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Registration No. 333-267388

PROSPECTUS

1,540,492 Shares of Common Stock
Up to 1,683,470 Shares of Common Stock Issuable Upon Exercise of the Bridge Warrants
Up to 139,356 Shares of Common Stock Issuable Upon Exercise of the Pre-Funded Warrants

Heart Test Laboratories, Inc.

This prospectus relates to the offer and resale from time to time by the selling securityholders named in this prospectus (the "Selling Shareholders") of shares of common stock, par value $0.001 per share ("Common Stock"), of Heart Test Laboratories, Inc., a Texas corporation ("Heart Test," "HeartSciences," the "Company," "we," "us" or "our"), consisting of (i) 1,540,492 shares of Common Stock, representing the shares issued upon the conversion of the Company' s 8% secured Senior Subordinated Convertible Loan Notes (the "Bridge Notes") that are held by Selling Shareholders as of the date of this prospectus; (ii) up to 1,683,470 shares of Common Stock (as adjusted following (a) consummation of the Company' s initial public offering (the "IPO") of units (the "Units") consisting of Common Stock and warrants to purchase shares of Common Stock (the "IPO Warrants"), as required under the terms of the Bridge Warrants (as defined below), and (b) the amendment to the Bridge Warrants in September 2022) issuable upon the exercise of the warrants to purchase shares of Common Stock that were issued with the Bridge Notes (the "Bridge Warrants" and together with the Bridge Notes, the "2021 Bridge Securities"); and (iii) up to 139,356 shares of Common Stock issuable upon the exercise of pre-funded warrants to purchase shares of Common Stock that were issued upon conversion of the Bridge Notes (the "Pre-Funded Warrants," and together with the Bridge Warrants, the "Warrants"). The shares of our Common Stock to be offered and resold pursuant to this prospectus are collectively referred to as the "Shares."

We will not receive any proceeds from the sale of the Shares under this prospectus, although we could receive up to approximately $7.2 million upon the exercise of all of the Warrants. Information regarding the Selling Shareholders, the number of Shares of Common Stock that may be sold by them and the times and manner in which they may offer and sell the Shares of Common Stock pursuant to this prospectus is provided under the sections titled "Selling Shareholders" and "Plan of Distribution," respectively, in this prospectus. We have not been informed by any of the Selling Shareholders that they intend to sell the Common Stock covered by this prospectus and do not know when or in what amount the Selling Shareholders may offer the Common Stock for sale. The Selling Shareholders may sell any, all, or none of the Common Stock offered by this prospectus.

Our Common Stock and IPO Warrants are listed on the Nasdaq Capital Market under the symbols "HSCS" And "HSCSW," respectively. On October 4, 2022, the closing price of our Common Stock was $1.40 per share and the closing price of our IPO Warrants was $0.1819.

We are an "emerging growth company" and a "smaller reporting company" as defined under the U.S. federal securities laws and, as such, have elected to comply with certain reduced reporting requirements.

Investing in our Common Stock involves a high degree of risk. See "Risk Factors" beginning on page 20.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is October 7, 2022.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with information that is different. The Selling Shareholders are offering to sell the Shares, and seeking offers to buy the Shares, only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of the Shares.

For investors outside of the United States: Neither we nor any of the Selling Shareholders have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

In this prospectus, unless the context suggests otherwise, references to “Heart Test,” “HeartSciences,” the “Company,” “we,” “us” and “our” refer to Heart Test Laboratories, Inc., a Texas corporation. References to “Fiscal 2023” refer to the 12-months ending April 30, 2023, references to “Fiscal 2022” refer to the 12-months ended April 30, 2022, and references to “Fiscal 2021” refer to the 12-months ended April 30, 2021.

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission (the “SEC”). Under this registration process, the Selling Shareholders may, from time to time, sell the securities offered by them described in this prospectus through any means described in the section titled “Plan of Distribution.” We will not receive any proceeds from the sale by such Selling Shareholders of the Shares offered by them described in this prospectus. We will receive proceeds from any exercise of the Warrants for cash.

Neither we nor the Selling Shareholders have authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus or any applicable prospectus supplement or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. Neither we nor the Selling Shareholders take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor the Selling Shareholders will make an offer to sell these Shares in any jurisdiction where the offer or sale is not permitted.

We may also provide a prospectus supplement or post-effective amendment to the registration statement to add information to, or update or change information contained in, this prospectus. Any statement contained in this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in such prospectus supplement or post-effective amendment modifies or supersedes such statement. Any statement so modified will be deemed to constitute a part of this prospectus only as so modified, and any statement so superseded will not be deemed to constitute a part of this prospectus. You should read both this prospectus and any applicable prospectus supplement or post-effective amendment to the registration statement together with the additional information to which we refer you in the section of this prospectus titled "*Where You Can Find Additional Information*."

TRADEMARKS AND TRADE NAMES

Our trademarks are the subject of trademark registrations in the United States as well as various other countries. Other brand names, names and trademarks contained in this prospectus are the property of their respective owners. Solely for convenience, trademarks, service marks and tradenames are referred to in this prospectus without the SM, TM and/or ® symbols or any typographical emphasis (such as italicized or underlined text), but such references are not intended to indicate, in any way, that the owner thereof will not assert, to the fullest extent under applicable law, such owner' s rights to their service marks, trade names and trademarks.

MyoVista®, *wav*ECG TM, HEARTSCIENCES, and Heart Test Laboratories are trademarks and/or service marks of the Company registered with the United States Patent and Trademark Office, or USPTO. Other trademarks, service marks and trade names in this prospectus are the property of their respective owners.

INDUSTRY AND MARKET DATA

This prospectus includes statistical, market and industry data and forecasts which we obtained from publicly available information and independent industry publications and reports that we believe to be reliable sources. These publicly available industry publications and reports generally state that they obtain their information from sources that they believe to be reliable, but they do not guarantee the accuracy or completeness of the information. Although we believe that these sources are reliable, we have not independently verified the information contained in such publications. We are liable for all information in this prospectus and the registration statement on Form S-1 filed with the U.S. Securities and Exchange Commission, or the SEC, of which this prospectus constitutes a part.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements made under "Prospectus Summary," "Risk Factors," "Use of Proceeds," and elsewhere in this prospectus and in the information incorporated by reference into this prospectus constitute forward-looking statements. In some cases, you can identify forward- looking statements by terminology such as "may," "will," "should," "expects," "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, from the U.S. Food and Drug Administration, or 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 MyoVista;

our ability to advance the development of the MyoVista, our full function conventional 12-lead electrocardiograph, or ECG, device that incorporates an additional proprietary artificial intelligence-based algorithm that has been designed with the expectation of detecting cardiac dysfunction caused by heart disease or age-related cardiac dysfunction, and future potential products;

our ability to launch sales of the MyoVista into the U.S. and any future potential products;

our assessment of the potential of the MyoVista and future potential products to diagnose certain indications;

our planned level of capital expenditures and liquidity;

our plans to continue to invest in research and development to develop technology for new products;

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 the MyoVista 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 impact of COVID-19 and resulting government actions on us;

the impact of competition and new technologies;

general market, political and economic conditions in the countries in which we operate;

our ability to internally develop new devices and intellectual property;

our expectations regarding the use of proceeds from the exercise of any Warrants;

changes in our strategy; and

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 this prospectus and in the information incorporated by reference into this prospectus in greater detail under the heading "Risk Factors" and elsewhere in this prospectus and in the information incorporated by reference into this prospectus. 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 prospectus.

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 prospectus 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.

Unless defined elsewhere, capitalized terms used in this prospectus are defined in the section of this prospectus titled "*Glossary of Terms*."

PROSPECTUS SUMMARY

This summary highlights information contained in greater detail elsewhere in this prospectus or incorporated by reference into this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our Common Stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto incorporated by reference into this prospectus. You should also consider, among other things, the information set forth under the sections titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements," in each case appearing elsewhere in this prospectus as well as the information incorporated by reference into this prospectus.

Company Overview

We are a medical technology company focused on applying innovative artificial intelligence, or 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, particularly in frontline or point-of-care clinical settings. HeartSciences' first product candidate for FDA clearance, the MyoVista *wav*ECG, or the MyoVista, is a resting 12-lead ECG that is also designed to provide diagnostic information related to cardiac dysfunction which has traditionally only been available through the use of cardiac imaging. The MyoVista also provides conventional ECG information in the same test. Our business model, which involves the use of the MyoVista device and consumables for each test, is expected to be "razor-razorblade" as the electrodes used with the MyoVista are proprietary to HeartSciences, and new electrodes are required for every test performed. As of September 30, 2022, we had 12 full-time employees.

Our device is not cleared for marketing by the FDA and our future success is dependent upon receiving FDA De Novo clearance for the MyoVista. Additional funding may be required as part of achieving FDA clearance and thereafter would be required to support the sales launch of the MyoVista into the U.S., provide working capital and support further research and development, or R&D.

We believe that there is currently no low-cost, front-line, medical device that is effective at screening for 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 heart disease test, in 2012, the United States Preventive Services Task Force conducted an evaluation of conventional ECG testing and stated: "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 current or former smoking, blood pressure and cholesterol levels."

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 the MyoVista to help address these limitations and extend the clinical capability of an ECG in detecting cardiac dysfunction. We apply AI-machine learning to the signal processed electrical signal of the heart. Our first algorithm, which is not yet FDA cleared, is designed to detect cardiac dysfunction caused by heart disease and/or age-related cardiac dysfunction.

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 are 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.

If we receive FDA clearance for the MyoVista, our main target markets would be frontline healthcare environments in the U.S., such as primary care, 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 treatment or intervention is required for most patients referred for cardiac imaging. We believe that adding the capability to detect cardiac dysfunction to a 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 the MyoVista, require FDA De Novo premarket review. The MyoVista 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. Based on feedback and communications with the FDA during 2020, we have been making modifications to our device and are partially through a new, pivotal clinical validation study and the device testing and development necessary for a revised FDA De Novo submission, which we expect to take place later in Fiscal 2023.

