 2024, due to the material weaknesses in internal control over financial reporting described below.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of our Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of our Company are being made only in accordance with authorizations of our management and directors; and (iii) 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 the 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.

Based on our management's assessment, our management has concluded that our internal control over financial reporting was not effective as of April 30, 2024 due to the material weaknesses that existed in our internal controls. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Based on management's assessment of our internal control over financial reporting as of April 30, 2024, the following material weaknesses existed as of that date, specifically relating to the following control activities: (i) lack of proper approval processes and review processes and documentation for such reviews; (ii) we did not maintain sufficient U.S. GAAP and SEC accounting resources commensurate with those required of a public company; and (iii) insufficient number of staff to maintain optimal segregation of duties and levels of oversight.

Notwithstanding the material weakness discussed above, our management, including our CEO and CFO, concluded that the financial statements in this Annual Report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented, in conformity with GAAP.

Remediation Plan for Material Weakness in Internal Control over Financial Reporting

During Fiscal 2024, we have taken and continue to take remedial steps to improve our internal controls over financial reporting, which includes establishing a more robust process related to review of complex accounting transactions, preparation of account reconciliations, and review of journal entries. Our Chief Financial Officer frequently attends continuing education for updates on accounting policies and procedures. We cannot assure you that these measures will significantly improve or remediate the material weaknesses described above. Management is monitoring the effectiveness of these and other processes, procedures and controls and will make any further changes deemed appropriate. We are committed to ensuring that our internal controls over financial reporting are designed and operating effectively. Management believes the foregoing actions will effectively remediate the material weaknesses, however, our material weaknesses will not be considered remediated until controls are in place for a period of time, the controls are tested, and management concludes that the controls are properly designed and operating effectively.

Attestation Report of the Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Because we are a smaller reporting company and a non-accelerated filer, our independent registered public accounting firm is not required to attest to or issue a report on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

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 fiscal year ended April 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

CEO and CFO Certifications

Exhibits 31.1 and 31.2 to this Annual Report are the Certifications of our CEO and CFO, respectively. These certifications are required in accordance with Section 302 of the Sarbanes-Oxley Act (the “Section 302 Certifications”). This Item 9A. of this Annual Report on Form 10-K, which you are currently reading, is the information concerning the Evaluation referred to above and in the Section 302 Certifications, and this information should be read in conjunction with the Section 302 Certifications for a more complete understanding of the topics presented.

Item 9B. Other Information.

No ne

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

Not applicable

GLOSSARY OF TERMS

The following definitions shall apply to the terms used in this Annual Report on Form 10-K.

Terms Used by and for United States Federal Regulators and Regulations

"510(k)" means a premarket notification submission to the FDA for determination that a medical device is substantially equivalent to another legally U.S. marketed medical device prior to such device being marketed.

"510(k) Clearance" means a determination from FDA that a device is substantially equivalent to another legally U.S. marketed medical device thereby authorizing the device to be marketed in the U.S.

"CARES Act" means the Coronavirus Aid, Relief and Economic Security Act.

"CDC" means the U.S. Centers for Disease Control and Prevention.

"Class II" means a classification of medical devices that are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include submission of a 510(k), performance standards, post-market surveillance, patient registries and FDA guidance documents.

"Covered Entities" means, collectively, health plans, health care clearinghouses and certain health care providers as provided for under HIPAA.

"CMS" means U.S. Centers for Medicare & Medicaid Services.

"De Novo" means the process for obtaining authorization from the FDA of a novel medical device that is low to moderate risk for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. Devices that are classified (or re-classified) into Class I or Class II through a De Novo classification request may be marketed and used as predicates for future premarket notification 510(k) submissions, when applicable.

"DOJ" means the U.S. Department of Justice.

"FCA" means the False Claims Act.

"FDA" means the U.S. Food and Drug Administration.

"FDCA" means the Federal Food, Drug and Cosmetic Act, as amended.

"FINRA" means the Financial Industry Regulatory Authority.

"GUDID" means the FDA's Global Unique Device Identification Database.

"HHS" means the U.S. Health and Human Services—Office of the Inspector General.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996, as amended.

"HITECH" means the Health Information Technology for Economic and Clinical Health Care Act.

"IRB" means the Institutional Review Board formally designated by the FDA regulations, which has oversite of a study being conducted at a clinical site.

"JOBS Act" means the Jumpstart our Business Startups Act of 2012.

"PMA" means a premarket approval application requesting the determination of the safety and effectiveness of Class III medical devices pursuant to a scientific and regulatory review by the FDA.

"QSR" means the FDA's Quality System Regulation, which is the current good manufacturing practice requirements for medical devices. The requirements govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act.

"SEC" means the U.S. Securities and Exchange Commission.

"Trade Laws" means, collectively, U.S. and foreign anticorruption, anti-money laundering, export control, sanctions and other trade laws and regulations.

"USPSTF" means the U.S. Preventive Services Task Force.

Terms Used in Jurisdictions Other Than the U.S.

"CE Mark" means Conformité Européene Mark.

"CJEU" means the Court of Justice of the European Union.

"EEA" means the European Economic Area.

"EU" means the European Union.

"EU MDR" means the EU Medical Device Regulation.

"GDPR" means the EU's General Data Protection Regulation.

"MDD" means the EU Medical Devices Directive.

"Privacy Shield" means the transfer framework, agreed to by the U.S. and the EU, for transferring data from the EU to the U.S., but which was invalidated in July 2020 by the CJEU.

"UK" means the United Kingdom.

Terms Used for Medical and Medical Device Related Purposes

"AI" means artificial intelligence.

"CAD" means coronary artery disease.

"CPT" means Current Procedural Terminology.

"CROs" means contract research organizations.

"diastolic phase" means the period of the heart's relaxation or filling phase (as opposed to the heart's period of contraction or pumping phase called "systolic") of a heartbeat.

"diastolic dysfunction" means impaired left ventricular relaxation and elevated filling pressures during the diastolic phase.

"ECG" means electrocardiogram or electrocardiograph as appropriate, which is also known by the acronym "EKG."

"echo" means an echocardiogram.

"GCP" means good clinical practice.

"HFpEF" means heart failure with preserved ejection fraction or where a patient is not yet classified as having systolic dysfunction, or, also known as severe diastolic dysfunction.

"HFrEF" means heart failure with reduced ejection fraction, or heart failure is classified with systolic dysfunction, also known as severe diastolic dysfunction.

"LV" means left ventricular.

"LVD" means left ventricular dysfunction.

"LVDD" means left ventricular diastolic dysfunction.

"sensitivity" means the true positive rate or the percentage probability of a positive test result identifying patient with a condition as compared to the gold standard test which in our case is an echo.

"specificity" means the true negative rate or the percentage probability of a negative test result identifying a patient without a condition as compared to the gold standard test, which in our case is an echo.

Terms Used in Connection with the Company and Our Products

"$1.5M Lender Warrants" means the warrants issued to holders of the $1.5M Notes as consideration for the extension of the maturity of the $1.5M Notes.

"$1.5M Notes" means our 12% secured subordinated convertible promissory notes in the aggregate principal amount of $1.5 million issued to accredited investors between December 2020 and April 2021.

"$130K Note" means our private placement on August 12, 2019 with FRV, an accredited investor, of an unsecured drawdown convertible promissory note in the amount of $130,000.

"$1M Lender Warrants" means the warrants issued to holders of the $1M Notes as consideration for the extension of the maturity of the $1M Notes.

"$1M Loan and Security Agreement" means Loan and Security Agreement by and among the Company, FRV and John Q. Adams, Sr. in April 2020 in connection with the $1M Notes, as amended by Amendment No. 1 dated September 30, 2021, Amendment No. 2 dated November 3, 2021, Amendment No. 3 dated May 24, 2022 and Amendment No. 4 dated January 24, 2023.

"$1M Notes" means our 12% secured, non-convertible promissory notes payable to FRV and John Q. Adams, Sr. in the aggregate principal amount of $1 million, as amended and restated.

"Certificate of Designations" means our Certificate of Designations, Number, Voting Power, Preferences and Rights of Series C Convertible Preferred Stock of Heart Test Laboratories, Inc., as filed with the Secretary of State of the State of Texas on March 12, 2019.

"Investor Warrants" means all outstanding warrants to purchase 5,294 shares of our Common Stock issued in connection with funding or as consideration for services rendered to the Company and excludes the Bridge Warrants, other Pre-Funded Warrants, $1M Lender Warrants and $1.5M Lender Warrants.

"IPO" refers to our initial public offering, completed on June 17, 2022.

"IPO Underwriter Warrants" means the warrants to purchase an aggregate of 1,050 shares of Common Stock that were issued to the underwriter in the IPO as a portion of the underwriting compensation payable in connection with the IPO.

"IPO Warrants" means all outstanding warrants to purchase shares of our Common Stock that were issued as part of the Units in the IPO plus additional warrants to purchase 2,250 shares of Common Stock that were issued in the IPO as a result of the underwriter's exercise of its over-allotment option in part.

"IT" means our information technology.

"MyoVista" means the branding associated with the MyoVista *wav*ECG device or MyoVista Insights Cloud Platform.

"MyoVista *wav*ECG" means the 12-lead ECG hardware device.

"MyoVista Insights Cloud Platform" means the platform for the delivery of AI-ECG algorithms via the cloud.

"Series A Preferred Stock" means our Series A convertible preferred stock, par value $0.001 per share, all outstanding shares of which converted to Common Stock in connection with our IPO.

"Series B Preferred Stock" means our Series B convertible preferred stock, par value $0.001 per share, all outstanding shares of which were cancelled in connection with our IPO.

"Series C Preferred Stock" means our Series C convertible preferred stock, par value $0.001 per share.

Terms Used in Connection with Our 2021 Bridge Financing

"2021 Bridge Financing" means our private placement, pursuant to a Securities Purchase Agreement, with a lead investor and additional accredited investors of the Bridge Notes and Bridge Warrants from December 2021 to February 2022, which were issued to such additional accredited investors in exchange for the secured subordinated convertible notes and warrants issued to them in an initial closing of a private placement in October 2021.

"2021 Bridge Securities" means, collectively, the Bridge Notes, the Pre-Funded Bridge Warrants and Bridge Warrants.

"Bridge Attribution Parties" are any Purchaser, together with its affiliates and any other person acting as a group as defined under Section 13(d) of the Exchange Act with regard to determining Maximum Percentage.

"Bridge Notes" means the 8% secured subordinated convertible notes we sold to Purchasers pursuant to the Bridge SPA.

"Bridge Purchasers" means the accredited investors who purchased our securities pursuant to the Bridge SPA.

"Bridge SPA" means the Securities Purchase Agreement we entered into with the Bridge Purchasers in connection with the 2021 Bridge Financing.

"Bridge Warrant Amendment No. 1" means Amendment No. 1 to Bridge Warrant by and between Heart Test Laboratories, Inc. and the lead investor under the Bridge SPA, dated September 8, 2022.

"Bridge Warrant Amendment No. 2" means Amendment No. 2 to Bridge Warrant by and between Heart Test Laboratories, Inc. and the lead investor under the Bridge SPA, dated February 3, 2023.

"Bridge Warrants" means warrants to purchase our Common Stock issued pursuant to the Bridge SPA. The term "Bridge Warrants" does not include the Pre-Funded Bridge Warrants.

"Bridge Maximum Percentage" means the beneficial ownership in excess of 4.99% of the number of shares of the Common Stock outstanding immediately prior to, and immediately after giving effect to, the conversion of all or any portion of the Bridge Notes as applied to Attribution Parties unless a holder has notified the Company that it has elected to increase the Maximum Percentage to 9.99%.

"OID" means the 10% original issue discount on our Bridge Notes.

"Pre-Funded Bridge Warrants" means the warrants issued in the event the number of shares of Common Stock to be issued to a Purchaser upon conversion of in the Bridge Notes would be in excess of the Maximum Percentage.

Terms Used in Connection with this Annual Report on Form 10-K Not Otherwise Listed

"ASC" means the Accounting Standards Codification.

"FRV" means Front Range Ventures, LLC.

"FRV Side Letter" means the letter agreement entered into by and between the Company and FRV on April 10, 2019.

"MD&A" means Management's Discussion & Analysis of Financial Condition and Results of Operations.

"Nasdaq" means The Nasdaq Stock Market LLC.

"Philips" means Koninklijke Philips N.V.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

Our business and affairs are managed under the direction of our Board of Directors, which currently consists of five members. The number of directors is determined by our Board of Directors, subject to the terms of our amended and restated certificate of formation and amended and restated bylaws.

Our Board of Directors is divided into three classes as nearly equal in size as is practicable. The composition of the Board of Directors is as follows:

- Class I, which consists of Brian Szymczak and Bruce Bent, whose terms will expire at our annual meeting of shareholders to be held in 2026;
- Class II, which consists of Mark Hilz and David R. Wells, whose terms will expire at our annual meeting of shareholders to be held in 2027; and
- Class III, which consists of Andrew Simpson, whose term will expire at our annual meeting of shareholders to be held in 2025.

Upon the expiration of the initial term of office for each class of directors, each director in such class shall be elected for a term of three years and serve until a successor is duly elected and qualified or until his or her earlier death, resignation or removal. Vacancies occurring on the Board of Directors, whether due to death, resignation, removal, retirement, disqualification or for any other reason, and newly created directorships resulting from an increase in the authorized number of directors, may be filled by a majority of the remaining members of the Board of Directors. Directors may be removed, but only for cause, with the affirmative vote of the holders of a majority of the voting power of our Common Stock and Preferred Stock voting together as a single class.

Director Independence

Under Nasdaq rules, independent directors must comprise a majority of a listed company's Board of Directors. In addition, Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees must be independent. Under Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of that Company's Board of Directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Ownership of a significant amount of our stock, by itself, does not constitute a material relationship.

Audit committee members of a listed company must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the Board of Directors, or any other board committee: (i) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries. We have an audit committee composed of three independent directors who each meet the Nasdaq audit committee independence standards for a listed company.

Nasdaq rules require that, subject to limited exceptions, a listed company's compensation committee must consist of at least two members, each of whom must be independent. In affirmatively determining the independence of any director who will serve on the compensation committee, the board of directors must consider all factors specifically relevant to determining whether a director has a relationship to the listed company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to (i) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the listed company to such director, and (ii) whether such director is affiliated with the listed company, a subsidiary of the listed company or an affiliate of a subsidiary of the listed company. We have a compensation committee composed of three independent directors.

Nasdaq rules require that director nominees must either be selected, or recommended for the board of director's selection, either by (i) independent directors constituting a majority of the board's independent directors in a vote in which only independent directors participate, or (ii) a nominations committee comprised solely of independent directors. We have a nominating and governance committee composed of three independent directors that recommends to our Board of Directors nominees for election as directors.

Our Board of Directors undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that that Bruce Bent, David R. Wells, and Brian Szymczak, representing a majority of our directors, do not have any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under Nasdaq rules and Rule 10A-3 under the Exchange Act. In making these determinations, our Board of Directors considered the relationships that each non-employee director has with our Company and all other facts and circumstances our Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Background and Experience of Directors and Executive Officers

When considering whether directors and nominees have the experience, qualifications, attributes or skills, taken as a whole, to enable our Board of Directors to satisfy its oversight responsibilities effectively in light of our business and structure, the Board of Directors focused primarily on each person's background and experience as reflected in the information discussed in each of the directors' individual biographies set forth below. We believe that our directors provide an appropriate mix of experience and skills relevant to the size and nature of our business.