We are using the funding from the IPO to continue our work towards FDA resubmission and clearance. Although our current aim is to achieve FDA clearance, which would allow us to market the MyoVista in the U.S., with the net proceeds of the IPO, there is no assurance that this will be the case. Additional funding will be required to support the sales launch of the MyoVista into the U.S., provide working capital and support further R&D. Our independent registered public accounting firm has issued an opinion on our audited financial statements incorporated by reference into this prospectus 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 have a working capital deficiency. These events and conditions indicate that a material uncertainty exists that may cast significant doubt on our ability to continue as a going concern. 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.

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" and, 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 had no previous symptoms. Statistics published by the U.S. Centers for Disease Control and Prevention, or CDC, show that in the United States heart disease is the leading cause of death for men, women, and people of most racial and ethnic groups. According to the CDC, one person dies from cardiovascular disease every 36 seconds and heart disease accounts for approximately one in four deaths. In 2018, 30.3 million U.S. adults were diagnosed with heart disease including 18.2 million adults with CAD. Approximately 605,000 patients in the U.S. have a heart attack each year with approximately 20% of deaths from CAD occurring in adults less than 65 years old. 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. Ischemic heart disease now represents 16% of global deaths and an estimated 17.9 million people died from cardiovascular diseases in 2019, representing 32% of all global deaths.

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 costs in the United States were approximately $363 billion in each of 2016 and 2017, 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, or CMS. There are a variety of effective, though expensive, diagnostic tests for patients used to detect heart disease. These are typically performed in a specialist cardiology or hospital setting and 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, that 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.

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 symptoms have ejection fraction measures that are not markedly abnormal. In addition, multiple articles published by the National Institutes of Health, or NIH, state that approximately 50% of heart failure, or HF, cases are due to severe diastolic dysfunction, also called heart failure with preserved ejection fraction. 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, or 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 valuable marker for almost all forms of heart disease and age-related cardiac abnormalities that may otherwise be missed by current conventional ECG devices.

Product and Technology

The MyoVista device 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 is a 12-lead resting ECG device that features our proprietary algorithm developed to detect cardiac dysfunction in the diastolic phase, specifically slower than normal left ventricular relaxation rates as defined by the American Society of Echocardiology Guidelines.

The MyoVista 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 respected resting ECG interpretive algorithm. The Glasgow Algorithm was developed and has been continuously improved over the years by a team of world-renowned ECG researchers. The Glasgow Algorithm is licensed to the Company pursuant to the Glasgow Licensing Agreement.

In the MyoVista, the conventional ECG (including the Glasgow Algorithm) and our proprietary algorithm which has been designed to detect diastolic abnormalities are combined as a single test with results presented separately. The MyoVista has a high-resolution touchscreen display and incorporates many easy and intuitive to use features commonly associated with a tablet device.

MyoVista device with 1 lead view of signal processed waveform

Market Opportunity

Diagnostic Gap

We believe that the significant diagnostic gap in heart disease is early identification. Heart disease often remains asymptomatic for many years as disease progresses 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 biggest cost for the US healthcare system at approximately $216 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 which is better able to detect heart disease at an early stage, along with the increasing number and type of health care settings creates a significant opportunity for a device such as the MyoVista.

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 2019, was estimated to average 78.9 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, or 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 in 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.

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 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 2018 National Ambulatory Medical Care Survey indicated that office-based patient care physicians, excluding anesthesiologists and federal facilities such as U.S. Department of Veterans Affairs clinics, ordered or provided 27 million ECG tests and four million stress ECGs during office visits, and the 2017 National Hospital Ambulatory Medical Care Survey showed that during ambulatory care visits to hospital emergency departments, an additional 28 million ECG tests were ordered or performed by hospital emergency departments.

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 is positioned to respond to the global need for more effective, low-cost ECG testing alternative for 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 the MyoVista as a new medical device that offers 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 significant history of medical problems.

Approximately 42% (approximately 26 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.

Market Strategy

General

Our objective is to make the MyoVista *wav*ECG a standard-of-care, as an affordable and valuable medical test. Our business model, which involves the capital sale of the MyoVista device and the use of proprietary supplies (electrodes) for each test, is "razor-razorblade." The electrode connection system is patented which, together with our proprietary high quality electrodes, facilitate high quality, stable ECG signal capture, which, we believe is important as the MyoVista analyzes frequency data as well as conventional ECG information. Because new electrodes are needed for each test, our proprietary electrodes, if purchased, would provide recurring per-test revenue for each MyoVista device sold. In short, unlike many new healthcare products, we do not expect to primarily rely on high device pricing and instead will seek to encourage adoption and to rely on recurring revenue as an important aspect of our business model.

Territories

Our initial sales focus will primarily be within the U.S. We intend to market the MyoVista 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 the MyoVista. 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 on cardiac dysfunction which the MyoVista is designed to provide, in addition to the conventional ECG information provided, could be extremely valuable.

The MyoVista' s 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, Walmart 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 will be on: cardiology; primary care providers that serve upper to middle income regions including concierge medicine providers; retail clinics; and insurers with high levels of Medicare Advantage patients.

Reimbursement

In addition to penetrating the health care settings described above, a key element of our strategy is to qualify for third-party payor reimbursement. This strategy has two stages. During the first stage, we intend to seek the support of the ACC to use existing Current Procedural Terminology, or CPT, codes for the standard ECG functionality of the MyoVista. 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 amount to pay a provider. While we cannot assure you that we will receive such approval by ACC, this would provide physicians with the ability to use existing 12-lead ECG reimbursement codes. 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.

After this initial stage, our longer-term reimbursement strategy is to obtain additional reimbursement for the MyoVista capabilities related to detecting cardiac dysfunction. While we cannot assure you that we will be successful in obtaining additional reimbursement codes, if we are successful, this could potentially provide total reimbursement that is larger than reimbursement for conventional ECG devices, which, in turn, could place the MyoVista at a competitive advantage as compared to conventional ECG devices. Any additional CPT codes that are issued and recognized by payors for the MyoVista related to our longer-term reimbursement strategy could provide a revenue advantage as compared to CPT codes for conventional ECG devices.

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 the MyoVista. Competitors could include traditional ECG manufacturers such as General Electric Company, or GE, Koninklijke Philips N.V., or Philips, and Nihon Kohden Corporation that may seek to innovate due to competition from HeartSciences, and new competitors that also see the opportunity to finally innovate 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 technology protection for our existing and any future proprietary algorithms (especially when developing proprietary algorithms). We believe that the combination of patents and trade secrets create valuable competitive barriers in favor of HeartSciences.

The USPTO has issued seven utility patents and one design patent to us. These patents expire from March 5, 2029 to August 27, 2040. We also have seven utility patents (which expire from September 20, 2036 to March 9,

2037) and fourteen design registrations granted by international jurisdictions such as China, Japan, South Korea, the United Kingdom, France, Germany and Australia, and have received allowances of further applications by the European Patent Office and in Israel. We also have several pending patent applications in several international jurisdictions including Brazil, Canada, India, South Korea, Mexico and the United Arab Emirates.

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

In January 2014, we entered into an invention assignment agreement, which we refer to as the MyoVista Technology Agreement, under which certain specified MyoVista 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 into a licensing agreement, which we refer to as the Glasgow Licensing Agreement, with The University Court of the University of Glasgow, under which we obtained a non-exclusive, worldwide license, renewing automatically every five years, 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.

Research and Development

The Company' s research and development, or R&D, staff designs our hardware, software and AI-based algorithms. Hardware development assistance is provided by outside consulting firms. The Company internally develops the signal processing software elements along with outside assistance. The user interface elements of the software are designed by the Company along with the assistance of outside consultants. The data science work necessary to build the AI-based algorithms is performed both internally and externally using outside consultants. Incorporation of all software elements into the MyoVista hardware is performed internally. We currently employ four full-time R&D staff.

We believe our research demonstrates the potential to develop further algorithms for a range of additional clinical indications. Studies involving use of the MyoVista have already been published demonstrating alternative clinical indications. We believe that in the future the ECG will have significantly greater clinical value and will facilitate far more effective heart disease screening and referral.

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, or 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 of 1933, as amended, or 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 $1.07 billion in annual revenue, have more than $700 million in market value of our Common Stock held by non-affiliates, 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, which means that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. 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 and we may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250 million as of the last business day of the second fiscal quarter or (ii) our annual revenue was less than $100 million during the 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 the 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 Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recent Developments

Initial Public Offering

On June 17, 2022, we completed the IPO of Units, with each Unit consisting of one share of Common Stock and an IPO Warrant to purchase one share of Common Stock. Each Unit was sold at a public offering price of $4.25 per Unit. We listed our Common Stock and IPO Warrants on the Nasdaq Stock Market, or Nasdaq, under the symbol "HSCS" and "HSCSW," respectively.

We 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. As of September 30, 2022, we have used approximately $1.8 million of the net proceeds from the IPO for costs related to achieving FDA clearance for the MyoVista device, to pay approximately $0.1 million of the accrued and unpaid interest under the $1M Loan and Security Agreement, and for working capital and general corporate purposes including personnel costs, capital expenditures and the costs of operating as a public company. We intend to use the remaining $3.4 million of the net proceeds from the IPO for costs directly related to achieving FDA clearance for the MyoVista device and for working capital and general corporate purposes, including personnel costs, capital expenditures and the costs of operating as a public company.

Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. The amounts and timing of our actual expenditures will depend upon numerous factors, including the progress of our global marketing and sales efforts, our development efforts and the overall economic environment. Therefore, our management will retain broad discretion over the use of the remaining proceeds from the IPO. We ultimately may use the remaining proceeds for different purposes than what we currently intend. Pending any ultimate use of any portion of the proceeds from the IPO, if the anticipated proceeds will not be sufficient to fund all the proposed purposes, our management will determine the order of priority for using the remaining proceeds, as well as the amount and sources of other funds needed.

Pending our use of the net proceeds from the IPO, we may invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities.

Conversion of Bridge Notes and Issuance of Pre-Funded Warrants

Upon consummation of the IPO, as required under the terms of the Bridge Notes, the Company issued, after taking into account the clerical error correction noted below, 1,544,114 shares of Common Stock and Pre-Funded Warrants to purchase 139,356 shares of Common Stock from the conversion of the Bridge Notes. Subsequent to the IPO, pursuant to provisions in the Bridge Notes limiting the number of shares of Common Stock into which the Bridge Notes were convertible, 61,913 shares of Common Stock into which the Bridge Notes converted were issued as a result of a clerical error and were cancelled and deemed null and void, *ab initio*, from the time of the conversion and issuance and a Pre-Funded Warrant to purchase an additional 61,913 shares of Common Stock was issued. The Pre-Funded Warrants have substantially the same terms as the Bridge Warrants except that the exercise price is $0.0001 per share. See "Description of Securities−Warrants−Warrants issued in connection with the 2021 Bridge Financing" for additional information. These shares and the Pre-Funded Warrants 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.

Warrant Amendment

On September 8, 2022, we entered into a written amendment to the Bridge Warrants, which we refer to as the Bridge Warrant Amendment, with the lead investor.

Upon consummation of the IPO, pursuant to the terms of the Bridge Warrants, the holders of the Bridge Warrants became entitled to purchase a total of 1,365,960 shares of Common Stock at an exercise price of $5.16 per share, subject to antidilution provisions with respect to the number of shares issuable upon exercise and full ratchet price protection on the exercise price whenever the Company issues shares of Common Stock for consideration per share less than the exercise price then in effect.

The Bridge Warrant Amendment, which was executed by the Company and the lead investor in the 2021 Bridge Financing (as defined in the Glossary of Terms), simplifies the Bridge Warrants and makes their terms more consistent with the IPO Warrants. As a result of the Bridge Warrant Amendment:

- the number of shares of Common Stock for which the Bridge Warrants are exercisable increased to a total 1,683,470 shares and such number is no longer subject to antidilution adjustments if the Company issues shares of Common Stock for consideration per share less than the exercise price then in effect. The 1,683,470 shares represent the total number of shares of Common Stock and Pre-Funded Warrants into which the Bridge Notes converted upon the IPO (therefore providing the former Bridge Note holders with one warrant for every share of Common Stock (or Pre-Funded Warrant) they received upon the Bridge Note conversion);
- the exercise price of the Bridge Warrants was reduced to $4.25 per share and the price protection provisions applicable to the exercise price of the Bridge Warrants whenever the Company issues shares of Common Stock were amended such that the exercise price will only be adjusted if such issuances are for consideration per share less than 80% of the exercise price then in effect, subject to certain exceptions; and
- the period for which the exercise price protection provisions apply was shortened from ending on December 15, 2023 to ending on June 15, 2023 (i.e. 12 months following the IPO).

The Company will issue new amended and restated Bridge Warrants reflecting the amendments set forth in the Bridge Warrant Amendment to the holders in exchange for the original Bridge Warrants.

As a result of the Bridge Warrant Amendment, the conversion price of our Series C convertible preferred stock, par value $0.001 per share, or the Series C Preferred Stock, was adjusted to $6.29. As adjusted, the Series C Preferred Stock is convertible into a total of 1,611,290 shares of Common Stock as of September 30, 2022.

Waiver of Series C Preferred Stock Registration Right

In August 2022, we entered into written waiver agreements, or the Series C Waiver, with the requisite holders of our Series C Preferred Stock, whereby such holders agreed to irrevocably waive their right to include the shares of Common Stock issued or issuable upon conversion of their Series C Preferred Stock in the registration statement of which this prospectus forms a part.

Grant of Patent

On September 20, 2022, the Company announced that it was granted a patent from the United States Patent and Trademark Office for ECG quantification of echocardiographic measures of diastolic function of the heart using AI methods.

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. The information contained on, or that can be accessed through, our website is not part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

THE OFFERING

Shares of Common Stock issued upon conversion of Bridge Notes offered by the Selling Shareholders	1,540,492 shares of Common Stock
Common Stock issuable upon exercise of Bridge Warrants offered by the Selling Shareholders	Up to 1,683,470 shares of Common Stock
Common Stock issuable upon exercise of Pre-Funded Warrants offered by the Selling Shareholders	Up to 139,356 shares of Common Stock
Common Stock outstanding	8,202,551 shares as of September 30, 2022
Use of proceeds	We are not selling any securities under this prospectus and we will not receive any proceeds from the sale of Shares of Common Stock by the Selling Shareholders. We will receive up to an aggregate of approximately $7.2 million from the exercise of the Warrants, assuming the full exercise thereof. We intend to use any and all net proceeds received from the exercise of the Warrants for costs directly related to achieving FDA clearance for the MyoVista device and for working capital and general corporate purposes, including personnel costs, capital expenditures and the costs of operating as a public company. See "Use of Proceeds."
Nasdaq Listing	Our Common Stock and IPO Warrants are listed on Nasdaq under the symbols "HSCS" and "HSCSW," respectively.
Risk factors	Investment in our Common Stock involves substantial risks. You should read this prospectus and the information incorporated by reference into this prospectus carefully, including the section entitled "Risk Factors" in this prospectus and the documents incorporated by reference and the financial statements and the related notes to those statements incorporated by reference in this prospectus, before investing in our Common Stock.

As of September 30, 2022, the number of shares of our Common Stock outstanding excludes:

20,667 shares of Common Stock issuable upon conversion of the 5,200 shares of Series C Preferred Stock issuable upon conversion of the $130K Note (as defined in the Glossary of Terms). This number of shares of Common Stock also excludes shares issuable pursuant to antidilution provisions set forth in the Series C Preferred Stock, which is dependent on the market price of our Common Stock at the time of conversion. See "Description of Securities–Antidilution Provisions" and "Description of Securities–Preferred Stock" for additional information;

1,611,290 shares of Common Stock issuable upon conversion of the 405,228 shares of issued and outstanding Series C Preferred Stock;

835,983 shares of Common Stock issuable upon the exercise of stock options issued to directors, employees and consultants of the Company, of which 394,037 have vested;

76,421 shares of Common Stock issuable upon exercise of the Investor Warrants, the $1M Lender Warrants and the $1.5M Lender Warrants (each as defined in the Glossary of Terms). See “Description of Securities−Warrants” for more information;

1,725,000 shares of Common Stock issuable upon exercise of the IPO Warrants; and

105,000 shares of Common Stock issuable upon exercise of the warrants issued to the underwriter in the IPO.

SUMMARY OF FINANCIAL DATA

The following table summarizes our financial data. We have derived the following statements of operations data for Fiscal 2022 and Fiscal 2021 from our audited financial statements incorporated by reference into this prospectus. We have derived the following statements of operations data for the three months ended July 31, 2022 and 2021, and the balance sheet data as of July 31, 2022, from our unaudited interim condensed financial statements incorporated by reference into this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary financial data should be read in conjunction with our prior filings and with our financial statements and related notes included elsewhere in this prospectus.

	Three Months Ended July 31,		Year Ended April 30,	
	2022	2021	2022	2021
	(Unaudited)			
Revenue	$3,200	$7,484	$14,373	$25,604
Cost of sales	2,036	5,756	7,890	10,665
Gross margin	1,164	1,728	6,483	14,939
Operating expenses:				
Research and development	434,198	401,114	3,001,532	1,708,447
Selling, general and administrative	997,063	275,060	1,714,350	874,620
Gain on disposal of property and equipment	–	–	–	(1,663)
Total operating expenses	1,431,261	676,174	4,715,882	2,581,404
Loss from operations	(1,430,097)	(674,446)	(4,709,399)	(2,566,465)
Other income (expense)				
Interest expense	(143,607)	(77,605)	(371,619)	(132,454)
Gain on extinguishment of debt	–	250,200	250,200	250,200
Other income	401	–	2,558	–
Other expense	–	–	–	(3,451)
Total other income (expense)	(143,206)	172,595	(118,861)	114,295
Net loss	$(1,573,303)	$(501,851)	$(4,828,260)	$(2,452,170)
Net loss per share, basic and diluted	$(0.28)	$(0.15)	$(1.45)	$(0.74)
Weighted average common shares outstanding, basic and diluted	5,645,230	3,313,841	3,318,892	3,313,841

	July 31, 2022 (Unaudited)	April 30, 2022	April 30, 2021
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$4,272,499	$918,260	$723,481
Accounts receivable	–	2,321	–
Inventory	677,669	674,139	750,774
Prepaid expenses	445,924	49,383	94,750
Other current assets	40,374	40,374	69,037
Deferred offering costs	–	246,400	–
Total current assets	5,436,466	1,930,877	1,638,042
Property and equipment, net	70,870	70,035	94,669
Right-of-use assets, net	59,923	88,535	194,660
TOTAL ASSETS	$5,567,259	$2,089,447	$1,927,371
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)			
CURRENT LIABILITIES			
Accounts payable	$455,744	$694,745	$335,781
Accrued expenses	505,547	1,053,636	288,927
Operating lease liabilities	61,546	90,968	107,632
Current portion of notes payable	130,000	1,630,000	130,000
PPP loans payable	–	–	250,200
Other current liabilities	389,186	1,220	1,220
Total current liabilities	1,542,023	3,470,569	1,113,760
LONG-TERM LIABILITIES			
Notes payable	1,000,000	4,441,807	2,500,000
Accrued expenses	137,967	232,868	132,234
Operating lease liabilities	–	–	90,967
Total long-term liabilities	1,137,967	4,674,675	2,723,201
TOTAL LIABILITIES	2,679,990	8,145,244	3,836,961
COMMITMENTS AND CONTINGENCIES			
STOCKHOLDERS EQUITY (DEFICIT)			
Series A, B, and C convertible preferred stock, $0.001 par value, 20,000,000 shares authorized and 620,000 designated; 412,589 shares issued and outstanding as of July 31, 2022 and 483,265 shares issued and outstanding as of April 30, 2022 and 2021.	413	483	483
Common stock, $0.001 par value, 500,000,000 shares authorized; 8,174,375 shares issued and outstanding as of July 31, 2022, 3,323,942 shares issued and outstanding as of April 30, 2022, and 3,313,841 shares issued and outstanding as of April 30, 2021.	8,173	3,323	3,313
Additional paid-in capital	58,854,894	48,343,305	47,661,262
Accumulated deficit	(55,976,211)	(54,402,908)	(49,574,648)
TOTAL STOCKHOLDERS EQUITY (DEFICIT)	2,887,269	(6,055,797)	(1,909,590)
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)	$5,567,259	$2,089,447	$1,927,371

SUMMARY OF RISK FACTORS

Our business is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following the prospectus summary and in Item 1A. of our Annual Report on Form 10-K for Fiscal 2022 in the section entitled "Risk Factors" incorporated by reference into this prospectus. 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 in the "Risk Factors" section in this prospectus, in the documents incorporated by reference into this prospectus and in any prospectus supplements 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;
- Our future operating results are dependent on regulatory approval for the MyoVista, which we have not received as of the date of this prospectus;
- 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;
- 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 to the market in a timely manner. If we do not obtain and maintain the regulatory registrations and clearances for our device, we will be unable to market and sell the MyoVista in the United States, Europe or other regions;
- Our success will be dependent upon physician acceptance; and
- If third-party payors do not provide adequate coverage and reimbursement for the use of the MyoVista, our revenue will be negatively impacted.