The following table sets forth certain information regarding our executive officers and directors of the Company:

Board of Directors and Executive Officers

Name	Age	Position
Andrew Simpson	56	President, Chief Executive Officer and Chairman of the Board of Directors
Mark Hilz	66	Chief Operating Officer, Secretary and Director
Danielle Watson	42	Chief Financial Officer and Treasurer
Bruce Bent*	68	Director
David R. Wells*	61	Director
Brian Szymczak*	51	Director

* Independent Director

Andrew Simpson — *President, Chief Executive Officer and Chairman of the Board of Directors*

Since March 2022, Andrew Simpson has served as our President and Chief Executive Officer. Mr. Simpson has also served as the Chairman of our Board of Directors, since June 2013, and as a director of our Company since July 2012. Mr. Simpson has over 30 years' experience across a variety of business sectors and sizes. He was Group CEO of The Peel Group from 2006 to 2010, which is a large private company in the UK which, at the time, had approximately $8 billion of business assets across the real estate, ports, airports, energy, media, telecoms and environmental sectors. He was a main board director of Speedy Hire plc from 2003 to 2006 (during which time it became a FTSE 250 company) and during his tenure was Managing Director of its Equipment Rental division which had revenues of approximately $200 million and was also responsible for the Group's development and expansion which included seventeen acquisitions and several non-core divestments. Mr. Simpson qualified as a Chartered Accountant with Price Waterhouse and spent eight years working in investment banking at Rothschild, advising on a wide variety of merger and acquisition transactions, debt and equity fundraisings, IPOs and other advisory assignments. Mr. Simpson graduated with first class honors in 1991 from Sheffield Hallam University in the UK where he received a Bachelor of Arts (honors) in Accounting and Management Control.

Board Membership Qualifications: Our Board of Directors has concluded that Mr. Simpson is well-qualified to serve on our Board of Directors and has the requisite qualifications, skills and perspectives based on, among other factors, him being our Chief Executive Officer and his extensive business, investment banking, capital markets, merger and acquisition transactions and public company experience.

Mark Hilz — *Chief Operating Officer, Secretary and Director*

Since March 2022, Mark Hilz has served as our Chief Operating Officer and Secretary and, since June 2013, has also been a director of our Company. Mr. Hilz served as the Chief Executive Officer of the Company from June 2013 until March 2022. Mr. Hilz has over 30 years of experience as a President and/or CEO of multiple startup companies. He was previously CEO of INX Inc., a technology infrastructure consulting company. INX Inc. started in 2000 and grew to $400 million in revenue. INX Inc. was traded on Nasdaq, completed multiple offerings until it was acquired in December 2011. Prior to that, Mr. Hilz founded and was CEO of a technology logistics outsourcing firm, PC Service Source Inc., that grew to over $160 million in revenue. Mr. Hilz raised the startup capital from traditional venture capital sources and after four years of operations took PC Service Source Inc. public in an initial public offering as a Nasdaq global listed company. Mr. Hilz's experience includes raising venture capital as well as multiple successful public offerings and numerous merger and acquisition transactions as both a buyer and a seller.

Board Membership Qualifications: Our Board of Directors has concluded that Mr. Hilz's extensive experience in building and operating companies from start-up to public companies including mergers and acquisitions transactions and a strong understanding of capital markets, provides valuable knowledge to our Board of Directors.

Danielle Watson — *Chief Financial Officer and Treasurer*

Since April 2022, Danielle Watson has served as our Chief Financial Officer. Prior to her appointment to Chief Financial Officer, Ms. Watson, a CPA, served as the Company's Financial Controller since November 2021. Ms. Watson brings over 17 years of financial experience to her role. Before joining the Company, Ms. Watson held senior leadership roles at Moss Adams, LLP from November 2007 to November 2021 where she provided audit and assurance services to both public and privately held companies with an emphasis in financial reporting, consolidations, strategic planning, purchase price accounting, and SEC reporting. Ms. Watson earned her Bachelor of Science, with a double concentration in accounting and finance from Texas Christian University and her Master of Science in accounting from the University of Texas at Arlington and is an active Certified Public Accountant in Texas.

Bruce Bent — *Director*

Since May 2020, Bruce Bent has served as a director of our Company. Mr. Bent has more than 35 years of experience in financial management. From September 2014 to February 2022, Mr. Bent has served as Chairman of Net Zero Renewable Energy Inc. (fka Enerdynamic Hybrid Technologies Corp.). In addition, since March 2018, Mr. Bent has served as Chairman for Astro Aerospace Ltd., an OTC listed public company. From June 2020 to January 2024, Mr. Bent has been Vice President and Chief Financial Officer Emeritus of The Matthews Group, referred to in this section as Matthews, and, from August 2004 to June 2020, he served as the Chief Financial Officer of Matthews as well as president of various Canadian subsidiaries of Matthews. Mr. Bent retired from Matthews in January 2024. Matthews is a $500M real estate development company. During his tenure with Matthews, among other projects, Mr. Bent was integral in the completion of a $1.7 billion dollar corporate headquarters building for Encana (now Ovintiv Inv., NYSE: OVV). Since April 2000, Mr. Bent has served as president of MSW Investments Limited, a family office providing early stage financing. Mr. Bent graduated from the University of Manitoba with a Bachelor of Commerce (honors) and obtained his Chartered Professional Accounting designation from the Province of Ontario.

Board Membership Qualifications: Our Board of Directors has concluded that Mr. Bent's extensive financial experience provides valuable knowledge to our Board of Directors. Mr. Bent also serves as the chairman of our Audit Committee and our "audit committee financial expert." For more information, see "— Board Committees — Audit Committee."

David R. Wells — *Director*

Since December 2022, David R. Wells, has served as a director of our Company. Mr. Wells is the Chief Financial Officer of Envoy Medical, Inc., a publicly traded medical device company in the hearing health space, a position he began in August, 2023. Also, Mr. Wells is a partner of Atlas Bookkeeping, LLC, a technology based financial services firm providing bookkeeping and reporting for emerging growth and small cap public and privately held companies, which he founded in October 2022. Prior to that, Mr. Wells served as the Chief Financial Officer of GHS Investments, LLC, a privately held "super value" fund focused on small to mid-cap companies, from June 2021 to September 2022, and served as the Chief Financial Officer of ENDRA Life Sciences Inc., a publicly traded clinical diagnostics technology company, initially on an interim basis beginning in May 2014, and on a continuing basis beginning in 2017 until June 2021. Mr. Wells was the founder of Wells Compliance Group, a technology-based services firm supporting the financial reporting needs of publicly traded companies and privately held firms whose investor or shareholder base required timely GAAP-compliant financial reporting. During his time at StoryCorp Consulting, Inc. (d/b/a/ Wells Compliance Group) from September 2009 to June 2021, Mr. Wells consulted with several emerging growth publicly traded companies. He possesses over 30 years of experience in finance, operations and administrative positions. Mr. Wells holds an MBA from Pepperdine University and a BS in Finance and Entrepreneurship from Seattle Pacific University.

Board Membership Qualifications: Our Board of Directors has concluded that Mr. Well's extensive experience with public company accounting and financial matters, capital markets and corporate governance provides valuable knowledge to our Board of Directors.

Brian Szymczak — *Director*

Since 2014, Brian Szymczak, has served as a director of our Company. Mr. Szymczak is currently the principal of The Law Office of Brian Szymczak PLLC where he specializes in providing legal counsel to medical technology clients. Mr. Szymczak previously led the legal and compliance functions for Apollo Endosurgery, Inc., referred to in this section as Apollo, in Austin, Texas where he served as Vice President of Legal and Compliance until Apollo's acquisition in 2023 by Boston Scientific. In this role, Mr. Szymczak managed legal disputes and litigation matters and provided general legal counsel to the company's leadership, sales, operations, research and development, and human resources groups. Prior to working at Apollo, from 2006 to 2014, Mr. Szymczak served in various roles including as Associate General Counsel and Director of Legal Affairs for a medical device manufacturer and from, 1999 to 2006, worked as an associate at the law firm of Baker Botts, LLP where he counseled clients on patent and other intellectual property matters in a variety of industries. Mr. Szymczak is a 1999 graduate of Duke University School of Law and holds a Bachelor of Science in Mechanical Engineering from Texas A&M University.

Director Designation: Mr. Szymczak was designated a director of our Company pursuant to the MyoVista Technology Agreement, which grants Guangren "Gary" Chen the right to designate a person of his choosing to sit on our Board of Directors.

Board Membership Qualifications: Our Board of Directors has concluded that Mr. Szymczak's breadth of experience working as general counsel for listed medical device manufacturers provides valuable knowledge to our Board of Directors.

Board Committees

Our Board of Directors has three standing committees: an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Under Nasdaq rules and Rule 10A-3 under the Exchange Act, the membership of the Audit Committee is required to consist entirely of independent directors, subject to applicable phase-in periods. The following is a brief description of our committees.

Audit Committee

Our Audit Committee is a separately-designated audit committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. In accordance with our audit committee charter, our audit committee oversees our corporate accounting and financial reporting processes and our internal controls over financial reporting; evaluates our independent registered public accounting firm's qualifications, independence and performance; engages and provides for the compensation of our independent registered public accounting firm; approves the retention of our independent registered public accounting firm to perform any proposed permissible non-audit services; reviews our financial statements; reviews our critical accounting policies and estimates and internal controls over financial reporting; and discusses with management and our independent registered public accounting firm the results of the annual audit and the reviews of our quarterly financial statements. We believe that our Audit Committee members meet the requirements for financial literacy under the current requirements of the Sarbanes-Oxley Act, Nasdaq and SEC rules and regulations. The Audit Committee is currently composed of Bruce Bent, David R. Wells, and Brian Szymczak. Our Board of Directors has determined that Mr. Brent is an "audit committee financial expert" as defined by SEC rules. Nasdaq rules require that all of the members of the Audit Committee meet the independence standards set forth above, subject to the applicable phase-in periods of Nasdaq. Our Board of Directors has determined that Bruce Bent, David R. Wells, and Brian Szymczak meet the independence requirements of the Sarbanes-Oxley Act, Rule 10A-3 under the Exchange Act and the applicable listing standards of Nasdaq.

Compensation Committee

In accordance with our compensation committee charter, our Compensation Committee reviews and recommends policies relating to compensation and benefits of our officers and employees, including reviewing and approving corporate goals and objectives relevant to compensation of our Chief Executive Officer and our other senior officers, evaluating the performance of these officers in light of those goals and objectives and setting compensation of these officers based on such evaluations. The Compensation Committee also administers the issuance of stock options and other awards under our equity-based incentive plans. We believe that the composition of our Compensation Committee meets the requirements for independence under, and the functioning of our compensation committee complies with, any applicable requirements of the Sarbanes-Oxley Act, Nasdaq and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us. The Compensation Committee is composed of Bruce Bent, David R. Wells, and Brian Szymczak.

Nominating and Governance Committee

In accordance with our nominating and governance committee charter, our Nominating and Governance Committee recommends to our Board of Directors nominees for election as directors, and meets as necessary to review director and nominees for election as directors; recommends members for each committee of the Board of Directors; oversees corporate governance standards and compliance with applicable listing and regulatory requirements; develops and recommends to our Board of Directors governance principles applicable to the company; and oversees the evaluation of our Board of Directors and its committees. We believe that the composition of our Nominating and Governance Committee meets the requirements for independence under, and the functioning of our Nominating and Governance Committee complies with, any applicable requirements of the Sarbanes-Oxley Act, Nasdaq and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us. The Nominating and Governance Committee is composed of Bruce Bent, David R. Wells, and Brian Szymczak.

Family Relationships

There are no family relationships between or among any of our directors or executive officers or persons nominated or chosen by us to become directors or executive officers.

Board Meetings and Attendance

During Fiscal 2024, our Board of Directors held ten meetings and also took action by written consent on fourteen occasions. During Fiscal 2024, each of our current directors attended at least 75% of all Board meetings and the meeting of the committees on which they served (during the period for which they served).

Board Leadership Structure

Currently, the office of Chairman of our Board of Directors and Chief Executive Officer are held by Andrew Simpson. Due to our size and early stage of operations, we believe it is currently most effective to have the Chairman of our Board of Directors and Chief Executive Officer positions be held by the same individual. Under our Bylaws, the Chairman of our Board of Directors is responsible for coordinating our Board of Directors' activities, including the scheduling of meetings and the determination of relevant agenda items.

Risk Oversight and Compensation Risk Assessment

Our Board of Directors oversees a company-wide approach to risk management. Our Board of Directors determines the appropriate risk level for us, assesses the specific risks faced by us, and reviews the steps taken by our management to manage those risks. While our Board of Directors has ultimate oversight responsibility for the risk management process, its committees oversee risk in certain specified areas.

Specifically, our Compensation Committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements, and the incentives created by the compensation awards it administers. Our Audit Committee oversees management of enterprise risks and financial risks, as well as potential conflicts of interests. Our Board of Directors is responsible for overseeing the management of risks associated with the independence of our Board of Directors.

Our management also reviews and reports on potential areas of risk at the request of the Audit Committee or other members of our Board of Directors.

We believe that our compensation policies and practices do not create inappropriate or unintended significant risk to our Company as a whole. We also believe that our incentive compensation arrangements provide incentives that do not encourage risk-taking beyond our ability to effectively identify and manage significant risks, are compatible with effective internal controls and our risk management practices and are supported by the oversight and administration of the Compensation Committee with regard to executive compensation programs.

Changes to the Procedures by Which Security Holders May Recommend Nominees to Our Board of Directors

Our Nominating and Governance Committee has not adopted a procedure by which shareholders may recommend nominees to our Board of Directors.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics applicable to all of our directors, officers and employees, including our Chief Executive Officer and Chief Financial Officer, which is a "code of ethics" as defined by applicable SEC rules. The purpose and role of this code is to, among other things, focus our directors, officers and employees on areas of ethical risk, provide guidance to help them recognize and deal with ethical issues, provide mechanisms to report unethical or unlawful conduct and to help enhance and formalize our culture of integrity, honesty and accountability. If we make any amendments to this code, other than technical, administrative or other non-substantive amendments, or grant any waivers, including implicit waivers, from any provision of this code that applies to our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, and that relates to an element of the SEC's "code of ethics" definition, then we will disclose the nature of the amendment or waiver in the "Governance" section of our investor relations/corporate governance website https://ir.heartsciences.com.

Compensation Committee Interlocks and Insider Participation

None of the members of our Compensation Committee is an executive officer or employee of our Company. None of our executive officers serves as a member of the board of directors or Compensation Committee of any entity that has one or more executive officers serving on our Board of Directors or Compensation Committee.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act, requires directors, officers and beneficial owners of more than 10% of our common stock (a "10% Stockholder") to file reports of ownership and reports of changes in ownership with the SEC. Such persons are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file. Based on a review of those reports, all Section 16 reporting persons timely complied with all applicable Section 16(a) filing requirements during Fiscal 2024.

Policy Regarding Attendance at Annual Meetings of Stockholders

We do not have a policy with regard to board members' attendance at annual meetings. We expect that our Chairman and one or more of the other directors will attend our annual meeting or stockholders or at any adjournment or postponement thereof.

Item 11. Executive Compensation.