Risks Related to Product Development and Regulatory Approval:

- Our device 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 determinations from the FDA that each device is substantially equivalent to another legally U.S. marketed medical device thereby authorizing the device to be marketed in the U.S. ("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; and

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.

Risks Related to Our Intellectual Property:

If we are unable to obtain and maintain effective patent rights for our device, 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 device, and we might be required to litigate or obtain licenses from third parties in order to develop or market our device. 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 this Offering and the Ownership of our Securities:

Although our Common Stock began trading on The Nasdaq Stock Market LLC on June 15, 2022, we do not know whether an active, liquid trading market for our Common Stock will develop or, if developed, be sustained, or what the trading price of our Common Stock will be in the future. Our Common Stock may trade at a price below the price you paid and it may be difficult for you to sell the Common Stock you purchase;

The market price of our Common Stock has been and may continue to 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 in addition to the Shares offered by this prospectus could cause our stock price to decline; and

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.

RISK FACTORS

Investing in our Common Stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information incorporated by reference into this prospectus or in any prospectus supplement as well as the risk factors included in Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended April 30, 2022, before making a decision to invest in our Common Stock. Our business, results of operations, financial condition and prospects could also be harmed by risks and uncertainties that are not presently known to us or that we currently believe are not material. If any of the following risks actually occur, our business, platform, reputation, brand, results of operations, financial condition and prospects could be materially and adversely affected. In such event, the market price of our Common Stock could decline, and you could lose all or part 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 during its development stage. We have incurred losses in each year since our inception, including net losses of approximately $4.8 million and $2.4 million for Fiscal 2022 and Fiscal 2021, respectively, and a net loss of approximately $1.6 million for the three months ended July 31, 2022. As of July 31, 2022, we had an accumulated deficit of approximately $56.0 million and shareholder' s equity of approximately $2.9 million.

Even if we obtain regulatory approval for sales launch of the MyoVista 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 the MyoVista 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 device 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 a medical device, 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.

Our future operating results are dependent on regulatory approval for the MyoVista, which we have not received as of the date of filing of this prospectus.

The MyoVista is our only current product candidate. 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 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 the MyoVista to the market in a timely manner. If we do not obtain and maintain the regulatory registrations and clearances for our device, we will be unable to market and sell the MyoVista in the United States, Europe or other regions." Any factor that adversely impacts the approval, development and sales launch of the MyoVista into the U.S. will have a negative impact on our business, financial condition and results of operations. We may face several challenges with respect to launching sales of the MyoVisto 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 the MyoVista or sell it 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 the MyoVista;
- 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 the MyoVista;
- third-party payors may not agree to reimburse patients for any or all of the charges related to testing the MyoVista, which may adversely affect physicians' adoption and use of the device; 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 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 the MyoVista, 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 the MyoVista 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 the MyoVista. 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 of the MyoVista 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 the MyoVista, 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 the MyoVista if we receive approval for sales launch of the MyoVista 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 the MyoVista and any future product 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 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. 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 incorporated by reference into this prospectus 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 have a working capital deficiency. 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 to the market in a timely manner. If we do not obtain and maintain the regulatory registrations and clearances for our device, we will be unable to market and sell the MyoVista 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 Federal Food, Drug, and Cosmetic Act, or the FDCA.

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 MyoVista is 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 a De Novo application in late 2019. The FDA determined that the Company would need to undertake a new algorithm validation clinical study using patients gathered from institutions that were not part of the studies used for algorithm development. Due to the time of completion of the study, submission of the new validation study results requires a new De Novo submission. The new validation study is currently underway and we intend to submit a new De Novo application for the MyoVista later in Fiscal 2023. Additional clinical studies are being conducted as part of the outcome of the previous application process. The De Novo process can be expensive, lengthy and unpredictable. De Novo classification requests require the performance of at least one clinical trial. Despite the time, effort and cost, we may not ultimately be successful in completing the review process and our De Novo 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 the MyoVista, which may limit the market for the device in the United States.

In order to sell the device in member countries of the European Economic Area, or EEA, our device must comply with the essential requirements of the EU Medical Device Regulation (EU), or EU MDR, 2017/745. Compliance with these requirements is a prerequisite to be able to affix the Conformité Européene mark, or CE Mark, to our device, without which it cannot be sold or marketed in the EEA.

The Company previously achieved a CE Mark under the EU Medical Devices Directive or the MDD in February 2017. The Medical Device Directive was established on June 14, 1993 but the EU Medical Devices Directive, or the MDD regulatory framework, has since been replaced by EU MDR. In order to sell in member countries of the European Economic Area, or EEA, our device must now comply with the essential requirements of the newer, updated regulatory framework or 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 in the European Economic Area as well as other countries for which CE Mark represents an appropriate regulatory standard.

Sales of our device 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.

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 and on the willingness of hospitals, physicians, patients and/or third-party payors to use it. These parties may not use our device unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our device is safe, effective and cost-effective, on a stand-alone basis and relative to our competitors' products. If we fail to deliver a device 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 device through effective marketing, physicians tend to be slow in making changes to their medical treatment practices and may be hesitant to select our device 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 the MyoVista 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 the MyoVista.

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 the MyoVista 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, our revenue will be negatively impacted.

The MyoVista does 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 payor.

Our ability to successfully launch sales of the MyoVista into the U.S. and achieve market acceptance of the MyoVista 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 the MyoVista may be purchased by hospitals and other providers who will then seek reimbursement from third-party payors for the use of the MyoVista and, in many cases, the decision whether or not to purchase the MyoVista 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 the MyoVista 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 and American College of Cardiology to gain approval for use of the standard ECG reimbursement coding for the conventional ECG functions of the MyoVista. We will also seek to have private third-party payors provide reimbursement for the *wav*ECG proprietary algorithm, or the MyoVista Algorithm. We cannot assure you that these efforts will be successful to our 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.

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 consists mostly of off-the-shelf components and once we are able to sell the MyoVista, 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 device 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.

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

Even if we are successful in obtaining regulatory clearance or approval for the MyoVista and are able to launch sales of the MyoVista into the U.S., our future success will depend on our ability to enhance the MyoVista 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 the MyoVista 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 the MyoVista 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 the MyoVista at a competitive rate, if at all. Technological advances by one or more competitors or future entrants into the field may result in the MyoVista 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, Philips and Hill-Rom, 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 device 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 September 30, 2022, we had 12 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 the MyoVista to other available products. If reimbursement of our device 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 anticorruption, 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 anticorruption, 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 the MyoVista were to cause or contribute to injury or death. There is also the possibility that defects in the design or manufacture of the MyoVista 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 the MyoVista. 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.

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 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 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.

We face business disruption and related risks resulting from the outbreak of the COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

COVID-19 continues to mutate which may reduce the efficacy of treatments currently available and the final implications of the pandemic are difficult to estimate at this stage; however, it is clear that it has affected the lives of a large portion of the global population. At this time, the pandemic has caused states of emergency to be declared in various countries, travel restrictions to be imposed globally and quarantines established in certain jurisdictions.

COVID-19 infection of our workforce could result in a temporary disruption in our business activities. The spread of an infectious disease, including 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. The extent to which COVID-19 impacts our business will depend on future developments, which are

highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

Risks Related to Product Development and Regulatory Approval

Our device 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.

The MyoVista is 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 De Novo classification is granted, any future modifications to the device may require us to submit a 510(k) premarket notification or 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 device 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 of 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 FDA' s investigational device exemption, or 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 device 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 device 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 device 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 device 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 the MyoVista 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 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 device has 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 the MyoVista 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 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 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 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 device may harm our reputation in the marketplace, could potentially cause harm to the patient and that 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, the MyoVista 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 devices 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 device is cleared or approved, healthcare providers may misuse our device 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 device 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 device either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

If the MyoVista receives 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 device 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 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 device or to manufacture, market or distribute our device 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 device or the coverage and reimbursement available for our device and could limit the acceptance and availability of our device. 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 product 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, or EU, 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 U.S. and EU), 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 clearinghouses 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 will go 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 will take effect on January 1, 2023, was signed into law, and on July 8, 2021 the Colorado Privacy Act, which will take 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 prohibit or 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, or GDPR, which went into effect in May 2018, imposes stringent requirements for controllers and processors of personal data of individuals within the European Economic Area, or EEA. As Switzerland and the United Kingdom are not part of the EU 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 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, or 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 be 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 device, 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 issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our device, 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 device, 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 device, and we might be required to litigate or obtain licenses from third parties in order to develop or market our device. 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 device 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 counterclaim 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 commonplace. 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 device 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 may be third-party patents or patent applications with claims to materials, designs or methods of manufacture related to the use or manufacture of our device. There may be currently pending patent applications or continued patent applications that may later result in issued patents that our device 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 device 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 this Offering and the Ownership of our Securities

Although our Common Stock began trading on The Nasdaq Stock Market LLC on June 15, 2022, we do not know whether an active, liquid trading market for our Common Stock will develop or, if developed, will be sustained, or what the trading price of our Common Stock will be in the future. Our Common Stock may trade at a price below the price you paid and may be difficult for you to sell the Common Stock you purchase.