2024 Summary Compensation Table

The following table sets forth summary compensation information for our named executive officers consisting of: our President, Chief Executive Officer and Chairman of the Board of Directors, our Chief Operating Officer and Secretary, and our Chief Financial Officer and Treasurer (collectively, "named executive officers"). We had no other executive officers during Fiscal 2024 and Fiscal 2023. The following table includes all compensation earned by the named executive officers for the respective period, regardless of whether such amounts were actually paid during the period

Name and Position	Fiscal Years	Salary($)	Bonus ($)	Option Awards($) (1)	Total($)
Andrew Simpson					
President, Chief Executive Officer and Chairman of the Board of Directors	2024	300,000 (2)	—	—	300,000
	2023	234,139	30,000	191,805	455,944
Mark Hilz	2024	300,000	—	—	300,000
Chief Operating Officer and Secretary	2023	233,611	30,000	191,805	455,416
Danielle Watson	2024	179,317	—	—	179,317
Chief Financial Officer and Treasurer	2023	161,250	27,500	47,951	236,701

(1) Represents the full grant date value of the stock award or option grant, as applicable, calculated in accordance with FASB ASC Topic 718, *Compensation — Stock Compensation*. Our policy and assumptions made in the valuation of share-based payments are contained in Note 6 Stock-based Compensation to our Fiscal 2024 financial statements. The value of option 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.

(2) Includes $25,000 in accrued compensation paid subsequent to Fiscal 2024.

Named Executive Officer Employment Agreements

Employment Agreement with Andrew Simpson

On April 5, 2022, we entered into an employment agreement with Mr. Simpson, which automatically renews at the end of each one-year term unless otherwise terminated in accordance with its terms, and who currently has an annual salary of $350,000. If Mr. Simpson's employment is terminated by us for "Just Cause" or by Mr. Simpson for "Constructive Termination" (each as defined in his employment agreement, subject to our right to cure), he will be entitled to termination benefits, pursuant to which we will pay Mr. Simpson certain accrued obligations and prior year bonus amounts, if any and we will continue to cover costs for Mr. Simpson's health insurance and other benefits, if any, to which he may be entitled under our medical plans from the termination date through and inclusive of the lesser of twelve months or the period through the date on which he obtains other coverage. Mr. Simpson's employment agreement contains covenants relating to certain restrictive covenants, such as a non-compete, a non-solicitation covenant restricting his ability to solicit employees of our Company, and the requirement that they devote their full time and attention to the business of our Company.

Employment Agreement with Mark Hilz

On April 5, 2022, we entered into an employment agreement with Mr. Hilz, which automatically renews at the end of each one-year term unless otherwise terminated in accordance with its terms, who currently has an annual salary of $340,000. If Mr. Hilz's employment is terminated by us for "Just Cause" or by Mr. Hilz for "Constructive Termination" (each as defined in his employment agreement, subject to our right to cure), he will be entitled to termination benefits, pursuant to which we will pay Mr. Hilz certain accrued obligations and prior year bonus amounts, if any and we will continue to cover costs for Mr. Hilz's health insurance and other benefits, if any, to which the he may be entitled under the our medical plans from the termination date through and inclusive of the lesser of twelve months or the period through the date on which he obtains other coverage. Mr. Hilz's employment agreement covenants relating to certain restrictive covenants, such as a non-compete, a non-solicitation covenant restricting his

ability to solicit employees of our Company, and the requirement that they devote their full time and attention to the business of our Company.

Employment Agreement with Danielle Watson

On October 15, 2021, we entered into an employment agreement with Ms. Watson, effective as of November 4, 2021, who currently has an annual salary of $205,000 and participation in the Company's equity incentive plan, along with health insurance and other Company benefits. Ms. Watson's employment with us constitutes "at-will" employment, and therefore is for an unspecified duration and she may terminate her employment at any time, for any reason, with or without cause and with or without notice. Likewise, we may terminate her employment at any time, for any reason, with or without cause and with or without notice. Ms. Watson's employment agreement contains certain covenants relating to restrictive covenants, such as a non-compete, a non-solicitation covenant restricting her ability to solicit employees of our Company, and the requirement that she devote her full time and attention to the business of our Company.

2024 Outstanding Equity Awards at Fiscal Year End

The following table shows outstanding option awards granted to our named executive officers as of April 30, 2024:

	Option Awards				Stock Awards	
Name / Grant Date	Number of Securities Underlying Unexercised Options (#) Vested (1)	Number of Securities Underlying Unexercised Options (#) Unvested (1)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested (#)	Market Value of Shares or Units of Stock that Have Not Vested ($)
Andrew Simpson						
May 1, 2016	190	38	1,221	May 1, 2026		
March 14, 2018	—	228	1,518	March 14 2028		
November 1, 2018	—	228	1,518	November 1, 2028		
September 1, 2019	303	228	129	September 1, 2029		
November 6, 2020	265	265	116	November 6, 2030		
March 1, 2022	265	265	347	March 1, 2032		
March 20, 2023	1,000	2,000	97	March 20, 2033		
Mark Hilz						
May 1, 2016	190	38	1,221	May 1, 2026		
March 14, 2018	—	228	1,518	March 14 2028		
November 1, 2018	—	228	1,518	November 1, 2028		
September 1, 2019	303	228	129	September 1, 2029		
November 6, 2020	265	265	116	November 6, 2030		
March 1, 2022	265	265	347	March 1, 2032		
March 20, 2023	1,000	2,000	97	March 20, 2033		
Danielle Watson						
February 1, 2022	40	6	347	February 1, 2032		
March 1, 2022	46	—	347	March 1, 2032		
March 20, 2023	250	500	97	March 20, 2033		

(1) Represents options to purchase shares of Common Stock.

Non-Employee Director Compensation

The following table sets forth a summary of compensation for Fiscal 2024 that the we paid to our non-employee director. We do not sponsor a non-equity incentive plan or a non-qualified deferred compensation plan for our directors; therefore, these columns have been omitted from the following table. Additionally, we did not issue any stock awards to its directors during Fiscal 2024.

Name	Fees Earned or Paid in Cash ($) (1)	Option Awards ($)(2)	Total ($)(3)
Bruce Bent	60,000	—	60,000
Brian Szymczak	57,500	—	57,500
David R. Wells	57,500	—	57,500

(1) This column represents the amounts paid in cash to each director which was paid or accrued in Fiscal 2024.

(2) The amounts in this column reflect the aggregate grant date fair value of stock options granted in Fiscal 2024 to each director calculated in accordance with FASB ASC Topic 718. See Note 6 Stock-based Compensation to our financial statements included in this Annual Report on Form 10-K for a discussion of all assumptions made in the calculation of these amounts.

(3) The dollar value in this column for each director represents the sum of all compensation reflected in the previous columns.

The following table shows outstanding vested and unvested option awards (represented by the number of shares of Common Stock such awards entitle the holder to purchase) held by our directors as of April 30, 2024:

Name	Vested Option Awards	Unvested Option Awards	Total Awards
Bruce Bent	519	19	538
Brian Szymczak	713	69	782
David R. Wells	500	—	500

2023 Equity Incentive Plan

On March 15, 2023, our Board of Directors adopted the 2023 Equity Incentive Plan (the “Equity Incentive Plan”), subject to shareholder approval. The Equity Incentive Plan provides for the grant of nonstatutory stock options, incentive stock options, restricted stock, restricted stock units, performance units, performance shares, and other share-based awards. All of our employees, officers and directors, as well as consultants and advisors, are eligible to receive awards under the Equity Incentive Plan. On January 17, 2024, the shareholders approved the Equity Incentive Plan at our annual shareholder meeting.

Pursuant to the Equity Incentive Plan, as amended on November 27, 2023, we are authorized to issue up to 85,000 shares of our Common Stock plus (i) any shares of our Common Stock subject to options that expire or otherwise terminate without having been exercised in full, are tendered to or withheld by us for payment of an exercise price or for tax withholding obligations, or are forfeited to or repurchased by us due to failure to vest, with the maximum number of shares of our Common Stock to be added to the Equity Incentive Plan under this clause (ii) equal to 8,322 shares of our Common Stock. The number of shares of our Common Stock available for issuance under the Equity Incentive Plan will be subject to automatic increase on the first day of each of our fiscal years beginning with the fiscal year beginning May 1, 2024, so that the number of shares of our Common Stock available for issuance under the Equity Incentive Plan is equal to the least of: (i) 25% of the total number of shares of all classes of our Common Stock and preferred stock as converted to our Common Stock outstanding on the last day of the immediately preceding fiscal year, and (ii) a lesser number of shares of our Common Stock determined by the administrator of the Equity Incentive Plan.

As described below, incentive awards authorized under the Equity Incentive Plan include, but are not limited to, incentive stock options within the meaning of Section 422 of the Code. If an incentive award granted under the Equity Incentive Plan expires, terminates, is unexercised or is forfeited, or if any shares are surrendered to us in connection with the exercise of an incentive award, the shares subject to such award and the surrendered shares will become available for further awards under the Equity Incentive Plan. Set forth below is the summary of the principal features of the Equity Incentive Plan.

Administration — The Equity Incentive Plan is administered by our Compensation Committee or our board of directors in the absence of such a committee. Subject to the terms of the Equity Incentive Plan, the Equity Incentive Plan administrator may select participants to receive awards, determine fair market value of our shares, determine the types of awards and terms and conditions of awards and interpret provisions of the Equity Incentive Plan, to institute an exchange program (without stockholder approval) pursuant to which outstanding awards may be surrendered or cancelled in exchange for awards of the same type (which may have lower exercise prices and different terms), awards of a different type, and/or cash (except that the Equity Incentive Plan administrator may not, without stockholder approval, reprice any options or pay cash or issue new options in exchange for the surrender and cancellation of outstanding options), modify awards granted under the Equity Incentive Plan, and make all other determinations deemed necessary or advisable for administering the Equity Incentive Plan.

Grants — The Equity Incentive Plan authorizes the grant to participants of nonqualified stock options, incentive stock options, restricted stock awards, restricted stock units, performance shares, performance units or other share-based rewards intended to comply with Section 162(m) of the Code and SARs, as described below:

- Options granted under the Equity Incentive Plan entitle the grantee, upon exercise, to purchase up to a specified number of shares from us at a specified exercise price per share. The exercise price for shares of our Common Stock covered by an option generally cannot be less than the fair market value of our Common Stock on the date of grant unless agreed to otherwise at the time of the grant. In addition, in the case of an incentive stock option granted to an employee who, at the time the incentive stock option is granted, owns stock representing more than 10% of the voting power of all classes of stock of our Company or any parent or subsidiary, the per share exercise price will be no less than 110% of the fair market value of our Common Stock on the date of grant.

- Restricted stock awards and restricted stock units may be awarded on terms and conditions established by the Compensation Committee or our board of directors, which may include performance conditions for restricted stock awards and the lapse of restrictions on the achievement of one or more performance goals for restricted stock units.

- The Compensation Committee or our board of directors may make performance grants, each of which will contain performance goals for the award, including the performance criteria, the target and maximum amounts payable, and other terms and conditions.

- The Equity Incentive Plan authorizes the granting of stock awards. The Compensation Committee or our board of directors will establish the number of shares of our Common Stock to be awarded (subject to the aggregate limit established under the Equity Incentive Plan upon the number of shares of our Common Stock that may be awarded or sold under the Equity Incentive Plan) and the terms applicable to each award, including performance restrictions.

Non-Transferability of Awards — Unless the Equity Incentive Plan administrator provides otherwise, the Equity Incentive Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments — In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the Equity Incentive Plan, the Equity Incentive Plan administrator will adjust the number and class of shares that may be delivered under the Equity Incentive Plan and/or the number, class and price of shares covered by each outstanding award, and the numerical share limits set forth in the Equity Incentive Plan.

Dissolution, Liquidation — The Equity Incentive Plan provides that in the event of a proposed dissolution or liquidation of our Company, to the extent it has not been previously exercised, an award will terminate immediately prior to the consummation of such proposed action.

Dividends or Dividend Equivalents for Performance Awards — Notwithstanding anything to the foregoing herein, the right to receive dividends, dividend equivalents or distributions with respect to a performance award will only be granted to a participant if and to the extent that the underlying award is earned.

Merger, Change of Control — The Equity Incentive Plan provides that in the event of a merger or a change of control, as defined under the Equity Incentive Plan, each outstanding award will be treated as the Equity
Incentive Plan administrator determines, including, without limitation, that each award will be assumed or an equivalent option or right substituted by the successor corporation or a parent or subsidiary of the successor corporation.

Duration, Amendment, and Termination — Our Board of Directors has the power to amend, suspend or terminate the Equity Incentive Plan without stockholder approval or ratification at any time or from time to time. No change may be made that increases the total number of shares of our Common Stock reserved for issuance pursuant to incentive awards or reduces the minimum exercise price for options or exchange of options for other incentive awards, unless such change is authorized by our stockholders within one year of such change. Unless sooner terminated, the Equity Incentive Plan would terminate ten years after it was adopted.

Forfeiture Provisions — The Equity Incentive Plan administrator may provide by rule or regulation or in any award agreement, or may determine in any individual case, the circumstances in which awards shall be paid or forfeited in the event a participant ceases to be employed by us, or to provide services to us, prior to the end of a performance period, period of restriction or the exercise, vesting or settlement of such award. Except as set forth for options, generally awards will be forfeited if not earned or vested upon termination, unless otherwise provided for in an award agreement.

Adjustments for Stock Dividends and Similar Events — The Equity Incentive Plan administrator will make appropriate adjustments in outstanding awards and the number of shares of our Common Stock available for issuance under the Equity Incentive Plan, including the individual limitations on awards, to reflect dividends, splits, extraordinary cash dividends and other similar events.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters.

The following table sets forth information regarding beneficial ownership of our Common Stock and Series C Preferred Stock as of July 26, 2024 by:

- each person, or group of affiliated persons, known to us to be the beneficial owner of more than 5% of our outstanding Common Stock or Series C Preferred Stock;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the shares of capital stock indicated. Shares of capital stock that are issuable upon (i) the conversion of Series C Preferred Stock or (ii) the exercise of options or warrants exercisable within 60 days after July 26, 2024, are deemed outstanding for the purpose of computing the percentage ownership of the person holding such Series C Preferred Stock, options or warrants, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

We are not controlled by another corporation, by any foreign government or by any natural or legal persons except as set forth herein, and there are no arrangements known to us which would result in a change in control of our Company at a subsequent date. Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all shares shown to be beneficially owned by them, based on information provided to us by such shareholders. Unless otherwise noted below, each beneficial owner's address is c/o Heart Test Laboratories, Inc., 550 Reserve Street, Suite 360, Southlake, Texas 76092.

The percentage of beneficial ownership in the table below is based on 855,966 shares of our Common Stock and 380,440 shares of Series C Preferred Stock outstanding as of July 26, 2024.

	Beneficial Ownership				
	Number of Shares (1)		Percentages (2)		
Name of Beneficial Owner	Common Stock	Series C Preferred Stock	Common Stock	Series C Preferred Stock	Combined Voting Power (3)
Holders of 5% or more of each class of our securities:					
Front Range Ventures, LLC (4)	29,353	148,213	3.3%	39.0%	3.1%
John H. Matthews (5)	52,419	—	6.0%	—	5.6%
Mount Sinai (6)	64,798	—	7.4%	—	6.9%
Directors and executive officers:					
Andrew Simpson, President, CEO, and Chairman (7)	7,556	6,117	*	1.6%	*
Mark Hilz, Coo & Secretary (8)	6,877	2,080	*	*	*
Danielle Watson, CFO & Treasurer (9)	336	—	*	—	*
Bruce Bent, Director (10)	536	—	*	—	*
Brian Szymczak, Director (11)	851	400	*	*	*
David R. Wells, Director (12)	500	—	*	—	*
All directors and executive officers as a group (6 persons):	16,656	8,597	1.9%	2.3%	1.8%

* Less than 1%.