Although our Common Stock is listed on The Nasdaq Stock Market LLC, or Nasdaq, and began trading on June 15, 2022, an active trading market for our Common Stock may not be achieved or sustained. It may be difficult for you to sell your Common Stock without depressing the market price for the Common Stock or at all. Consequently, you may not be able to sell your Common Stock at or above the price you paid, or at all. Further, an inactive market may also impair our ability to raise capital by selling additional shares of Common Stock and it also may impair our ability to enter into strategic partnerships or acquire companies, products, or services by using our equity securities as consideration.

Prior to the IPO, there was not a public trading market for shares of our Common Stock. We cannot predict the extent to which investor interest in us will lead to the development of an active trading market or how active and liquid that market may become. If an active and liquid trading market does not develop or continue, you may have difficulty selling your Common Stock at an attractive price or at all. The initial public offering price per share of Common Stock and per IPO Warrant in the IPO was determined by agreement between us and the representative of the underwriters, and may not be indicative of the price at which shares of our Common Stock will trade in the public market in the future. The market price of our Common Stock may decline below the price you paid and you may not be able to sell your Common Stock at or above the price you paid, or at all.

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

The market price of our Common Stock is likely to be volatile, which may prevent you from being able to sell your Common Stock at or above the price you paid for your securities. 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, regardless of our actual operating performance, and we have little or no control over these factors.

Future sales of a substantial number of shares of our Common Stock by our existing shareholders in addition to the Shares offered by this prospectus could cause our stock price to decline.

We have a significant number of shares of restricted Common Stock that will become eligible for sale in the future. As of September 30, 2022, there were 8,202,551 shares of our Common Stock outstanding. In addition, as of September 30, 2022 there were 405,228 shares of Series C Preferred Stock outstanding that, as of such date, were convertible into 1,611,290 shares of Common Stock, a convertible note which could convert into 5,200 shares of Series C Preferred Stock (which could then convert into 20,667 shares of Common Stock), and warrants (including the Bridge Warrants and the Pre-Funded Warrants) and options exercisable for 4,565,230 shares of our Common Stock. All of the shares of Common Stock and IPO Warrants sold in the IPO became eligible for sale immediately upon issuance in the IPO. Additional shares will be eligible for sale in the public market upon (i) the effectiveness of the registration statement of which this prospectus forms a part, subject to the lock-up agreements entered into in connection with the IPO and applicable to the Shares offered for resale pursuant to this prospectus, and (ii) the expiration of the lock-up agreements entered into in connection with the IPO. Subject to any applicable lock-up agreements, pursuant to Rule 144 under the Securities Act as in effect on the date hereof, or Rule 144, beginning September 13, 2022, a person who holds restricted shares of Common Stock (assuming there are any restricted shares) and is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned these restricted shares for at least six months, would be entitled to sell an unlimited number of shares of our Common Stock, provided current public information about us is available. In addition, under Rule 144, a person who holds restricted shares in us and is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned these restricted shares for at least one year, would be entitled to sell an unlimited number of shares without regard to whether current public information about us is available. It is conceivable that following the holding period, many shareholders may wish to sell some or all of their shares. If our shareholders sell substantial amounts of our Common Stock in the public market at the same time, the market price of our Common Stock could decrease significantly due to an imbalance in the supply and demand of our Common Stock. Even if they do not actually sell the Common Stock, the perception in the public market that our shareholders might sell significant Common Stock could also depress the market price 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 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 provide more favorable relative recommendations about our competitors, the price of our Common Stock 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 or trading volume to decline.

Management has broad discretion as to the use of the proceeds from the IPO.

Our management has broad discretion in the allocation of the net proceeds from the IPO and could use such proceeds for purposes other than those contemplated at the time of the IPO or this offering. Our shareholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. For additional information regarding our anticipated uses of proceeds from cash exercises of the Bridge Warrants and Pre-Funded, see "Use of Proceeds."

We will need additional capital beyond the capital raised in our IPO, and the sale of additional shares of the Common Stock or equity or debt securities could result in additional dilution to our shareholders.

Although the net proceeds from our IPO are anticipated to be sufficient to achieve FDA clearance, which would allow us to market the MyoVista in the U.S., there is no assurance that this would be the case and further funding may be required. We will need to raise additional capital beyond the capital raised in the IPO in order to support the sales launch of the MyoVista into the U.S., provide working capital and support further R&D. Such additional capital may be raised through a combination of private and public equity offerings, debt financings and collaborations, and strategic and licensing arrangements. To the extent that we raise additional capital through the issuance of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Common Stock. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, without prior approval, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development, sales launch or marketing efforts or grant rights to develop and market product that we would otherwise prefer to develop and market ourselves.

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 2022 and Fiscal 2021.

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:

we did not maintain sufficient U.S. GAAP and SEC accounting resources commensurate with those required of a public company;

we did not employ month-end financial reporting controls that prevented timely production of accurate monthly financial reports;

we did not employ proper independent review of monthly financial reports to verify that such reports are accurate and reconciled properly to the supporting documentation schedules; and

we did not have strong accounting consideration and analysis over equity accounts and inventory valuation.

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.

We have begun implementation of a plan to remediate these material weaknesses. These remediation measures are ongoing and include hiring additional accounting and financial reporting personnel and implementing additional policies, procedures, and controls. We cannot assure you that these measures will significantly improve or remediate the material weaknesses described above. The implementation of these remediation measures is in the early stages and will require validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles. As a result, the timing of when we will be able to fully remediate the material weaknesses is uncertain, and we may not fully remediate these material weaknesses until later in the fiscal year ending April 30, 2023. 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 consolidated 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.

We and our independent registered public accounting firm were not required to perform an evaluation of our internal control over financial reporting as of either April 30, 2022 or April 30, 2021 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 September 30, 2022 our principal shareholders, officers and directors beneficially own approximately 29.27% of our Common Stock. They will therefore be able to exert significant control over matters submitted to our shareholders for approval.

As of September 30, 2022, our principal shareholders, officers and directors beneficially own approximately 29.27% of the outstanding shares of our Common 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.

Provisions of the IPO Warrants and the Bridge Warrants could discourage an acquisition of us by a third party.

In addition to the provisions of our amended and restated certificate of formation and amended and restated bylaws, certain provisions of the IPO Warrants and the Bridge Warrants could make it more difficult or expensive for a third party to acquire us. The IPO Warrants and the Bridge Warrants prohibit us from engaging in certain transactions constituting "fundamental transactions" unless, among other things, the surviving entity assumes our obligations under the IPO Warrants and the Bridge Warrants. These and other provisions of the IPO Warrants and the Bridge Warrants could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

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 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.

We are an "emerging growth company" as defined in the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, not being required to comply with any new requirements adopted by the Public Company Accounting Oversight Board, or the PCAOB, requiring mandatory audit firm rotation or a supplement to the auditor' s report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer, not being required to comply with any new audit rules adopted by the PCAOB after April 5, 2012 unless the SEC determines otherwise, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could remain an emerging growth company until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer. We cannot predict if investors will find our Common Stock less attractive if we choose to rely on these exemptions. If some investors find our Common Stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our Common Stock and our stock price may be more volatile. Further, as a result of these scaled regulatory requirements, our disclosure may be more limited than that of other public companies and you may not have the same protections afforded to shareholders of such companies.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. We have opted for taking advantage of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the Jobs Act.

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 of Directors. In addition, the Texas Business Organizations Code, or the TBOC, also contains certain provisions that could make an acquisition by a third party more difficult.

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, and therefore shareholders may have difficulty selling their shares of Common Stock.

USE OF PROCEEDS

We are not selling any securities under this prospectus and we will not receive any proceeds from the sale of securities by the Selling Shareholders, although we could receive up to approximately $7.2 million upon the cash exercise of all Bridge Warrants and Pre-Funded Warrants. Any amounts we receive from such exercises will be used for costs directly related to achieving FDA clearance for the MyoVista device and for working capital and general corporate purposes, including personnel costs, capital expenditures and the costs of operating as a public company. The holders of the Bridge Warrants and Pre-Funded Warrants are currently not obligated to exercise such Warrants and we cannot assure you that the holders of any of the foregoing will choose to exercise all or any portion of the Bridge Warrants or Pre-Funded Warrants.

MARKET PRICE AND DIVIDENDS ON COMMON EQUITY AND RELATED SHAREHOLDER MATTERS

Current Market Price and Number of Shareholders

Our Common Stock and IPO Warrants are listed on the Nasdaq Stock Market under the symbols “HSCS” and “HSCSW,” respectively. As of September 30, 2022, there were 371 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. On October 4, 2022, the closing price of our Common Stock was $1.40 per share and the closing price of our IPO Warrants was $0.1819.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our Common Stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors and will depend on our results of operations, financial condition, capital requirements, contractual restrictions and other factors deemed relevant by our Board of Directors.

Proceeds from IPO

On June 17, 2022, we closed on the sale of 1,500,000 Units in the IPO, with each Unit consisting of one share of Common Stock and one IPO Warrant to purchase one share of Common Stock at a combined public offering price of $4.25 per Unit. Additionally, in the IPO, the underwriter exercised the over-allotment option, in part, for 225,000 IPO Warrants at a public offering price of $0.01 per Warrant. The IPO was consummated pursuant to a Registration Statement on Form S-1, or the IPO Registration Statement, that was declared effective by the SEC on June 14, 2022. The IPO Registration Statement registered the Units sold in the offering, the shares of Common Stock and IPO Warrants comprising the Units, the IPO Warrants sold pursuant to the underwriter’ s over-allotment option, and the shares of Common Stock issuable upon exercise of the IPO Warrants. The IPO Registration Statement also registered the warrants to purchase an aggregate of 105,000 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, which we refer to as the Underwriter Warrants, as well as the shares of Common Stock issuable upon exercise of the Underwriter Warrants. The underwriter, as sole book-running manager and underwriter in the IPO, was The Benchmark Company LLC.