(1) For each person named in the table, the total number of shares of capital stock beneficially owned by such person to the best knowledge of the Company, is listed opposite of such person's name.

(2) For each person named in the table, the shares of capital stock indicated opposite such person’s name represents the percentage of the total number of the shares of capital stock beneficially owned by such person as a percentage of the shares of our outstanding capital stock indicated as a class.

(3) For each person named in the table, the voting percentage indicated opposite of such person’s name under the column “Combined Voting Power” represents the combined voting percentage of all shares of our Common Stock and all of our Series C Preferred Stock, on an as converted basis, owned by such person.

(4) Front Range Ventures, LLC’s (“FRV”) sole member is the L. Lee Stryker Irrevocable Trust U/A/D 09/10/1974. Bohemian Asset Management, Inc. who has voting and dispositive power with respect to the shares of our Common Stock on behalf of the L. Lee Stryker Irrevocable Trust U/A/D 09/10/1974. Includes (i) 28,277 shares of our Common Stock issuable upon conversion of 148,213 shares of our Series C Preferred Stock; and (ii) 1,076 shares of our Common Stock issuable upon exercise of $1M Lender Warrants.

(5) All of the shares are owned by either Matthews Holdings Southwest, Inc. or Mr. Matthews ("MSW"). Mr. Matthews, as sole controlling shareholder of Matthews Holdings Southwest, Inc., has sole voting and dispositive power over all such shares. Includes (i) 16 shares of our Common Stock issuable upon exercise of $1.5M Lender Warrants; (ii) 10,000 shares of our Common Stock issuable upon exercise of MSW Warrants, (iii) 1,177 shares of our Common Stock issuable upon exercise of IPO Warrants, and (iv) 1,500 shares of our Common Stock issuable upon the exercise of Pre-Funded Bridge Warrants.

(6) All of the shares are owned by Mount Sinai and its Board of Directors has sole voting and dispositive power over all such shares. Includes (i) 9,142 shares of our Common Stock issuable upon exercise of the MTS Warrants and (ii) 7,107 shares of our Common Stock issuable upon the exercise of the MTS Pre-Funded Warrants.

(7) Includes (i) 1,167 shares of our Common Stock issuable upon conversion of 6,117 shares of Series C Preferred Stock; (ii) 1 share of our Common Stock issuable upon exercise of $1.5M Lender Warrants; and (iii) options to purchase 2,023 shares of our Common Stock, which were issued as compensation for services rendered to the Company as its Chairman of the Board of Directors. Excludes 17 shares of our Common Stock owned by the

Simpson Family Benefit Trust, the trustee of which, Equiom (Guernsey) Limited, has voting and dispositive power over all such shares. Equiom (Guernsey) Limited disclaims beneficial ownership of all such shares.

(8) Includes (i) 396 shares of our Common Stock issuable upon conversion of 2,080 shares of Series C Preferred Stock; (ii) 1 share of our Common Stock issuable upon exercise of $1.5M Lender Warrants; and (iii) options to purchase 2,023 shares of our Common Stock issued as compensation for services as an officer of the Company.

(9) Includes options to purchase 336 shares of our Common Stock issued as compensation for services as an officer of the Company.

(10) Includes (i) 17 shares of our Common Stock held by Mr. Bent's spouse and (ii) 519 shares of our Common Stock issuable upon exercise of options issued as compensation for services rendered to the Company.

(11) Includes (i) 76 shares of our Common Stock issuable upon conversion of 400 shares of Series C Preferred Stock held jointly with Mr. Szymczak's spouse; (ii) 1 share of our Common Stock issuable upon exercise of $1.5M Lender Warrants; and (iii) 713 shares of our Common Stock issuable upon exercise of options issued as compensation for services rendered to the Company.

(12) Includes 500 shares of our Common Stock issuable upon exercise of options issued as compensation for services rendered to the Company.

Equity Compensation Plan Information

The following table reflects the number of shares of our Common Stock issuable upon the exercise of awards granted under our equity compensation plans approved and not approved by shareholders and the weighted average exercise price for such awards as of April 30, 2024.

Name of Plan	Number of shares of Common Stock to be issued upon exercise of outstanding options, warrants and rights	Weighted Average Exercise Price of Outstanding Options ($)	Number of shares remaining available for issuance under equity compensation plans (excluding the shares reflected in column (1)
Equity compensation plans approved by security holders (1)	18,815	$ 53.65	74,507
Equity compensation plans not approved by security holders	—	—	—
Total (1)	18,815	$ 53.65	74,507

(1) Represents securities issued under our Equity Incentive Plan

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

The following is a description of transactions or series of transactions since the beginning of Fiscal 2024 to which we were or will be a party, in which:

- The amount involved in the transaction exceeds, or will exceed, the lesser of $120,000 or one percent of the average of our total assets for the last two completed fiscal years; and

- in which any of our executive officers, directors or holders of five percent or more of any class of our capital stock, including their immediate family members or affiliated entities, had or will have a direct or indirect material interest.

For additional information regarding compensation arrangements for our named executive officers and directors, see “Executive Compensation.”

Related Party Transactions

$1M Loan and Security Agreement

In April 2020, the Company entered into a loan and security agreement (the “$1M Loan and Security Agreement”) pursuant to which a secured promissory note in the original principal amount of $500,000 was issued to each of FRV (the “FRV Note”) and John Q. Adams (the “JQA Note”), who were both shareholders of the Company at the time of issuance. John Q. Adams was also a Director of the Company at the time of entering into the $1M Loan and Security Agreement. Each party committed to lend a principal amount of $500,000, totaling $1,000,000, and the loan was drawn in three installments of $300,000 upon execution of the loan agreement, $350,000 on or about July 2, 2020 and $350,000 on or about September 4, 2020. The loan accrued interest at a rate of 12% per annum, compounded annually, payable at maturity. The Company is also required to pay default interest at a rate of 18% per annum, compounded annually, on any unpaid amounts after the applicable due date until the loan amounts are fully re-paid. The loan is collateralized by substantially all of the Company’s assets and intellectual property, except for the secured interest on the covered technology as discussed in Note 8.

The loan had an original maturity date of September 30, 2021, which was amended in September 2021 making the note repayable on demand. The loan was amended in November 2021, extending the maturity to September 30, 2022; further amended in May 2022 to extend the maturity to September 30, 2023; amended again in January 2023 to (i) further extend the maturity date of the FRV Note to September 30, 2024, on which date the principal amount and all accrued interest thereon would be due and payable; and (ii) amend the dates on which principal and accrued interest was due under the JQA Note, such that interest accrued since June 28, 2022 would be due and payable on September 30, 2023, and the principal amount together with all accrued interest after September 30, 2023 would be due and payable on March 31, 2024.

In connection with the amendment in May 2022, the Company agreed to pay Mr. Adams all accrued but unpaid interest on his note prior to September 30, 2022.

In October 2023, the Company issued to FRV and Mr. Adams warrants (“$1M Lender Warrants”) to purchase an aggregate of 2,000 shares of Common Stock as consideration for the extension of the interest maturity date to one lender.

On November 16, 2023, the Company entered into a note conversion letter agreement with John Q. Adams (the “Adams Note Conversion Letter Agreement”). Pursuant to the Adams Note Conversion Letter Agreement, in consideration for the conversion of the principal and interest in the amounts of $585,006 due under the JQA Note, on November 16, 2023, the Company: (1) issued 36,563 shares of Common Stock to Mr. Adams; and (2) entered into a Warrant Amendment Agreement with Mr. Adams, amending the $1M Lender Warrants owned by Mr. Adams to reduce the exercise price of an aggregate of 1,076 $1M Lender Warrants to $16.00 per share (the “Adams Warrant Amendment”).

MSW Note

On September 6, 2023, the Company entered into the MSW Note with Matthews Holdings Southwest, Inc., (the “Lender”). The MSW Note provided for an unsecured drawdown loan of up to $1.0 million, drawn in installments consisting of (i) $250,000 on or prior to September 8, 2023, (ii) $250,000 on or prior to September 20, 2023, and (iii) further drawdowns of up to $500,000 in such amounts and such times to be mutually agreed upon between the Company and Lender.

In September 2023, the Company drew $0.5 million under the MSW Note and issued warrants in lieu of a facility fee to purchase 5,000 shares of Common Stock exercisable at $100.00 per share, warrants to purchase 2,500 shares of Common Stock exercisable at $125.00 per share, and warrants to purchase 2,500 shares of Common Stock exercisable at $150.00 per share.

On November 16, 2023, the Company entered into a note conversion letter agreement with the Lender (the "MSW Note Conversion Letter Agreement"). Pursuant to the MSW Note Conversion Letter Agreement, in consideration for the conversion of the aggregate amount of $500,000 due under the MSW Note, on November 16, 2023, the Company (i) issued to the Lender 31,250 shares of Common Stock at a conversion price of $16.00 per share; and (ii) entered into a Warrant Amendment Agreement with the Lender, amending the warrants to reduce the exercise price of an aggregate of 10,000 warrants to $16.00 per share (the "MSW Warrant Amendment"). See further discussion in Note 5. In accordance with the terms, no interest was payable as the note converted prior to maturity.

Agreements with Mount Sinai

On September 20, 2023, the Company entered into multiple definitive license agreements (each a "License Agreement" and collectively, the "License Agreements") with Mount Sinai to commercialize a range of AI cardiovascular algorithms developed by Mount Sinai as well as a memorandum of understanding for ongoing cooperation encompassing de-identified data access, on-going research, and the evaluation of the MyoVista *wav*ECG. The License Agreements, of which there are eleven in total, cover rights to thirteen AI cardiovascular algorithms, two data science methods for use with ECG waveforms and three filed patents.

The closing of the transactions contemplated under the Securities Purchase Agreement (the "MTS Transaction"), dated as of September 20, 2023 (the "Securities Purchase Agreement"), by and between the Company and Mount Sinai, and the effectiveness of the licenses under the License Agreements, were subject to the satisfaction or waiver of certain closing conditions.

On November 16, 2023, and pursuant to the Securities Purchase agreement, the Company issued to Mount Sinai the following:

- 48,549 shares of Common Stock (the "Consideration Shares");
- pre-funded warrants to purchase up to 7,107 shares of Common Stock, with an exercise price per share of $0.001, which warrants were issued in lieu of shares of Common Stock issuable to Mount Sinai to ensure that the number of shares of Common Stock held by Mount Sinai does not exceed the Beneficial Ownership Limitation (the "MTS Pre-Funded Warrants"); and
- Common stock warrants to purchase up to 9,142 shares of Common Stock, having an exercise price per share equal to $50.60, (the "MTS Warrants" and collectively with the Consideration Shares and the MTS Pre-Funded Warrants, the "MTS Securities").

On December 1, 2023, the Company satisfied all material closing conditions of the Mount Sinai Securities Purchase Agreement and the MTS Warrants thereafter became fully exercisable by Mount Sinai. Registration rights related to the MTS Securities provide that on or prior to the date of one hundred and fifty days (150) days after the closing date, the Company shall prepare and file with the SEC a Registration Statement on Form S-1 (or such other form as applicable) covering the resale under the Securities Act of the MTS Securities issued to Mount Sinai, subject to any limitations imposed by the Nasdaq Rules. On March 5, 2024, the Company filed with the SEC a Registration Statement on Form S-1 registering the resale of the MTS Securities issued to Mount Sinai and the Registration Statement on Form S-1 was declared effective on March 13, 2024.

Agreements with Front Range Ventures

Pursuant to the FRV Side Letter, FRV has the right to designate a director of the Company, which has not been exercised as of the date of this Annual Report on Form 10-K.

Policy Related to Related Party Transactions

Our Board of Directors has adopted a formal, written related party transactions policy setting forth the Company's policies and procedures for the review, approval, or ratification of "related party transactions." For these purposes, a "related party" is (i) any person who is or was an executive officer, director, or director nominee of the Company at any time since the beginning of the Company's last fiscal year, (ii) a person who is or was an immediate family member of an executive officer, director, director nominee at any time since the beginning of the Company's last fiscal year, (iii) any person who, at the time of the occurrence or existence of the transaction, is the beneficial owner of more than 5% of any class of the Company's voting securities, (iv) any person who, at the time of the occurrence or existence of the transaction, is an immediate family member of a shareholder owning more than 5% of any class of the Company's voting securities or (v) any entity that, at the time of the occurrence or existence of the transaction, is a an entity in which a director of the Company is a partner, shareholder or executive officer or otherwise over which such director has influence or control. This policy applies to any transaction between the Company and a related party other than the following:

- Transactions available to all employees generally; and
- Transactions, which when aggregated with the amount of all similar transactions, involve less than $5,000.

Any related party transaction subject to this policy may only be consummated or may continue only if the Audit Committee approves or ratifies such transaction in accordance with the guidelines set forth in the policy and if the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party and the transaction is approved by the disinterested members of the Board of Directors. In addition, if the transaction involves compensation, the compensation must have been approved by the Compensation Committee.

Our Audit Committee will analyze the following factors, in addition to any other factors the members of the Audit Committee deem appropriate, in determining whether to approve a related-person transaction:

- The benefits to the Company;
- The impact on a director's independence in the event the related party is a director, an immediate family member of a director or an entity in which a director is a partner, shareholder or executive officer or otherwise over which such director has influence or control;
- The availability of other sources for comparable products or services;
- The terms of the related party transaction; and
- The terms available to unrelated third parties or to employees generally.

Our Audit Committee shall approve only those related party transactions that are in, or are not inconsistent with, the best interests of the Company and its shareholders, as the Audit Committee determines in good faith.

Director Independence

See "Item 10. Directors, Executive Officers and Corporate Governance — Director Independence" above.

Item 14. Principal Accounting Fees and Services.

The following table represents aggregate fees billed to during Fiscal 2024 and Fiscal 2023, by Haskell & White LLP, our independent registered public accounting firm.

	Year Ended April 30,	
	2024	2023
Audit Fees (1)	$ 98,600	$ 97,500
Audit Related Fees (2)	109,785	69,850
Total Fees	$ 208,385	$ 167,350

(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 the IPO and subsequent registration filings.