We 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. As of September 30, 2022, we have used approximately $1.8 million of the net proceeds from the IPO for costs related to achieving FDA clearance for the MyoVista device, to pay approximately $0.1 million of the accrued and

unpaid interest under the $1M Loan and Security Agreement, and for working capital and general corporate purposes including personnel costs, capital expenditures and the costs of operating as a public company. We intend to use the remaining $3.4 million of the net proceeds from the IPO for costs directly related to achieving FDA clearance and for working capital and general corporate purposes, including personnel costs, capital expenditures and the costs of operating as a public company.

DESCRIPTION OF SECURITIES

The following description summarizes the terms of our securities, 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 SEC of this prospectus, the forms of which are included as exhibits to the registration statement of which this prospectus forms a part.

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, or the TBOC. Our authorized capital stock consists of five hundred million (500,000,000) shares of Common Stock, par value $0.001 per share, and twenty million (20,000,000) shares of preferred stock, or Preferred Stock, par value $0.001 per share of which, as of September 30, 2022, there were 8,202,551 shares of Common Stock outstanding and held of record by 371 shareholders and 405,228 shares of Series C Preferred Stock (as defined below) outstanding that, as of such date, were convertible into 1,611,290 shares of Common Stock and held of record by 69 shareholders. Of our authorized Preferred Stock, six hundred thousand (600,000) shares have been designated as Series C Convertible Preferred Stock, or the Series C Preferred Stock, having a par value of $0.001 per share, of which 405,228 were outstanding as of September 30, 2022. Unless our Board of Directors determines otherwise, we will issue all shares of our capital stock in uncertificated form.

On June 17, 2022, we consummated the IPO of Units, with each Unit consisting of (a) one share of our Common Stock and (b) an IPO Warrant to purchase one share of our Common Stock, and additional IPO Warrants through the exercise, in part, of the underwriter' s over-allotment option in the IPO. Our executive officers and directors have entered into lock-up agreements with the underwriter in the IPO that will, subject to certain customary exceptions, restrict the sale of the shares of our Common Stock and certain other securities held by them for 12 months following June 15, 2022, the date of the underwriting agreement entered into with the underwriter in connection with the IPO, or the underwriting agreement. In addition, certain of our shareholders have entered into substantially similar lock-up agreements, except their lock-up agreements will expire six months following the date of the underwriting agreement. As of September 30, 2022, a total of 3,005,710 shares of our Common Stock are subject to such lock-up agreements entered into by our executive officers and directors and certain shareholders. These lock-up agreements further provide that the Bridge Conversion Shares (as defined below) are instead subject to the Bridge Lock-up Agreements (as defined below). The shares of Common Stock issued upon conversion of the Bridge Notes (the "Bridge Conversion Shares") are subject to lock-up agreements entered into in connection with the 2021 Bridge Financing (the "Bridge Lock-Up Agreements"). Pursuant to the Bridge Lock-Up Agreements, the former holders of the Bridge Notes have agreed not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any Bridge Conversion Shares for a period commencing on the date of the IPO and continuing until after (i) the three month anniversary of the IPO with respect to one-third of the Bridge Conversion Shares, which occurred on September 15, 2022, (ii) the four month anniversary of the IPO with respect to an additional one-third of the Bridge Conversion Shares, and (iii) the five month anniversary of the IPO with respect to the remaining Bridge Conversion Shares. As of September 30, 2022, a total of 1,029,409 shares of our Common Stock are subject to the Bridge Lock-Up Agreements. After the expiration of the applicable period, whether under the lock-up agreements entered into in connection with the IPO or under the Bridge Lock-up Agreements, the shares of Common Stock held by our directors, executive officers and shareholders may be sold subject to the restrictions under applicable securities laws or by means of registered public offerings.

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.

As of September 30, 2022, there were 405,228 shares of Series C Preferred Stock outstanding that, as of such date, were convertible into 1,611,290 shares of Common Stock. At the consummation of the IPO, all of our previously outstanding shares of Series A convertible preferred stock, par value $0.001 per share, or Series A Preferred Stock, were converted into 703,290 shares of Common Stock and all or our previously outstanding shares of Series B convertible preferred stock, par value $0.001 per share, or Series B Preferred Stock, were cancelled. As a result, there are no longer any 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 September 30, 2022, the liquidation preference was approximately $10.1 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. Additionally, pursuant to the FRV Side Letter, Front Range Ventures, LLC, or FRV, is entitled to appoint a member of the Board of Directors as well as a board observer, for so long as FRV holds at least 71,000 shares of Series C Preferred Stock.

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 September 30, 2022, the conversion price of the Series C Preferred Stock was $6.29 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 $16.50 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. As of the date of this prospectus, no such sale has occurred.

Warrants

Investor Warrants

The Company issued warrants, or the Investor Warrants, in connection with funding or as consideration for services rendered to the Company. The Investor Warrants have terms ranging from five to ten years from the date of issuance. As of September 30, 2022, there were Investor Warrants to purchase 56,726 shares of Common Stock at exercise prices ranging from $3.47 to $15.18 per share.

Warrants issued in connection with the 2021 Bridge Financing

We issued the Bridge Warrants to originally purchase 775,420 shares of Common Stock in connection with the 2021 Bridge Financing. The Bridge Warrants expire in five years after the date of issuance, beginning on December 22, 2026, with an initial exercise price of $9.08 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 a written amendment to the Bridge Warrants, which we refer to as the Bridge Warrant Amendment. The Bridge Warrant Amendment 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 1,365,960 shares to a total of 1,683,470 shares, (ii) lowering the exercise price to $4.25 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 $4.125 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.

The exercise price of the Bridge Warrants (as amended by the Bridge Warrant Amendment) is subject to adjustment for certain events such as stock dividends, splits, and reverse splits or other combinations and, if and whenever on or prior to June 15, 2023, there are issuances of shares of Common Stock or securities convertible into or exercisable for shares of Common Stock at a price less than 80% of the exercise price of the Bridge Warrants, in which event the exercise price will be reduced to 125% of the price at which such newly issued shares of Common Stock or securities convertible into or exercisable for shares of Common Stock were issued. 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.

In addition to the Bridge Warrants, in the event any holder (including its Attribution Parties) of the Bridge Notes who would beneficially own 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, may elect to receive a pre-funded warrant, or the Pre-Funded Warrants, for all shares in excess of such percentage.

The Pre-Funded Warrants have substantially the same terms as the Bridge Warrants except that the exercise price is $0.0001 per share. Pre-Funded Warrants to purchase a total of 139,356 shares of Common Stock are outstanding as of the date of this prospectus. For more information regarding the Bridge Warrants, please see "Item 7. Management' s Discussion and Analysis of Financial Condition and Results of Operations−Description

of Indebtedness" in our the Annual Report on Form 10-K filed with the SEC on July 29, 2022 incorporated by reference into this prospectus.

$1M Lender Warrants

In November 2021, the Company issued warrants to purchase 15,152 shares of our Common Stock, which we refer to as the $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. The $1M Lender Warrants expire on September 30, 2026. The $1M Lender Warrants are exercisable for Common Stock at an exercise price equal to the lower of (i) $6.05 per share and (ii) a 30% discount to the offering price for the sale of Common Stock in an initial public offering. Pursuant to the terms of the $1M Lender Warrants, the amount allocated to each share of Common Stock in the IPO was $4.24 and as a result, the exercise price of the $1M Lender Warrants was $2.89 per share as of September 30, 2022.

$1.5M Lender Warrants

In November 2021, the Company also issued warrants to purchase 4,545 shares of our Common Stock, which we refer to as the $1.5M Lender Warrants, to noteholders of the $1.5M Notes as consideration for the extension of the maturity of the $1.5M Notes to October 31, 2022. The $1.5M Lender Warrants expire on October 12, 2026. The $1.5M Lender Warrants are exercisable for Common Stock at an exercise price equal to the lower of (i) $6.05 per share and (ii) a 30% discount to the offering price for the sale of Common Stock in an initial public offering. Pursuant to the terms of the $1.5M Lender Warrants, the amount allocated to each share of Common Stock in the IPO was $4.24 and as a result, the exercise price of the $1.5M Lender Warrants was $2.89 per share as of September 30, 2022.

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 included as exhibits to the registration statement of which this prospectus is a part. 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, 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 effect 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 $4.25 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 Transfer & 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.

Underwriter Warrants

At the consummation of the IPO, we issued warrants to the underwriter, or the Underwriter Warrants, to purchase 105,000 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 Warrants expire at 5:00 P.M. New York City time on June 17, 2027, have an exercise price equal to $4.25, 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 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 Warrants and any shares of Common Stock issued upon exercise of the Underwriter 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 September 30, 2022, there were time-based options to purchase a total of 254,215 shares of Common Stock at an average exercise price of $11.79 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 September 30, 2022, there were performance-based options to purchase a total of 581,768 shares of Common Stock at an average exercise price of $5.16 per share.

Antidilution Provisions

As of September 30, 2022, 1,611,290 shares of Common Stock issuable upon conversion of the Series C Preferred Stock are subject to antidilution 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. As of September 30, 2022, 1,683,470 shares of Common Stock issuable upon exercise of outstanding Bridge Warrants are subject to antidilution price protection provisions that reduce the exercise price if and whenever on or prior to June 15, 2023 there are issuances of shares of Common Stock or securities convertible into or exercisable for shares of Common Stock at a price less than 80% of the exercise price of the Bridge Warrants, in which event the exercise price will be reduced to 125% of the price at which such newly issued shares of Common Stock or securities convertible into or exercisable for shares of Common Stock were issued.

Lock-up Agreements

We agreed with the underwriter in the IPO that we will not, without the prior consent of the underwriter, directly or indirectly sell, offer, contract or grant any option to sell, pledge, transfer, or otherwise dispose of or enter into any transaction which may result in the disposition of any Common Stock or securities convertible into, exchangeable or exercisable for any Common Stock for a period ending December 15, 2022, which is six months after the date of the underwriting agreement.