Audit Committee Pre-Approval Policies and Procedures

The Audit Committee is responsible for the appointment, compensation and oversight of the work of the independent registered public accounting firm and approves in advance any services to be performed by the independent registered public accounting firm, whether audit-related or not. The Audit Committee reviews each proposed engagement to determine whether the provision of services is compatible with maintaining the independence of the 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, Financial Statement Schedules.

a) List of the following documents filed as a part of the report:

(1) Financial Statements (Included in Item 8 of this Annual Report)

The financial statements of the Company included in this Annual Report include:

- Balance Sheets as of April 30, 2024 and 2023
- Statements of Operations for the years ended April 30, 2024 and 2023
- Statement of Stockholders' Equity for the years ended April 30, 2024 and 2023
- Statements of Cash Flows for the years ended April 30, 2024 and 2023
- Notes to the Financial Statements

(2) Financial Statement Schedules

All schedules have been omitted since they are either not applicable or the information is contained elsewhere in this Annual Report.

b) Exhibits

Exhibit Number	Exhibit Description
1.1	Underwriting Agreement dated June 15, 2022 by and between the Company and The Benchmark Company, LLC (incorporated by reference to Exhibit 1.1 to our Current Report on Form 8-K filed on June 15, 2022)
1.2	Equity Distribution Agreement, dated as of September 18, 2023 by and between the Company and Maxim Group LLC (incorporated by reference to Exhibit 1.2 to our Registration Statement on Form S-3, filed with the SEC on September 18, 2023)
1.3	Amendment No. 1 to Equity Distribution Agreement dated November 9, 2023 between Heart Test Laboratories, Inc. and Maxim Group LLC (incorporated by referred to Exhibit 1.1 to our Current Report on Form 8-K filed with the SEC on November 13, 2023)
1.4	Amendment No. 2 to Equity Distribution Agreement dated November 17, 2023 between Heart Test Laboratories, Inc. and Maxim Group LLC (filed as Exhibit 1.3 on our Current Report on Form 8-K filed with the SEC on November 17, 2023)
3.1	Amended and Restated Certificate of Formation of Heart Test Laboratories, Inc. (incorporated by reference to Exhibit 3.1 to our Registration Statement on Form S-1 filed May 17, 2022)
3.2	Certificate of Designations, Number, Voting Power, Preferences and Rights of Series C Convertible Preferred Stock of Heart Test Laboratories, Inc. (incorporated by reference to Exhibit 3.2 to our Registration Statement on Form S-1 filed May 17, 2022)
3.3	Second Amended and Restated Bylaws of Heart Test Laboratories, Inc. (incorporated by reference to Exhibit 3.3 to our Registration Statement on Form S-1 filed May 17, 2022)
3.4	Form of Certificate of Amendment to Amended and Restated Certificate of Formation of Heart Test Laboratories, Inc. (incorporated by reference to Exhibit 3.4 to Amendment No. 1 to our Registration Statement on Form S-1 filed June 6, 2022)
3.5	Certificate of Amendment to Amended and Restated Certificate of Formation of Heart Test Laboratories, Inc., as amended (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed June 23, 2022)
3.6	Certificate of Amendment to the Amended and Restated Certificate of Formation, dated as of May 6, 2024 (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed May 6, 2024)
4.1	Form of Registration Rights Agreement by and between Heart Test Laboratories, Inc. and Buyers listed as signatories thereto, dated December 22, 2021 (incorporated by reference to Exhibit 4.2 to our Registration Statement on Form S-1 filed May 17, 2022)

4.2	Form of Registration Rights Agreement by and among Heart Test Laboratories, Inc. and the parties listed as signatories thereto related to the Series C Preferred Stock (incorporated by reference to Exhibit 4.3 to our Registration Statement on Form S-1 filed May 17, 2022)
4.3	Form of Bridge Warrant (incorporated by reference to Exhibit 4.4 to our Registration Statement on Form S-1 filed May 17, 2022)
4.4	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.5 to our Registration Statement on Form S-1 filed May 17, 2022)
4.5	Form of $1M Lender Warrant and $1.5M Lender Warrant (incorporated by reference to Exhibit 4.6 to our Registration Statement on Form S-1 filed May 17, 2022)
4.6	Form of Investor Warrant (incorporated by reference to Exhibit 4.7 to our Registration Statement on Form S-1 filed May 17, 2022)
4.7	Representative's Warrant Agreement issued June 17, 2022 (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed June 23, 2022)
4.8	Warrant Agent Agreement dated June 17, 2022 between Heart Test Laboratories, Inc. and American Stock Transfer & Trust Company, LLC (incorporated by reference to Exhibit 4.2 to our Current Report on Form 8-K filed June 23, 2022)
4.9	Form of Certificated Warrant (incorporated by reference to Exhibit 4.10 to Amendment No. 2 to our Registration Statement on Form S-1 filed June 10, 2022)
4.10	Amendment No. 1 to Bridge Warrants dated September 8, 2022 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 9, 2022).
4.11	Form of Amendment No. 2 to Bridge Warrants dated February 3, 2023 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 3, 2022).
4.12	Form of Amended and Restated Warrant to Purchase Common Stock, as amended through February 3, 2023 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 22, 2023).
4.13	Form of Pre-Funded Warrant, issued pursuant to Amendment No. 2 to Warrants to Purchase Common Stock (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K/A, filed with the SEC on March 14, 2023).
4.14	Form of Warrant to Purchase Common Stock dated September 7, 2023 (incorporated by reference to Exhibit 4.1 our Current Report on Form 8-K, filed with the SEC on September 7, 2023)
4.15	Form of Pre-Funded Purchase Warrant dated as of September 20, 2023 (incorporated by reference to Exhibit 4.1 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
4.16	Form of Common Stock Warrant dated September 20, 2023 (incorporated by reference to Exhibit 4.2 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
4.17*	Description of Securities
10.1	MyoVista Technology Agreement, by and between Heart Test Laboratories, Inc. and Guangren "Gary" Chen, dated December 31, 2013 (incorporated by reference to Exhibit 10.1 to our Registration Statement on Form S-1 filed May 17, 2022)
10.2	First Amendment of MyoVista Technology Agreement by and between Heart Test Laboratories, Inc. and Guangren "Gary" Chen, dated March 13, 2017 (incorporated by reference to Exhibit 10.2 to our Registration Statement on Form S-1 filed May 17, 2022)
10.3	Master Assignment by and between Heart Test Laboratories, Inc. and Guangren "Gary" Chen, dated January 1, 2014 (incorporated by reference to Exhibit 10.3 to our Registration Statement on Form S-1 filed May 17, 2022)
10.4	Security Agreement and Pledge by and between Heart Test Laboratories, Inc. and Guangren "Gary" Chen, dated March 14, 2014 (incorporated by reference to Exhibit 10.4 to our Registration Statement on Form S-1 filed May 17, 2022)
10.5	Evaluation, Option and License Agreement by and between Heart Test Laboratories, Inc. and The University Court of The University of Glasgow, dated June 2, 2015 (incorporated by reference to Exhibit 10.5 to our Registration Statement on Form S-1 filed May 17, 2022)
10.6	Exercise of Option Agreement by and between Heart Test Laboratories, Inc. and The University Court of The University of Glasgow, dated December 23, 2015 (incorporated by reference to Exhibit 10.6 to our Registration Statement on Form S-1 filed May 17, 2022)
10.7	$130K Note by and between Heart Test Laboratories, Inc. and Front Range Ventures, LLC, dated August 12, 2019 (incorporated by reference to Exhibit 10.7 to our Registration Statement on Form S-1 filed May 17, 2022)

10.8	$1M Loan and Security Agreement by and among Heart Test Laboratories, Inc., Front Range Ventures, LLC and John Q. Adams, Sr., dated April 24, 2020 (incorporated by reference to Exhibit 10.8 to our Registration Statement on Form S-1 filed May 17, 2022)
10.9	Amendment No. 1 to the $1M Loan and Security Agreement, dated September 30, 2021 (incorporated by reference to Exhibit 10.9 to our Registration Statement on Form S-1 filed May 17, 2022)
10.10	Amendment No. 2 to the $1M Loan and Security Agreement, dated November 3, 2021 (incorporated by reference to Exhibit 10.10 to our Registration Statement on Form S-1 filed May 17, 2022)
10.11	Form of $1.5M Note (incorporated by reference to Exhibit 10.11 to our Registration Statement on Form S-1 filed May 17, 2022)
10.12	Form of Amendment No. 1 to the Form of $1.5M Note by and among Heart Test Laboratories, Inc. and the Requisite Noteholders, dated November 2, 2021 (incorporated by reference to Exhibit 10.12 to our Registration Statement on Form S-1 filed May 17, 2022)
10.13	Form of Securities Purchase Agreement by and between Heart Test Laboratories, Inc. and Purchasers listed as signatories thereto, dated December 22, 2021 (incorporated by reference to Exhibit 10.13 to our Registration Statement on Form S-1 filed May 17, 2022)
10.14	Form of Bridge Note (incorporated by reference to Exhibit 10.14 to our Registration Statement on Form S-1 filed May 17, 2022)
10.15	Consulting Agreement by and between Heart Test Laboratories, Inc. and Kyngstone Limited, Inc., dated June 25, 2013 (incorporated by reference to Exhibit 10.15 to our Registration Statement on Form S-1 filed May 17, 2022)
10.16	FRV Side Letter by and between Heart Test Laboratories, Inc. and Front Range Ventures, LLC, dated April 10, 2019 (incorporated by reference to Exhibit 10.16 to Amendment No. 1 to our Registration Statement on Form S-1 filed June 6, 2022)
10.17†	Amended and Restated Employment Agreement by and between Heart Test Laboratories, Inc. and Mark Hilz, dated April 5, 2022 (incorporated by reference to Exhibit 10.17 to our Registration Statement on Form S-1 filed May 17, 2022)
10.18†	Employment Agreement by and between Heart Test Laboratories, Inc. and Andrew Simpson, dated April 5, 2022 (incorporated by reference to Exhibit 10.18 to our Registration Statement on Form S-1 filed May 17, 2022)
10.19	Form of Amendment No. 3 to the $1M Loan and Security Agreement, dated May 2022 (incorporated by reference to Exhibit 10.19 to our Registration Statement on Form S-1 filed May 17, 2022)
10.20	Form of Amendment No. 2 to the Form of $1.5M Note by and among Heart Test Laboratories, Inc. and the Requisite Noteholders, dated May 2022 (incorporated by reference to Exhibit 10.20 to our Registration Statement on Form S-1 filed May 17, 2022)
10.21†	Form of Time-Based Vesting Nonstatutory Stock Option Agreement of Heart Test Laboratories, Inc. (incorporated by reference to Exhibit 10.21 to our Registration Statement on Form S-1 filed May 17, 2022)
10.22†	Form of Performance-Based Vesting Nonstatutory Stock Option Agreement of Heart Test Laboratories, Inc (incorporated by reference to Exhibit 10.22 to our Registration Statement on Form S-1 filed May 17, 2022)
10.23	Amendment No. 4 to the $1M Loan and Security Agreement, dated January 24, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 24, 2023).
10.24	Purchase Agreement, dated as of March 10, 2023, by and between the Company and Lincoln Park (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on March 10, 2023).
10.25	Registration Rights Agreement, dated as of March 10, 2023, by and between the Company and Lincoln Park (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed with the SEC on March 13, 2023).
10.26†	Heart Test Laboratories, Inc. 2023 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on March 16, 2023).
10.27†	Form of the Company's Incentive Stock Option Agreement under the Company's 2023 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on March 23, 2023).

10.28†	Form of the Company's Non-Qualified Stock Option Agreement under the Company's 2023 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed with the SEC on March 23, 2023).
10.29†	Amendment No. 1 to the Heart Test Laboratories, Inc. 2023 Equity Incentive Plan (incorporated by reference to Exhibit 10.29 to the Registration Statement on Form S-8, filed with the SEC on February 26, 2024)
10.30	Amendment No. 2 License Agreement by and between Heart Test Laboratories, Inc. and The University Court of The University of Glasgow, dated March 31, 2023.
10.31	Senior Unsecured Promissory Drawdown Loan Note by and among Heart Test Laboratories, Inc., and Matthews Southwest Holdings, Inc., dated September 6, 2023 and executed on September 7, 2023 (incorporated by reference to Exhibit 10.1 our Current Report on Form 8-K, filed with the SEC on September 7, 2023)
10.32	Securities Purchase Agreement, dated as of September 20, 2023, by and between the Company and Icahn School of Medicine at Mount Sinai (incorporated by reference to Exhibit 10.1 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.33	License: Pulmonary Embolism Detection From the Electrocardiogram Using Deep Learning (incorporated by reference to Exhibit 10.2 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.34	License: Deep Learning Algorithm to Predict PVC-Related Cardiomyopathy (incorporated by reference to Exhibit 10.3 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.35	License: Deep Learning on ECGs to Derive Left and Right Ventricular Function (incorporated by reference to Exhibit 10.4 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.36	License: Prediction of right ventricular size and systolic function from the 12-lead ECG (incorporated by reference to Exhibit 10.5 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.37	License: Deep learning for electrocardiograms to identify left heart valvular dysfunction – aortic stenosis (incorporated by reference to Exhibit 10.6 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.38	License: Deep learning for electrocardiograms to identify left heart valvular dysfunction – mitral regurgitation (incorporated by reference to Exhibit 10.7 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.39	License: HeartBEiT: Vision Transformers improve diagnostic performance for electrocardiograms (incorporated by reference to Exhibit 10.8 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.40	License: Derivation of low Left Ventricular Ejection fraction based on a foundational vision transformer (HeartBEiT) (incorporated by reference to Exhibit 10.9 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.41	License: Diagnosis of Hypertrophic Cardiomyopathy using a model derived from a foundational vision transformer (HeartBEiT) (incorporated by reference to Exhibit 10.10 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.42	License: Diagnosis of STEMI using a model derived from a foundational vision transformer (HeartBEiT) (incorporated by reference to Exhibit 10.11 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.43	License: Electrocardiogram Deep Learning Interpretability Toolbox (incorporated by reference to Exhibit 10.12 our Current Report on Form 8-K, filed with the SEC on September 21, 2023)
10.44	Amendment No. 5 to the $1M Loan and Security Agreement, dated September 29, 2023 (incorporated by reference to Exhibit 10.45 to our Registration Statement on Form S-1 filed October 16, 2023)
10.45	Note Conversion Letter Agreement, dated November 16, 2023, by and between Heart Test Laboratories, Inc. and Matthews Southwest Holdings, Inc. (filed as Exhibit 10.1 on our Current Report on Form 8-K, filed with the SEC on November 17, 2023)
10.46	Note Conversion Letter Agreement, dated November 16, 2023, by and between Heart Test Laboratories, Inc. and John Q. Adams (filed as Exhibit 10.2 on our Current Report on Form 8-K, filed with the SEC on November 17, 2023)
10.47	Warrant Amendment, dated November 16, 2023, by and between Heart Test Laboratories, Inc. and Matthews Southwest Holdings, Inc. (filed as Exhibit 10.3 on our Current Report on Form 8-K, filed with the SEC on November 17, 2023)

10.48	Warrant Amendment, dated November 16, 2023, by and between Heart Test Laboratories, Inc. and John Q. Adams (filed as Exhibit 10.4 on our Current Report on Form 8-K, filed with the SEC on November 17, 2023)
10.49†	Employment Agreement by and between Heart Test Laboratories, Inc. and Danielle Watson, dated October 15, 2021 (incorporated by reference to Exhibit 10.19 to our Registration Statement on Form S-1 filed October 16, 2023)
21.1*	List of Subsidiaries of the Company
23.1*	Consent of Haskell & White LLP
24.1*	Power of Attorney (included on signature pages of this report)
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1*	Heart Test Laboratories, Inc. Compensation Recovery Policy
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF *	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith
** Furnished herewith
† Management contract or compensatory plan or arrangement

Item 16. Form 10-K Summary

We have elected not to include summary information.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Heart Test Laboratories, Inc.

Dated: July 29, 2024

By: */s/ Andrew Simpson*
Name: Andrew Simpson
Title: President, Chief Executive Officer, and Chairman of the Board of Directors
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Andrew Simpson, Mark Hilz and Danielle Watson and each or any one of them, each with full power of substitution and re-substitution, his true and lawful attorney-in-fact and agent, to sign any amendments to this report, 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, or his or her substitute or substitutes, 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 in the capacities and on the dates indicated.

Name	Title	Date
/s/ *Andrew Simpson* Andrew Simpson	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	July 29, 2024
/s/ *Danielle Watson* Danielle Watson	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	July 29, 2024
/s/ *Mark Hilz* Mark Hilz	Chief Operating Officer, Secretary and Director	July 29, 2024
/s/ *Bruce Bent* Bruce Brent	Director	July 29, 2024
/s/ *David R. Wells* David R. Wells	Director	July 29, 2024
/s/ *Brian Szymczak* Brian Szymczak	Director	July 29, 2024

Exhibit 4.17

DESCRIPTION OF SECURITIES

General

The following description summarizes the terms of the securities of Heart Test Laboratories, Inc. (referred to herein as the "Company," "we," "us" and "our"), our amended and restated certificate of formation, as amended ("Certificate of Formation"), and our second amended and restated bylaws ("Bylaws"). As it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our Certificate of Formation and Bylaws, as in effect as of the date of filing with the U.S. Securities and Exchange Commission (the "SEC") of our Annual Report on Form 10-K for our fiscal year ended April 30, 2024 (the "Annual Report"), the forms of which are filed as exhibits to the Annual Report.

Our purpose is to engage in any lawful act or activity for which corporations may now or hereafter be organized under the Texas Business Organizations Code (the "TBOC"). Our authorized capital stock consists of five hundred million (500,000,000) shares of common stock, par value $0.001 per share (the "Common Stock"), and twenty million (20,000,000) shares of preferred stock, (the "Preferred Stock"), par value $0.001 per share of which, as of July 26, 2024, there were 855,966 shares of Common Stock outstanding and held of record by 292 shareholders and 380,440 shares of Series C Preferred Stock (as defined below) outstanding that, as of such date, were convertible into 72,546 shares of Common Stock and held of record by 64 shareholders. Of our authorized Preferred Stock, 600,000 shares have been designated as Series C Convertible Preferred Stock, having a par value of $0.001 per share (the "Series C Preferred Stock"). Unless our Board of Directors determines otherwise, we will issue all shares of our capital stock in uncertificated form.

Common Stock

Holders of our Common Stock are entitled to one vote for each share held of record on all matters on which shareholders are entitled to vote generally, including the election or removal of directors, subject to certain limitations. The holders of our Common Stock do not have cumulative voting rights in the election of directors. Upon our liquidation, dissolution or winding up and after payment in full of all amounts required to be paid to creditors and to the holders of preferred stock having liquidation preferences, if any, the holders of our Common Stock will be entitled to receive pro rata our remaining assets available for distribution on a pro rata basis. Holders of our Common Stock do not have preemptive, subscription, redemption or conversion rights. The Common Stock will not be subject to further calls or assessment by us. There will be no redemption or sinking fund provisions applicable to the Common Stock. All outstanding shares of our Common Stock are fully paid and non-assessable. The rights, powers, preferences and privileges of holders of our Common Stock will be subject to those of the holders of any shares of our Preferred Stock, including any Preferred Stock we may authorize and issue in the future.

As a Texas corporation, we are subject to certain restrictions on dividends under the TBOC. Generally, a Texas corporation may pay dividends to its shareholders out of its surplus (the excess of its assets over its liabilities and stated capital) unless the dividend would render the corporation insolvent.

The declaration, amount and payment of any future dividends will be at the sole discretion of our Board of Directors. Our Board of Directors may take into account general and economic conditions, our financial condition and results of operations, our available cash and current and anticipated cash needs, capital requirements, contractual, legal, tax and regulatory restrictions and implications on the payment of dividends by us to our shareholders.

We currently expect to retain all future earnings for use in the operation and expansion of our business and have no current plans to pay dividends.

Preferred Stock

Our Certificate of Formation authorizes our Board of Directors to establish one or more series of Preferred Stock (including convertible Preferred Stock). Unless required by law or by the TBOC, the authorized shares of Preferred Stock will be available for issuance without further action by our shareholders.

Our Board of Directors will be able to determine, with respect to any series of Preferred Stock, the powers including preferences and relative participations, optional or other special rights, and the qualifications, limitations or restrictions thereof, of that series, including, without limitation:

- the designation of the series;

- the number of shares of the series, which our Board of Directors may, except where otherwise provided in the preferred stock designation, increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares then outstanding);
- whether dividends, if any, will be cumulative or non-cumulative and the dividend rate of the series;
- the dates at which dividends, if any, will be payable;
- the redemption rights and price or prices, if any, for shares of the series;
- the terms and amounts of any sinking fund provided for the purchase or redemption of shares of the series;
- the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding-up of the affairs of the Company;
- whether the shares of the series will be convertible into shares of any other class or series, or any other security, of the Company or any other corporation and, if so, the specification of the other class or series or other security, the conversion price or prices or rate or rates, any rate adjustments, the date or dates as of which the shares will be convertible and all other terms and conditions upon which the conversion may be made;
- restrictions on the issuance of shares of the same series or of any other class or series; and
- the voting rights, if any, of the holders of the series.

We will be able to issue a series of Preferred Stock that could, depending on the terms of the series, impede or discourage an acquisition attempt or other transaction that some, or a majority, of the holders of our Common Stock might believe to be in their best interests or in which the holders of our Common Stock might receive a premium for their Common Stock over the market price of the Common Stock. In addition, the issuance of Preferred Stock may adversely affect the rights of holders of our Common Stock by restricting dividends on the Common Stock, diluting the voting power of the Common Stock or subordinating the liquidation rights of the Common Stock. As a result of these or other factors, the issuance of Preferred Stock may have an adverse impact on the market price of our Common Stock.

Series C Preferred Stock

As of July 26, 2024, there were 380,440 shares of Series C Preferred Stock outstanding that, as of such date, were convertible into 72,546 shares of Common Stock. As of July 26, 2024, there were no shares of Series A Preferred Stock or Series B Preferred Stock outstanding.

The Series C Preferred Stock was issued from April 2019 to October 2020 to accredited investors and has a liquidation preference to the Common Stock. As of July 26, 2024, the liquidation preference was approximately $9.5 million. An amendment to, or waiver of rights of the Series C Preferred Stock requires the approval of holders of a majority of the outstanding shares of the Series C Preferred Stock which must include Front Range Ventures, LLC, or FRV, for so long as FRV holds at least 71,000 shares of Series C Preferred Stock. Additionally, pursuant to the FRV Side Letter, for so long as FRV holds at least 71,000 shares of Series C Preferred Stock, it is entitled to appoint a member of the Board of Directors as well as a board observer, (the "Appointment Rights"). As of July 26, 2024, FRV has not exercised its Appointment Rights.

Voting and Dividends

The holders of the shares of the Series C Preferred Stock have voting rights equal to an equivalent number of shares of the Common Stock into which it is convertible and vote together as one class with the Common Stock.

The holders of the Series C Preferred Stock are entitled to receive dividends at an annual rate of $1.50 per share. Such dividends shall accrue and are payable out of funds legally available, are payable only when and if declared by the Board of Directors, and are noncumulative. The Company is not permitted to declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company (other than dividends on shares of the Common Stock payable in shares of Common Stock) unless the holders of the shares of the Series C Preferred Stock then outstanding first receive, or simultaneously receive, a dividend on each outstanding share of the Series C Preferred Stock in an amount at least equal to the greater of (i) the amount of the aggregate dividends then accrued on such share of the Series C Preferred Stock and not previously paid and (ii) in the case of a dividend on the Common Stock or any class or series that is convertible into Common Stock, that dividend per share of Series C Preferred Stock as would equal the product of (1) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Common Stock and (2) the number of shares of Common Stock issuable upon conversion of a share of the Series C Preferred Stock.

No dividends have been declared to date on any shares of Preferred Stock.

Liquidation

In the event of any liquidation, dissolution or winding up of the Company, either voluntarily or involuntarily, the holders of the Series C Preferred Stock are entitled to receive, prior and in preference to the holders of the Common Stock, a per share amount equal to 1.0 times the original issue price ($25.00 per share) plus any accrued but unpaid dividends thereon.

If upon the liquidation, dissolution or winding up of the Company, the assets of the Company that are legally available for distribution to the holders of the Series C Preferred Stock are insufficient to permit the payment to such holders of the full amounts above, then the entire assets of the Company that are legally available for distribution shall be distributed with equal priority and pro rata among the holders of the Series C Preferred Stock in proportion to what they would otherwise be entitled to receive.

After the payment of the full Series C Preferred Stock liquidation preference and unpaid accrued dividends, the holders of the Series C Preferred Stock shall participate in the distribution of the entire remaining assets of the Company legally available for distributions pro rata to holders of the Common Stock on an as converted basis. The sale of a majority of the capital stock of the Company or the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company or any subsidiary of the Company of all or substantially all the assets of the Company and its subsidiaries taken as a whole shall be a deemed liquidation for the purpose of the Series C Preferred Stock.

Conversion

Each share of Series C Preferred Stock is convertible, at the option of the holder, at any time after the date of issuance of such share, into such number of fully paid and non-assessable shares of Common Stock determined by dividing the original issue price of $25.00 by the conversion price for such series in effect at the time of conversion for the Series C Preferred Stock. The conversion price for the Series C Preferred Stock is subject to adjustment in accordance with conversion provisions contained in our Certificate of Designations, Number, Voting Power, Preferences and Rights of Series C Convertible Preferred Stock dated March 12, 2019. As of July 26, 2024, the conversion price of the Series C Preferred Stock was $131.04 per share. See “—Antidilution Provisions” below.

Each share of Series C Preferred Stock automatically converts into shares of Common Stock at the conversion price at the time in effect immediately upon the Company’s sale of its Common Stock in a public offering provided that the offering price is not less than $1,650.00 per share (as adjusted for recapitalizations, stock combinations, stock dividends, stock splits and the like) and which results in aggregate cash proceeds of not less than $20.0 million before underwriting discounts, commissions, and fees.

Warrants

Investor Warrants

The Company issued warrants, (the "Investor Warrants"), in connection with various funding transactions or as consideration, in lieu of cash, for amounts billed in respect of services rendered to us. The Investor Warrants have terms ranging from five to ten years from the date of issuance. As of July 26, 2024, there were Investor Warrants to purchase 7,294 shares of Common Stock at exercise prices ranging from $5.15 to $825.00 per share.

MSW Warrants

In September 2023, we issued warrants in lieu of a facility fee payment in connection with entering into the MSW Note with Matthews Southwest Holdings. These warrants have a five-year term from the date of issuance. As of July 26, 2024, there were 10,000 Existing MSW Warrants at an original exercise prices ranging from $100.00 to $150.00 per share. On November 16, 2023, we entered into a Warrant Amendment Agreement with Matthews Southwest Holdings, amending the Existing MSW Warrants to reduce the exercise price of an aggregate of 10,000 Existing MSW Warrants to $16.00 per share.

Warrants issued in connection with the 2021 Bridge Financing

We issued the Bridge Warrants to originally purchase 775 shares of Common Stock in connection with the 2021 Bridge Financing. The Bridge Warrants expire five years after the date of issuance, beginning on December 22, 2026, with an initial exercise price of $908.00 per share, subject to certain adjustments. No holder of a Bridge

Warrant may exercise any portion of a Bridge Warrant if, after giving effect to such exercise, such holder (together with its Attribution Parties) would beneficially own in excess of 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of such holder's Bridge Warrant. This limitation may be waived by a holder, at its election, upon not less than 61 days' prior notice to the Company, to change the limitation to 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of such holder's warrant. Any exercise of the Bridge Warrants resulting in a number of shares in excess of 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the exercise shall be deemed null and void and shall be cancelled ab initio.

On September 8, 2022, we entered into an amendment to the Bridge Warrants ("Bridge Warrant Amendment No. 1"). The Bridge Warrant Amendment No. 1 amended the Bridge Warrants by (i) increasing the number of shares of Common Stock for which the Bridge Warrants are exercisable from a total of 13,677 shares to a total of 16,849 shares, (ii) lowering the exercise price to $425.00 per share, (iii) providing that, until June 15, 2023, the exercise price will be further adjusted whenever the Company issues shares of Common Stock for consideration per share that when multiplied by 1.25 is less than the exercise price then in effect, subject to certain exceptions, (iv) confirming that, for purposes of the Bridge Warrants, the value of each share of Common Stock and each IPO Warrant was deemed to be $412.50 and $0.125, respectively, (v) providing that the number of shares of Common Stock underlying the Bridge Warrants will only be adjusted if the Company(a) pays a stock dividend on one or more classes of its then outstanding shares of Common Stock or otherwise makes a distribution on any class of capital stock that is payable in shares of Common Stock, (b) subdivides (by any stock split, stock dividend, recapitalization or otherwise) one or more classes of its then outstanding shares of Common Stock into a larger number of shares or (c) combines (by combination, reverse stock split or otherwise) one or more classes of its then outstanding shares of Common Stock into a smaller number of shares, and (vi) amending the formula for calculating Black Scholes values.

On February 3, 2023, we entered into a second amendment to the Bridge Warrants ("Bridge Warrant Amendment No. 2"). The Bridge Warrant Amendment No. 2 amended the Bridge Warrants by (i) lowering the exercise price of $425.00 for a period of ten (10) business days beginning February 3, 2023 and ending February 16, 2023 (the "Limited Period"), during which period the exercise price was set at $100.00, subject to adjustments set forth in the Bridge Warrant; (ii) providing that during the Limited Period, the holder was able, in its sole discretion, to elect a cashless exercise of the Bridge Warrant in whole or in part, pursuant to which the holder received a net number of shares of Common Stock equal to one-third of the total number of shares into which the Bridge Warrant could otherwise have been exercised; and (iii) removing the exercise price adjustment provisions of the Bridge Warrants with limited exceptions for transactions such as stock dividends, stock splits, stock combinations and reverse stock splits. Additionally, the Bridge Warrant Amendment No. 2 provided that in the event that the aggregate number of shares of Common Stock to be received by a holder upon an exercise of its Bridge Warrant during the Limited Period would result in such holder's receiving shares of Common Stock in excess of its applicable Bridge Maximum Percentage, in lieu of delivery of shares of Common Stock in excess of the Bridge Maximum Percentage, the holder would receive such excess shares as pre-funded warrants substantially in the form of the Pre-Funded Bridge Warrants, with certain exercise price adjustment provisions removed. Further, the Bridge Warrant Amendment No. 2 included a waiver of Section 4(w) of the Bridge SPA, which placed certain restrictions on the Company's ability to issue securities for a specified period of time.

During the Limited Period, the Bridge Warrants were exercised for (i) a total of 11,736 shares of Common Stock at an exercise price of $100.00 per share or pursuant to cashless exercises in which the holder received a net number of shares of Common Stock equal to one-third of the total number of shares with respect to which the Bridge Warrant was exercised and (ii) the Remaining Pre-Funded Bridge Warrant to purchase 1,500 shares of Common Stock. At the end the Limited Period, Remaining Bridge Warrants to purchase a total of 2,989 shares of Common Stock remained outstanding, with the exercise price adjusted back to $425.00 per share, subject to future adjustments as set forth in the Remaining Bridge Warrants.

The exercise price of the Remaining Bridge Warrants (as amended by the Bridge Warrant Amendment No. 1 and the Bridge Warrant Amendment No. 2) is subject to adjustment for certain events such as stock dividends, splits, and reverse splits or other combinations, but not otherwise as the result of issuances of additional securities by the Company, even if such issuances are at prices below the exercise price of the Bridge Warrants. Upon an adjustment of the exercise price as a result of a stock dividend, split, reverse split, combination or similar event, the number of shares of Common Stock to be received shall be proportionately adjusted. Otherwise, there are no antidilution provisions that result in adjustments to the number of shares of Common Stock to be received upon exercise of the Bridge Warrants.