In addition, each of our executive officers and directors agreed with the underwriter in the IPO, subject to certain customary exceptions, not to directly or indirectly sell, offer, contract or grant any option to sell, pledge, transfer, or otherwise dispose of or enter into any transaction which may result in the disposition of any Common Stock or securities convertible into, exchangeable or exercisable for any Common Stock, without the prior written consent of the representative, for a period ending June 15, 2023, which is 12 months after the date of the underwriting agreement. In addition, certain of our shareholders have entered into substantially similar lock-up agreements except that such agreements cover a period ending December 15, 2022. As September 30, 2022, a

total of 3,005,710 shares of our Common Stock are subject to such lock-up agreements entered into by our executive officers and directors and certain shareholders. These lock-up agreements further provide that the Bridge Conversion Shares are instead subject to the Bridge Lock-up Agreements. Pursuant to the Bridge Lock-Up Agreements, the holders of the Bridge Notes have agreed not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any Bridge Conversion Shares for a period commencing on the date of the IPO and continuing until after (i) the three month anniversary of the IPO with respect to one-third of the Bridge Conversion Shares, which occurred on September 15, 2022, (ii) the four month anniversary of the IPO with respect to an additional one-third of the Bridge Conversion Shares, and (iii) the five month anniversary of the IPO with respect to the remaining Bridge Conversion Shares. As of September 30, 2022, a total of 1,029,409 shares of our Common Stock are subject to the Bridge Lock-Up Agreements.

Registration Rights

In connection with the 2021 Bridge Financing, we entered into a registration rights agreement, or the Registration Rights Agreement, with the purchasers of the Bridge Notes (the "Purchasers") pursuant to which we agreed to file a resale registration statement, no later than September 12, 2022, with respect to the shares of Common Stock issuable upon conversion of the Bridge Notes, exercise of the Bridge Warrants and the Pre-Funded Warrants, or resulting from antidilution provisions in the Bridge Notes, the Bridge Warrants and the Pre-Funded Warrants, or any securities issued or then issuable upon any stock split, dividend or other distribution, recapitalization or similar event, collectively referred to as the "Registrable Securities." In the event that the Registration Statement relating to the resale of the Registrable Securities is not declared effective by the SEC on or prior to November 11, 2022, we are required to pay to each holder of Registrable Securities an amount in cash equal to two percent of the principal amount of such holder' s Bridge Notes. The registration statement of which this prospectus forms a part is being filed to satisfy our obligation under the Registration Rights Agreement to register the Registrable Securities.

We have also previously granted certain registration rights to the holders of the Series C Preferred Stock. Under the terms of this 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. In August 2022, we entered into written waiver agreements with the requisite holders of our Series C Preferred Stock whereby such holders agreed, on behalf of all holders of Series C Preferred Stock, to irrevocably waive their right to include their Series C Registrable Securities in the registration statement of which this prospectus forms a part.

We have also granted certain unlimited "piggyback" registration rights to the underwriter in the IPO under the Underwriter Warrants. For more information, see "−Underwriter 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, 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 September 30, 2022, 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 $66^2/_3\%$ 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. No assurance can be given that an active trading market will develop for our Common Stock or the IPO Warrants or, if developed, be sustained.

Transfer agent and registrar

The transfer agent and registrar for our Common Stock and Warrants is American Stock Transfer & Trust Company, LLC.

SELLING SHAREHOLDERS

The shares of Common Stock being offered by the Selling Shareholders are those previously issued to the Selling Shareholders upon conversion of the Bridge Notes and those issuable to the Selling Shareholders upon exercise of the Bridge Warrants and the Pre-Funded Warrants. For additional information regarding the issuances of Shares upon exercise of the Bridge Warrants and the Pre-Funded Warrants, see "Description of Securities−Warrants−Warrants issued in connection with the 2021 Bridge Financing." We are registering the offer and sale of the Shares in order to permit the Selling Shareholders to offer the Shares for resale from time to time. John Matthews, a beneficial owner of more than 5% of our outstanding Common Stock, Patrick Kanouff, a director of the Company, and Hong Zhang, a principal software engineer for the Company, are holders of Bridge Warrants. There have been no other material relationships within the past three years between us and the Selling Shareholders other than in respect of the 2021 Bridge Financing, the transactions contemplated thereunder and the ownership of our securities.

Selling Shareholder Information

The table below lists the names of the Selling Shareholders and other information regarding the beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations thereunder) of the shares of Common Stock beneficially owned by each of the Selling Shareholders as of September 30, 2022. The second column includes all shares of Common Stock issuable upon exercise of all outstanding warrants and options that are exercisable within 60 days of September 30, 2022, all shares of Common Stock issuable upon conversion of the Series C Preferred Stock and the number of shares of Common Stock beneficially owned by each Selling Shareholder based on each Selling Shareholder' s ownership of shares of Common Stock (including the Shares being offered by this prospectus) but taking account of any limitations on exercise of the Warrants as described below.

The third column lists the Shares of Common Stock being offered by this prospectus by the Selling Shareholders and does not take in account any limitations on the exercise of the Warrants set forth therein. Under the terms of the Warrants held by Selling Shareholders, no Selling Shareholder may exercise the Bridge Warrants or Pre-Funded Warrants to the extent such exercise would cause such Selling Shareholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock that would exceed 4.99% of our then outstanding Common Stock following such exercise. The number of shares in the second column reflects this limitation. The Selling Shareholders may sell all, some or none of their Shares in this offering. See "Plan of Distribution."

Unless otherwise indicated, the address for each Selling Shareholder listed in the table below is c/o Heart Test Laboratories, Inc., 550 Reserve St, Suite 360, Southlake, Texas 76092.

Name of Selling Shareholder (1)	Number of Shares of Common Stock Owned Prior to Offering (2)	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus (3)	Number of Shares of Common Stock Owned After Offering (4)	Percentage of Beneficial Ownership After Offering (4)
Cavalry Investment Fund, LP (5)	409,307	839,864	25,973	*
John H. Matthews (6)	1,048,538	395,282	721,476	7.3 %
Lary Conel Snodgrass (7)	359,333	159,974	199,359	2.0 %
Paul Buchanan (8)	337,508	111,526	225,982	2.3 %
Stewart Entertainment Ventures LLC (9)	333,000	238,884	94,116	1.0 %
Paul Knuckley (10)	228,970	79,986	148,984	1.5 %
Kenneth B. Tator and Maureen Tator (11)	213,026	23,898	189,128	1.9 %
Ronnie Evans	204,207	79,662	124,545	1.3 %
Patrick Kearney	166,730	119,672	47,058	*
Daniel Simpson	159,743	119,980	39,763	*
Scott Sullivan	158,639	79,986	78,653	*
Kema Fund LLC (12)	157,648	157,648	–	*
Raymond Pettitt (13)	157,253	79,986	77,267	*
John J. Bussa and Marilyn L. Bussa (14)	149,407	79,986	69,421	*
Philip Tracy	137,258	79,508	57,750	*
Anna Parafinczuk	116,259	32,660	83,599	*
Chad P. Wick (15)	112,782	43,770	69,012	*
Paul A. Smith Jr.	105,690	79,662	26,028	*
Intracoastal Capital LLC (16)	104,782	76,364	28,418	*
David Micucci	103,309	79,780	23,529	*
Daniel Hogan (17)	103,046	19,914	83,132	*
Ricardo Villalobos	98,092	79,268	18,824	*
Joanne Stewart	79,730	79,730	–	*
Kyerin Holdings Pty Ltd as trustee for The Kyerin Investment Trust (18)	67,374	29,474	37,900	*
Alistair McGeorge	66,980	30,270	36,710	*
Hong Zhang and Jingfang Luo (19)	63,116	39,830	23,286	*
Moradu Pty Ltd as trustee for BM Family Trust (20)	49,948	11,948	38,000	*
John Prevatt	49,043	19,706	29,337	*
Candlestick Lane Investments, LP (21)	35,682	15,860	19,822	*
Nigel Atkinson	30,802	9,956	20,846	*
Rachel Angel (22)	30,505	9,956	20,549	*
Malcolm Lanyon	21,636	15,774	5,862	*
Michael Pantuso	20,582	19,824	758	*
Patrick Kanouff (23)	17,658	15,764	1,894	*
Roger Powdrill	11,794	7,966	3,828	*

* Less than 1%.

(1) The Selling Shareholders purchased or received the Shares and Warrants that they currently beneficially own in the ordinary course of business and, at the time of purchase of such securities, the Selling Shareholders had no agreements or understanding, directly or indirectly with any person to distribute securities.

(2) All of the Warrants, which are exercisable for the Shares offered hereby, contain certain beneficial ownership limitations, which provide that a holder of the Warrants will not have the right to exercise any portion of its Warrants if such holder, together with its affiliates and attribution parties, would beneficially own in excess of 4.99% of the number of shares of Common Stock outstanding immediately after giving effect to such exercise, provided that upon at least 61 days' prior notice to us, a holder may increase or decrease such limitation up to a maximum of 9.99% of the number of shares of Common Stock outstanding (each such limitation, a "Beneficial Ownership Limitation"). Additionally, shareholders may have acquired shares on the open market without the Company' s knowledge that may not be reflected.

(3) Represents all Shares issued to the Selling Shareholders upon conversion of the Bridge Notes and all Shares issuable upon exercise of the Warrants and does not take into account any limitations on the exercise of Warrants.

(4) We do not know when or in what amounts a Selling Shareholder may offer Shares for sale. The Selling Shareholders might not sell any or might sell all of the Shares offered by this prospectus. Because the Selling Shareholders may offer all or some of the Shares pursuant to this offering, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the Shares, we cannot estimate the number of the shares of Common Stock that will be held by the Selling Shareholders after completion of the offering. However, for purposes of this table, we have assumed that, after completion of the offering, none of the Shares covered by this prospectus will be held by the Selling Shareholders.

(5) Cavalry Fund GP, LLC is the general partner of Cavalry Investment Fund LP. As such, Cavalry Fund GP, LLC may be deemed to beneficially own (as that term is defined in Rule 13d-3 under the Securities Exchange Act of 1934) all of the shares set forth opposite Cavalry Investment Fund LP' s name. Thomas Walsh is the Manager of Cavalry Fund GP, LLC. Each of Mr. Walsh and Cavalry Investment Fund LP disclaim beneficial ownership of these securities. The address of this Selling Shareholder is c/o Cavalry Investment Fund, LP, 82 East Allendale Rd., Suite 5B, Saddle River, NJ 07458.