All Pre-Funded Bridge Warrants that were issued upon conversion of the Bridge Notes have been exercised

in full and are no longer outstanding as of the date of the Annual Report, although the Remaining Pre-Funded Bridge Warrant issued in connection with Bridge Warrant Amendment No. 2 remains outstanding.

$1M Lender Warrants

In November 2021, we also issued warrants to purchase 152 shares of our Common Stock. ("$1M Lender Warrants"), to the lenders of the $1M Notes as consideration for the extension of the maturity of the $1M Loan and Security Agreement to September 30, 2022. The $1M Loan and Security Agreement was further amended in May 2022 to extend the maturity date to September 30, 2023 and amended again in January 2023 to (i) further extend the maturity date of the portion of the $1M Notes issued to one lender (in the principal amount of $0.5 million) to March 31, 2024 and (ii) further extend the maturity date of the remaining portion of the $1M Notes issued to the other lender (in the principal amount of $0.5 million) to September 30, 2024. The $1M Loan and Security Agreement was further amended in September 2023 to extend the interest maturity date to one lender to December 31, 2023. In October 2023, we issued additional $1M Lender Warrants to purchase 2,000 shares of our Common Stock to lenders of the $1M Notes as consideration for the extension of the interest maturity date to one lender. The exercise prices of the $1M Lender Warrants range from $16.00 to $289.00 per share as of July 26, 2024. On November 16, 2023, we entered into the Adams Warrant Amendment, amending the $1M Lender Warrants owned by Adams to reduce the exercise price of an aggregate of 1,076 $1M Lender Warrants to $16.00 per share.

$1.5M Lender Warrants

In November 2021, we issued the $1.5M Lender Warrants exercisable for 71 shares of our Common Stock to noteholders of the $1.5M Notes as consideration for the extension of the maturity of the $1.5M Notes to January 31, 2023. The $1.5M Lender Warrants expire on October 12, 2026. The exercise price of the $1.5M Lender Warrants was $289.00 per share as of July 26, 2024.

Mount Sinai Warrants

On September 20, 2023, we entered into the License Agreements with Mount Sinai to commercialize a range of AI cardiovascular algorithms developed by Mount Sinai. On November 15, 2023, we closed the transactions contemplated under the Mount Sinai Securities Purchase Agreement and the licenses under the License Agreements, which became effective on that date. As consideration, we issued pre-funded warrants to purchase up to 7,107 shares of our Common Stock with an exercise price per share of $0.001 and warrants to purchase up to 9,142 shares of our Common Stock with an exercise price per share of $50.60.

IPO Warrants

The following summary of certain terms and provisions of the IPO Warrants that were included in the Units issued in the IPO, plus the additional IPO Warrants issued as a result of the exercise, in part, of the underwriter's over- allotment option in the IPO, is not complete and is subject to, and qualified in its entirety by, the provisions of the warrant agent agreement between us and American Stock Transfer & Trust Company, LLC, as warrant agent, and the form of warrant, both of which are filed as exhibits to the Annual Report. Prospective investors should carefully review the terms and provisions set forth in the warrant agent agreement, including the annexes thereto, and the form of warrant.

Exercisability. The IPO Warrants are exercisable at any time until 5:00 P.M. New York City time on June 17, 2027. The IPO Warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of Common Stock underlying the IPO Warrants under the Securities Act of 1933, as amended, or the Securities Act, is effective and available for the issuance of such shares of Common Stock, or an exemption from registration under the Securities Act is available for the issuance of such shares of Common Stock, by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. If a registration statement registering the issuance of the Common Stock underlying the IPO Warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such Common Stock, the holder may, in its sole discretion, elect to exercise the IPO Warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the IPO Warrant. No fractional shares of Common Stock will be issued in connection with the exercise of an IPO Warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price. We will not affect the exercise of any portion of the IPO Warrants, and the holder will not have the right to exercise any portion of the IPO Warrants, and any such exercise shall be null and void and treated as if never made, to the extent

that after giving effect to such exercise, the holder together with its affiliates and certain other persons specified in the IPO Warrants collectively would own beneficially in excess of 4.99% (or, upon election by a holder prior to the issuance of any IPO Warrants, 9.99%) of the shares of Common Stock outstanding immediately after giving effect to such exercise.

Exercise Price. The exercise price per share purchasable upon exercise of the IPO Warrants is $425.00 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our shares of Common Stock and also upon any distributions of assets, including cash, stock or other property to our shareholders.

Transferability. Subject to applicable laws, the IPO Warrants may be offered for sale, sold, transferred or assigned without our consent.

Warrant Agent. The IPO Warrants were issued in registered form under a warrant agent agreement between American Stock Trading & Trust Company, LLC, as warrant agent, and us. The IPO Warrants shall be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company ("DTC") and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Fundamental Transactions. In the event of a fundamental transaction, as described in the IPO Warrants and generally including any reorganization, recapitalization or reclassification of our ordinary shares, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding shares of Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our shares of Common Stock, the holders of the IPO Warrants will be entitled to receive upon exercise of the IPO Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the IPO Warrants immediately prior to such fundamental transaction.

Rights as a Shareholder. Except as otherwise provided in the IPO Warrants or by virtue of such holder's ownership of our shares of Common Stock, the holder of an IPO Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the IPO Warrant.

Governing Law. The IPO Warrants and the warrant agent agreement are governed by New York law.

IPO Underwriter Warrants

At the consummation of the IPO, we issued warrants to the underwriter, or the Underwriter's Warrants, to purchase 1,050 shares of Common Stock, representing 7.0% of the aggregate number of shares of Common Stock underlying the Units sold in the IPO. The Underwriter's Warrants expire at 5:00 P.M. New York City time on June 17, 2027, have an exercise price equal to $425.00, which is equal to 100% of the public offering price per Unit in the IPO, provide for a "cashless" exercise, and contain certain antidilution adjustments (but excluding any price based antidilution). The Underwriter's Warrants contain provisions for unlimited "piggyback" registration rights for a period of no greater than three (3) years from the date of the IPO in compliance with FINRA Rule 5110(g)(8)(D). Pursuant to FINRA Rule 5110(e), the Underwriter's Warrants and any shares of Common Stock issued upon exercise of the Underwriter's Warrants may not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days beginning on the date of commencement of sales of the IPO, except certain transfers of such securities, including: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the IPO and the officers or partners thereof, if all securities so transferred remain subject to lock-up restriction set forth in Section 4(a) of the Underwriter's Warrant for the remainder of the time period; (iii) if the aggregate amount of our securities held by the underwriter or related persons do not exceed 1% of the securities offered in the IPO; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth in Section 4(a) of the Underwriter's Warrant for the remainder of the time period.

Options

The Company grants certain employees and board members stock option awards where vesting is contingent upon a service period, as it believes that such awards better align the interests of its employees with those of its

shareholders. Stock option awards are granted with an exercise price equal to or above the market price of the Company's stock at the date of grant. Certain stock option awards provide for accelerated vesting if there is a change in control, as defined in the option agreement. Stock options may not, subject to certain limited exceptions, be exercised when an employee leaves the Company. Where option awards are granted based on service periods, they generally vest quarterly based on three years of continuous service for executive directors and employees, or 12 months continuous service for directors and have 10-year contractual terms. At July 26, 2024, there were time-based options to purchase a total of 20,159 shares of Common Stock at an average exercise price of $121.00 per share.

The Company also grants stock option awards where vesting is contingent upon meeting various departmental and/or company-wide performance goals, including, in some instances, FDA and/or CE Mark regulatory approval and/or certain EBITDA and funding thresholds. Such performance-based stock options are expected to vest when the performance criteria and metrics have been met. These stock options have a term of ten years. At July 26, 2024, there were performance-based options to purchase a total of 5,456 shares of Common Stock at an average exercise price of $502.00 per share.

Equity Incentive Plan

See "Executive Compensation — 2023 Equity Incentive Plan" section in Part III of the Annual Report.

Antidilution Provisions

As of July 26, 2024, approximately 72,546 shares of Common Stock issuable upon the conversion of Series C Preferred Stock were subject to anti-dilution protection provisions. The holders of these securities may be entitled to receive additional shares of Common Stock upon conversion of the Series C Preferred Stock.

Registration Rights

We previously granted certain registration rights to the holders of the Series C Preferred Stock. Under the terms of the registration rights agreement, which we refer to as the Series C Registration Rights Agreement, the holders of the Series C Preferred Stock owning not less than 30% of (i) the Common Stock issuable or issued upon conversion of the Series C Preferred Stock; and (ii) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clause (i) above, referred to herein as the Series C Registrable Securities, and the anticipated aggregate offering price, net of certain expenses, would exceed $10 million, may demand that the Company file a registration statement relating to the Series C Registrable Securities owned by the holders who have demanded such registration. In addition, if at any time when it is eligible to use a Form S-3 registration statement, the Company receives a request from holders of at least twenty-five percent (25%) of the Series C Registrable Securities then outstanding that the Company file a Form S-3 registration statement with respect to outstanding Series C Registrable Securities of such holders having an anticipated aggregate offering price, net of certain expenses, of at least $3 million, then the Company will be required to file a registration statement relating to the resale of the Series C Registrable Securities owned by such holders. Finally, if the Company proposes to register (including, for this purpose, a registration effected by the Company for shareholders other than the holders of the Series C Preferred Stock) any of the Common Stock under the Securities Act in connection with the public offering of such securities solely for cash, the Company is required to give each holder of Series C Registrable Securities notice of such registration and such holders may include their Series C Registrable Securities in such registration statement.

We have also agreed to grant certain unlimited "piggyback" registration rights to the underwriters' representative in connection with the underwriters' representative's warrants. For more information, see "— Underwriter's Warrants" above.

Annual Shareholder Meetings

Our Bylaws provide that annual shareholder meetings will be held at a date, time and place, if any, as exclusively selected by our Board of Directors. To the extent permitted under applicable law, we may conduct meetings by remote communications, including by webcast.

Anti-takeover Effects of Certain Provisions of Our Certificate of Formation, Bylaws and Texas Law

Our Certificate of Formation and Bylaws and the TBOC contain provisions, which are summarized in the following paragraphs, that are intended to enhance the likelihood of continuity and stability in the composition of

our Board of Directors. These provisions are intended to avoid costly takeover battles, reduce our vulnerability to a hostile change of control and enhance the ability of our Board of Directors to maximize shareholder value in connection with any unsolicited offer to acquire us. However, these provisions may have an anti-takeover effect and may delay, deter or prevent a merger or acquisition of the Company by means of a tender offer, a proxy contest or other takeover attempt that a shareholder might consider in its best interest, including those attempts that might result in a premium over the prevailing market price for the shares of Common Stock held by shareholders.

Authorized but unissued capital stock

Texas law does not require shareholder approval for any issuance of authorized shares. However, the listing requirements of The Nasdaq Stock Market LLC, or the Nasdaq, which apply so long as our securities are listed on the Nasdaq, require shareholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of Common Stock. Additional shares that may be issued in the future may be used for a variety of corporate purposes, including future public offerings, to raise additional capital or to facilitate acquisitions.

Our Board of Directors may generally issue shares of Preferred Stock on terms calculated to discourage, delay or prevent a change of control of the Company or the removal of our management. Moreover, our authorized but unissued shares of Preferred Stock are available for future issuances without shareholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, to facilitate acquisitions and employee benefit plans.

One of the effects of the existence of unissued and unreserved shares of Common Stock or Preferred Stock may be to enable our Board of Directors to issue shares to persons friendly to current management, which issuance could render more difficult or discourage an attempt to obtain control of the Company by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of our management and possibly deprive our shareholders of opportunities to sell their shares of Common Stock at prices higher than prevailing market prices.

Classified Board of Directors

Our Certificate of Formation provides that our Board of Directors be divided into three classes of directors, with the classes to be as nearly equal in number as possible, and with the directors serving three-year terms. As a result, approximately one-third of our Board of Directors will be elected each year. The classification of directors will have the effect of making it more difficult for shareholders to change the composition of our Board of Directors. Our Certificate of Formation and Bylaws provide that, subject to any rights of holders of Preferred Stock to elect additional directors under specified circumstances, the number of directors will be fixed from time to time exclusively pursuant to a resolution adopted by the Board of Directors.

Removal of directors; vacancies

Under the TBOC, unless otherwise provided in our Certificate of Formation, directors serving on a classified board may be removed by the shareholders only for cause. Our Certificate of Formation provides that directors may be removed only for cause. In addition, our Certificate of Formation also provides that, subject to the rights granted to one or more series of Preferred Stock then outstanding, any vacancy occurring in our Board of Directors may be filled by election at an annual or special meeting of the shareholders called for that purpose or by the affirmative vote of a majority of the directors then in office (even if the remaining directors constitute less than a quorum of the Board of Directors), and any director so chosen shall hold office for the remainder of the term to which the director has been selected and until such director’s successor shall have been elected and qualified.

No cumulative voting

Under Texas law, the right to vote cumulatively does not exist unless the certificate of formation specifically authorizes cumulative voting. Our Certificate of Formation does not authorize cumulative voting. Therefore, shareholders holding a majority in voting power of the shares of our stock entitled to vote generally in the election of directors will be able to elect all our directors.

Special shareholder meetings

Our Certificate of Formation provides that special meetings of our shareholders may be called at any time by the Board of Directors, the chairman of the Board of Directors or the chief executive officer of the Company. Our Bylaws prohibit the conduct of any business at a special meeting other than as specified in the notice for such meeting. These provisions may have the effect of deferring, delaying or discouraging hostile takeovers, or changes

in control or management of the Company.

Requirements for advance notification of director nominations and shareholder proposals

Our Bylaws establish advance notice procedures with respect to shareholder proposals and the nomination of for election as directors, other than nominations made by or at the direction of the Board of Directors or a committee of the Board of Directors. In order for any matter to be "properly brought" before a meeting, a shareholder will have to comply with advance notice requirements and provide us with certain information. Generally, to be timely, a shareholder's notice must be received at our principal executive offices not less than 75 days nor more than 100 days prior to the first anniversary date of the immediately preceding annual meeting of shareholders. Our Bylaws also specify requirements as to the form and content of a shareholder's notice. Our Bylaws allow the chairman of the meeting at a meeting of the shareholders to adopt rules and regulations for the conduct of meetings which may have the effect of precluding the conduct of certain business at a meeting if the rules and regulations are not followed. These provisions may also defer, delay or discourage a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to influence or obtain control of the Company.

Shareholder action by written consent

Our Certificate of Formation provides that any action required or permitted to be taken at an annual or special meeting of shareholders may be taken by written consent in lieu of a meeting of shareholders only with the unanimous written consent of our shareholders.

Amendment and restatement of bylaws

Our Bylaws provide that the Board of Directors is expressly authorized to make, alter, amend, change, add to, rescind or repeal, in whole or in part, our Bylaws without a shareholder vote in any matter not inconsistent with the laws of the State of Texas and our Certificate of Formation.

The combination of the classification of our Board of Directors and the lack of cumulative voting will make it more difficult for shareholders to replace our Board of Directors as well as for another party to obtain control of us by replacing our Board of Directors. Because our Board of Directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing shareholders or another party to effect a change in management.

These provisions may have the effect of deterring hostile takeovers or delaying or preventing changes in control of our management or the Company, such as a merger, reorganization or tender offer. These provisions are intended to enhance the likelihood of continued stability in the composition of our Board of Directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of the Company. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions are also intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. Such provisions may also have the effect of preventing changes in management.

Dissenters' rights of appraisal and payment

Under the TBOC, with certain exceptions, our shareholders will have appraisal rights in connection with a merger, a sale of all or substantially all of our assets, an interest exchange or a conversion. Pursuant to the TBOC, shareholders who properly request and perfect appraisal rights in connection with such merger, sale of all or substantially all of our assets, interest exchange or conversion will have the right to receive payment of the fair value of their shares as agreed to between the shareholder and the Company or, if they are unable to reach agreement, as determined by the State District Court in Tarrant County, Texas.

Shareholders' derivative actions

Under the TBOC, any of our shareholders may bring an action in our name to procure a judgment in our favor, also known as a derivative action, provided that the shareholder bringing the action (i) is a holder of our shares at the time of the transaction to which the action relates or such shareholder became a shareholder by operation of law from a person that was a shareholder at the time of the transaction to which the action relates and (ii) fairly and adequately represents the interests of the Company in enforcing the right of the Company.

Limitations on liability and indemnification of officers and directors

The TBOC authorizes corporations to limit or eliminate the personal liability of directors to corporations and their shareholders for monetary damages for breaches of directors' fiduciary duties (other than breaches of the directors' duty of loyalty to corporations or their shareholders), subject to certain exceptions. Our Certificate of Formation includes a provision that limits the personal liability of directors for monetary damages for an act or omission in the director's capacity as a director to the fullest extent permitted by Texas law. However, exculpation will not apply to any director if the director has acted in bad faith, engaged in intentional misconduct, knowingly violated the law, authorized illegal dividends or redemptions, derived an improper benefit from his or her actions as a director or engaged in an act or omission for which the liability of the director is expressly provided by an applicable statute.

Our Certificate of Formation provides that we must indemnify our directors and officers to the fullest extent authorized by the TBOC. We also are expressly authorized to carry directors' and officers' liability insurance providing indemnification for our directors, officers and certain employees for some liabilities. We believe that these indemnification provisions and insurance will be useful to attract and retain qualified directors and officers.

The limitation of liability and indemnification provisions in our Certificate of Formation and Bylaws may discourage shareholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our shareholders. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

As of July 26, 2024 there is no pending material litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought.

Business combinations

Under Title 2, Chapter 21, Subchapter M of the TBOC, we may not engage in certain "business combinations" with any "affiliated shareholder," or any affiliate or associate of the affiliated shareholder for a three-year period following the time that the shareholder became an affiliated shareholder, unless:

- prior to such time, our Board of Directors approved either the business combination of the transaction which resulted in the shareholder becoming an affiliated shareholder; or
- not less than six months after the affiliated shareholders' share acquisition date, the business combination is approved by the affirmative vote at a meeting, and not by written consent, of holders of at least 66⅔% of our outstanding voting shares that are not owned by the affiliated shareholder or an affiliate or associate of the affiliated shareholder.

Generally, a "business combination" includes a merger, asset or stock sale or other similar transaction. Subject to certain exceptions, an "affiliated shareholder" is a person who beneficially owns (as determined pursuant to Title 2, Chapter 21, Subchapter M of the TBOC), or within the previous three years beneficially owned, 20% or more of our outstanding voting shares. For purposes of this section only, "voting share" has the meaning given to it in Title 2, Chapter 21, Subchapter M of the TBOC.

Under certain circumstances, this provision will make it more difficult for a person who would be an "affiliated shareholder" to effect various business combinations with the Company for a three-year period. This provision may encourage companies interested in acquiring the Company to negotiate in advance with our Board of Directors because the shareholder approval requirement would be avoided if our Board of Directors approves either the business combination or the transaction that results in such shareholder becoming an affiliated shareholder. These provisions also may have the effect of preventing changes in our Board of Directors and may make it more difficult to accomplish transactions which shareholders may otherwise deem to be in their best interests.

Listing

Our Common Stock and the IPO Warrants are listed on the Nasdaq under the symbol "HSCS" and "HSCSW," respectively.

Transfer agent and registrar

The transfer agent and registrar for our Common Stock and IPO Warrants is Equiniti Trust Company, LLC.

Exhibit 21.1

LIST OF SUBSIDIARIES

Heart Test Laboratories, Inc.,
a Texas corporation

Subsidiaries	**Jurisdiction**
None	N/A

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-3 (File No. 333-274554) and Form S-8 (File No. 333-277374) of Heart Test Laboratories, Inc. dba HeartSciences (the "Company") of our audit report dated July 29, 2024 relating to the financial statements of the Company as of and for each of the years ended April 30, 2024 and 2023 included in the Company's Annual Report on Form 10-K for the year ended April 30, 2024.

Our report dated July 29, 2024 contains an explanatory paragraph that states the Company has experienced recurring losses, negative cash flows from operations, and limited capital resources. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

HASKELLL & WHITE LLP

Irvine, CA
July 29, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Simpson, certify that:

(1) I have reviewed this Annual Report on Form 10-K of Heart Test Laboratories, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 29, 2024

By: */s/ Andrew Simpson*
Name: Andrew Simpson
Title: President, Chief Executive Officer, and Chairman of the Board of Directors

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Danielle Watson, certify that:

(1) I have reviewed this Annual Report on Form 10-K of Heart Test Laboratories, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 29, 2024

By: */s/ Danielle Watson*
Name: Danielle Watson
Title: Chief Financial Officer and Treasurer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Heart Test Laboratories, Inc. (the "Company") on Form 10-K for the year ended April 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew Simpson, as the Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or section 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 29, 2024

By: */s/ Andrew Simpson*
Name: Andrew Simpson
Title: President, Chief Executive Officer, and Chairman of the Board of Directors

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Heart Test Laboratories, Inc. (the "Company") on Form 10-K for the year ended April 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Danielle Watson, as the Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or section 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 29, 2024

By: */s/ Danielle Watson*
Name: Danielle Watson
Title: Chief Financial Officer and Treasurer

Exhibit 97.1

HEART TEST LABORATORIES, INC.
Compensation Recovery Policy

As adopted on December 29, 2023

Heart Test Laboratories, Inc. (the "**Company**") is committed to strong corporate governance. As part of this commitment, the Company's Board of Directors (the "**Board**") has adopted this clawback policy called the Compensation Recovery Policy (the "**Policy**"). The Policy is intended to further the Company's pay-for-performance philosophy and to comply with applicable law by providing for the reasonably prompt recovery of certain executive compensation in the event of an Accounting Restatement. Capitalized terms used in the Policy are defined below, and the definitions have substantive impact on its application so reviewing them carefully is important to your understanding.

The Policy, which was approved as set forth above, is intended to comply with Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), with Exchange Act Rule 10D-1 and with the listing standard of the national securities exchange (the "**Exchange**") on which the securities of the Company are listed. The Policy will be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act, Exchange Act Rule 10D-1 and with the listing standards of the Exchange, including any interpretive guidance provided by the Exchange.

In summary, the Policy provides rules related to the reasonably prompt recovery of certain incentive-based compensation received by Covered Executives. The application of the Policy to Covered Executives is not discretionary, except to the limited extent provided below, and applies without regard to whether Covered Executive was at fault.

Persons Covered by the Policy

The Policy is binding and enforceable against all "**Covered Executives**," which means each individual who is or was ever designated as an "executive officer" by the Board in accordance with Exchange Act Rule 3b-7 (a "**Section 16 Officer**"). Each Covered Executive will be required to sign and return to the Company an acknowledgement that such Covered Executive will be bound by the terms and comply with the Policy. The failure to obtain such acknowledgement will have no impact on the applicability or enforceability of the Policy.

Administration of the Policy

The Compensation Committee (the "**Committee**") of the Board has full delegated authority to administer the Policy. The Committee is authorized to interpret and construe the Policy and to make all determinations necessary, appropriate, or advisable for the administration of the Policy. In addition, if determined in the discretion of the Board, the Policy may be administered by the independent members of the Board or another committee of the Board made up of independent members of the Board, in which case all references to the Committee will be deemed to refer to the independent members of the Board or the other Board committee. All determinations of the Committee will be final and binding and will be given the maximum deference permitted by law.

Events Requiring Application of the Policy

If the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the

previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (an "**Accounting Restatement**"), then the Committee must determine what compensation, if any, must be recovered.

Compensation Covered by the Policy

The Policy applies to certain **Incentive-Based Compensation** (certain terms used in this Section are defined below) that is **Received** on or after October 2, 2023 (the "**Effective Date**"), during the **Covered Period** while the Company has a class of securities listed on a national securities exchange. Such Incentive-Based Compensation is considered "**Clawback Eligible Incentive-Based Compensation**" if the Incentive-Based Compensation is Received by a person after such person became a Section 16 Officer and the person served as a Section 16 Officer at any time during the performance period for the Incentive-Based Compensation. The Incentive-Based Compensation that must be recovered is the amount of Clawback Eligible Incentive-Based Compensation that exceeds the amount of Clawback Eligible Incentive-Based Compensation that otherwise would have been Received had such Clawback Eligible Incentive-Based Compensation been determined based on the restated amounts (such compensation, as computed without regard to any taxes paid, the "**Excess Compensation**," is referred to in the listings standards as "erroneously awarded incentive-based compensation").

To determine the amount of Excess Compensation for Incentive-Based Compensation based on stock price or total shareholder return, where it is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the amount must be based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received and the Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange.

"**Incentive-Based Compensation**" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs. The following items of compensation are not Incentive-Based Compensation under the Policy: salaries, bonuses paid solely at the discretion of the Committee or Board that are not paid from a bonus pool that is determined by satisfying a Financial Reporting Measure, bonuses paid solely upon satisfying one or more subjective standards and/or completion of a specified employment period, non-equity incentive plan awards earned solely upon satisfying one or more strategic measures or operational measures, and equity awards for which the grant is not contingent upon achieving any Financial Reporting Measure performance goal and vesting is contingent solely upon completion of a specified employment period (e.g., time-based vesting equity awards) and/or attaining one or more non-Financial Reporting Measures.

"**Financial Reporting Measures**" are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the U.S. Securities and Exchange Commission.

Incentive-Based Compensation is "**Received**" under the Policy in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment, vesting, settlement or grant of the Incentive-Based Compensation occurs after the end of that period. For the avoidance of doubt, the Policy does not apply to Incentive-Based Compensation for which the Financial Reporting Measure is attained prior to the Effective Date.

"**Covered Period**" means the three completed fiscal years immediately preceding the Accounting Restatement Determination Date. In addition, Covered Period can include certain transition periods resulting from a change in the Company's fiscal year. The Company's obligation to recover Excess Compensation is not dependent on if or when the restated financial statements are filed.

"**Accounting Restatement Determination Date**" means the earliest to occur of: (a) the date the Board, a committee of the Board, or one or more of the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; and (b) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

Repayment of Excess Compensation

The Company must recover such Excess Compensation reasonably promptly and Covered Executives are required to repay Excess Compensation to the Company. Subject to applicable law, the Company may recover such Excess Compensation by requiring the Covered Executive to repay such amount to the Company by direct payment to the Company or such other means or combination of means as the Committee determines to be appropriate (these determinations do not need to be identical as to each Covered Executive). These means may include:

- requiring reimbursement of cash Incentive-Based Compensation previously paid;
- seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
- offsetting the amount to be recovered from any unpaid or future compensation to be paid by the Company or any affiliate of the Company to the Covered Executive;
- cancelling outstanding vested or unvested equity awards; and/or
- taking any other remedial and recovery action permitted by law, as determined by the Committee.

The repayment of Excess Compensation must be made by a Covered Executive notwithstanding any Covered Executive's belief (whether legitimate or non-legitimate) that the Excess Compensation had been previously earned under applicable law and therefore is not subject to clawback.

In addition to its rights to recovery under the Policy, the Company or any affiliate of the Company may take any legal actions it determines appropriate to enforce a Covered Executive's obligations to the Company or to discipline a Covered Executive, including (without limitation) termination of employment, institution of civil proceedings, reporting of misconduct to appropriate governmental authorities, reduction of future compensation opportunities or change in role. The decision to take any actions described in the preceding sentence will not be subject to the approval of the Committee and can be made by the Board, any committee of the Board, or any duly authorized officer of the Company or of any applicable affiliate of the Company.

Limited Exceptions to the Policy

The Company must recover the Excess Compensation in accordance with the Policy except to the limited extent that the conditions set forth below are met, and the Committee determines that recovery of the Excess Compensation would be impracticable: (i) the direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered. Before reaching this conclusion, the Company must make a reasonable attempt to recover such Excess Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange; or (ii) Recovery would

likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the legal requirements as such.

Other Important Information in the Policy

The Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002, as amended, that are applicable to the Company's Chief Executive Officer and Chief Financial Officer, as well as any other applicable laws, regulatory requirements, rules, but the Policy supersedes in full all of the clawback policies of the Company that were in effect prior to the Effective Date to the extent such policies were applicable with respect to Covered Executives and the operative portions of such policies shall have no further force or effect on or after the Effective Date.

Notwithstanding the terms of any of the Company's organizational documents (including, but not limited to, the Company's bylaws), any corporate policy or any contract (including, but not limited to, any indemnification agreement), neither the Company nor any affiliate of the Company will indemnify or provide advancement for any Covered Executive against any loss of Excess Compensation. Neither the Company nor any affiliate of the Company will pay for or reimburse insurance premiums for an insurance policy that covers potential recovery obligations. In the event the Company is required to recover Excess Compensation from a Covered Executive who is no longer an employee pursuant to the Policy, the Company will be entitled to seek such recovery in order to comply with applicable law, regardless of the terms of any release of claims or separation agreement such individual may have signed.

The Committee or Board may review and modify the Policy from time to time.

If any provision of the Policy or the application of any such provision to any Covered Executive is adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of the Policy or the application of such provision to another Covered Executive, and the invalid, illegal or unenforceable provisions will be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

The Policy will terminate and no longer be enforceable when the Company ceases to be listed issuer within the meaning of Section 10D of the Exchange Act.

ACKNOWLEDGEMENT

• I acknowledge that I have received and read the Compensation Recovery Policy (the "**Policy**") of Heart Test Laboratories, Inc. (the "**Company**").

• I understand and acknowledge that the Policy applies to me, and all of my beneficiaries, heirs, executors, administrators or other legal representatives and that the Company's right to recovery in order to comply with applicable law will apply, regardless of the terms of any release of claims or separation agreement I have signed or will sign in the future.

• I agree to be bound by and to comply with the Policy and understand that determinations of the Committee (as such term is used in the Policy) will be final and binding and will be given the maximum deference permitted by law.

• I understand and agree that my current indemnification rights, whether in an individual agreement or the Company's organizational documents, exclude the right to be indemnified for amounts required to be recovered under the Policy.

• I understand that my failure to comply in all respects with the Policy is a basis for termination of my employment with the Company and any affiliate of the Company as well as any other appropriate discipline.

• I understand that neither the Policy, nor the application of the Policy to me, gives rise to a resignation for good reason (or similar concept) by me under any applicable employment agreement or arrangement.

• I acknowledge that if I have questions concerning the meaning or application of the Policy, it is my responsibility to seek guidance from the Company's Chief Financial Officer, Chief Legal Officer (if any) or my own personal advisers.

• I acknowledge that neither this Acknowledgement nor the Policy is meant to constitute an employment contract.

Please review, sign and return this form to the Company's Chief Financial Officer.

Executive

_
(*print name*)

_
(*signature*)

_
(date)