(6) All of the shares are owned of record by either Mr. Matthews or Matthews Holdings Southwest, Inc. Mr. Matthews, as the controlling shareholder of Matthews Holdings Southwest, Inc., has sole voting and dispositive power over all shares owned by Matthews Holdings Southwest, Inc. The address of this Selling Shareholder is c/o Matthews Holdings Southwest, Inc., 320 W. Main St., Lewisville, TX 75057.

(7) All of the shares are owned of record by Mr. Snodgrass, Lary Snodgrass Family Limited or Snodgrass Children' s Limited. Mr. Snodgrass has sole voting and dispositive power over all of the shares owned by Lary Snodgrass Family Limited or Snodgrass Children' s Limited.

(8) All of the shares are owned by Mr. Buchanan, Mr. Buchanan' s wife, the Buchanan Family Discretionary Trust or PBU Investments Limited. Mr. Buchanan is the general partner of PBU Investments Limited. Mr. Buchanan has sole voting and dispositive power over all shares owned by him as an individual and by PBU Investments Limited and may be deemed to have beneficial ownership (pursuant to Section 13(d) of the Exchange Act) of such shares. Mrs. Buchanan has sole voting and dispositive power over all such shares owned by her as an individual. Mr. Buchanan and Mrs. Buchanan as trustees for the Buchanan Family Discretionary Trust have shared voting and dispositive power over all such shares and both may be deemed to have beneficial ownership (pursuant to Section 13(d) of the Exchange Act) of all shares. Mr. Buchanan and Mrs. Buchanan, as a married couple, may also be deemed to have beneficial ownership (pursuant to Section 13(d) of the Exchange Act) of each other' s shares.

(9) All of the shares are owned of record by Stewart Entertainment Ventures LLC. Mark Stewart, as the managing member of Stewart Entertainment Ventures LLC, has sole voting and dispositive power over all such shares.

(10) All of the shares are owned of record by either Mr. Knuckley or PSKS Investments, L.P. Mr. Knuckley, as general partner of PSKS Investments, L.P., has sole voting and dispositive power over all shares owned by PSKS Investments.

(11) All of the shares are owned of record by Mr. Tator, Mrs. Tator, Mr. Tator and Mrs. Tator as joint tenants and the Kenneth B. Tator Revocable Trust. Mr. Tator is the trustee for the Kenneth B. Tator Revocable Trust. Mr. Tator has sole voting and dispositive power over all shares owned by him as an individual and held by the Kenneth B. Tator Revocable Trust and may be deemed to have beneficial ownership (pursuant

to Section 13(d) of the Exchange Act) of such shares. Mrs. Tator has sole voting and dispositive power over all shares owned by her as an individual. Mr. Tator and Mrs. Tator have shared voting and dispositive power over shares held jointly by them as joint tenants and both may be deemed to have beneficial ownership (pursuant to Section 13(d) of the Exchange Act) of all shares. Mr. Tator and Mrs. Tator, as a married couple, may also be deemed to have beneficial ownership (pursuant to Section 13(d) of the Exchange Act) of each other' s shares.

(12) All of the shares are owned of record by Kema Fund LLC. Mr. Andrew Gilbert, as managing partner of Kema Fund LLC, has sole voting and dispositive power over all such shares.

(13) All of the shares are owned of record by either Mr. Pettitt or Mrs. Pettitt. Each of Mr. Pettitt and Mrs. Pettitt have sole voting and dispositive power over their respective shares owned separately. Mr. Pettitt and Mrs. Pettitt, as a married couple, may be deemed to have beneficial ownership (pursuant to Section 13(d) of the Exchange Act) of each other' s shares.

(14) All of the shares are owned of record by Mr. Bussa and Mrs. Bussa as joint tenants. Mr. Bussa and Mrs. Bussa have shared voting and dispositive power over all such shares.

(15) All of the shares are owned of record by either Mr. Wick or Ms. Feyten. Each of Mr. Wick and Ms. Feyten have sole voting and dispositive power over their respective shares owned separately. Mr. Wick and Ms. Feyten, as a married couple, may be deemed to have beneficial ownership (pursuant to Section 13(d) of the Exchange Act) of each other' s shares.

(16) All of the shares are owned of record by Intracoastal Capital LLC, and Mitchell P. Kopin and Daniel B. Asher, each of whom are managers of Intracoastal Capital LLC, have shared voting and dispositive power over all such shares and may be deemed to have beneficial ownership (pursuant to Section 13(d) of the Exchange Act) of such shares. The address of this Selling Shareholder is c/o Intracoastal Capital LLC, 245 Palm Trail, Delray Beach, FL 33483.

(17) All of the shares are owned of record by either Mr. Hogan or Mrs. Hogan. Each of Mr. Hogan and Mrs. Hogan have sole voting and dispositive power over their respective shares owned separately. Mr. Hogan and Mrs. Hogan, as a married couple, may be deemed to have beneficial ownership (pursuant to Section 13(d) of the Exchange Act) of each other' s shares.

(18) All of the shares are held of record by Kyerin Holdings Pty Ltd as the fiduciary trustee for The Kyerin Investment Trust. Stephen Dunn, director of Kyerin Holding Pty Ltd, has sole voting and dispositive power over all such shares.

(19) All of the shares are owned of record by Mr. Zhang and his wife, Ms. Luo, as joint tenants. Mr. Zhang and Ms. Luo have shared voting and dispositive power over all such shares. Mr. Zhang is a principal software engineer for the Company.

(20) All of the shares are held of record by Moradu Pty Ltd as trustee for BM Family Trust. Mr. Jonathan Cook, a director of Moradu Pty Ltd, has sole voting and dispositive power over all such shares.

(21) All of the shares are owned of record by Candlestick Lane Investments, LP. Mr. Daniel J. Verret, President of Candlestick Lane Investments, LP, has sole voting and dispositive power over all such shares.

(22) All of the shares are owned of record by either Mr. Angel or Mrs. Angel. Each of Mr. Angel and Mrs. Angel have sole voting and dispositive power over their respective shares owned separately. Mr. Angel and Mrs. Angel, as a married couple, may be deemed to have beneficial ownership (pursuant to Section 13(d) of the Exchange Act) of each other' s shares.

(23) Mr. Kanouff is a member of the Board of Directors of the Company.

PLAN OF DISTRIBUTION

We are registering the shares of Common Stock issued upon conversion of the Bridge Notes and issuable upon exercise of the Bridge Warrants and Pre-Funded Warrants, which we refer to collectively as the Shares, to permit the resale of these Shares by the holders thereof from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the Selling Shareholders of the Shares, although we will receive the exercise price of any Bridge Warrants or Pre-Funded Warrants not exercised by the Selling Shareholder on a cashless exercise basis. We will bear all fees and expenses incident to our obligation to register the Shares.

Each Selling Shareholder of the Shares and any of their pledgees, assignees and successors-in-interest may, from time to time, sell all or a portion of their Shares covered hereby on the Nasdaq or through one or more underwriters, broker-dealers or agents. If the Shares are sold through underwriters or broker-dealers, the Selling Shareholders will be responsible for underwriting discounts or commissions or agent' s commissions. The Shares may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions, pursuant to one or more of the following methods:

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing or settlement of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the Shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales made after the date the registration statement of which this prospectus forms a part is declared effective by the SEC;
- in transactions through broker-dealers that agree with the Selling Shareholders to sell a specified number of such Shares at a stipulated price per share;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Shareholders may also sell securities under Rule 144 promulgated, or any other exemption from registration, under the Securities Act of 1933, if available, rather than under this prospectus. In addition, the Selling Shareholders may transfer the Shares by other means not described in this prospectus. If the Selling Shareholders effect such transactions by selling Shares to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the Selling Shareholders or commissions from purchasers of the Shares for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the Shares or otherwise, the Selling Shareholders may enter into hedging transactions

with broker-dealers, which may in turn engage in short sales of the Shares in the course of hedging in positions they assume. The Selling Shareholders may also sell shares of Common Stock short and deliver Shares covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The Selling Shareholders may also loan or pledge shares of Common Stock to broker-dealers that in turn may sell such shares.

The Selling Shareholders may pledge or grant a security interest in some or all of the Warrants or Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the Shares from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending, if necessary, the list of Selling Shareholders to include the pledgee, transferee or other successors in interest as Selling Shareholders under this prospectus. The Selling Shareholders also may transfer and donate the Shares in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

To the extent required by the Securities Act and the rules and regulations thereunder, the Selling Shareholders and any broker-dealer participating in the distribution of the Shares may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the Shares is made, a prospectus supplement, if required, will be distributed, which will set forth the aggregate amount of Shares being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the Selling Shareholders and any discounts, commissions or concessions allowed or re-allowed or paid to broker-dealers.

Under the securities laws of some states, the Shares may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the Shares may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any Selling Shareholder will sell any or all of the Shares registered pursuant to the registration statement of which this prospectus forms a part.

The Selling Shareholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the Shares by the Selling Shareholders and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the Shares to engage in market-making activities with respect to the Shares. All of the foregoing may affect the marketability of the Shares and the ability of any person or entity to engage in market-making activities with respect to the Shares.

We will pay all expenses of the registration of the Shares pursuant to the registration rights agreement, estimated to be $40,000 in total, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, a Selling Shareholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the Selling Shareholders against liabilities, including some liabilities under the Securities Act in accordance with the registration rights agreements or the Selling Shareholders will be entitled to contribution. We may be indemnified by the Selling Shareholders against civil liabilities, including liabilities under the Securities Act that may arise from any written information furnished to us by the Selling Shareholder specifically for use in this prospectus, in accordance with the related registration rights agreements or we may be entitled to contribution.

Once sold under the registration statement of which this prospectus forms a part, the Shares will be freely tradable in the hands of persons other than our affiliates.

LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Jackson Walker L.L.P., Dallas, Texas.

EXPERTS

The financial statements incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended April 30, 2022 have been so incorporated in reliance on the report of Haskell & White LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1, which includes exhibits, schedules and amendments, under the Securities Act with respect to the securities we are offering pursuant to this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement, as permitted by the rules and regulations of the SEC. For further information with respect to us and our securities, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the contract, agreement or other document summarized, but are not complete descriptions of all terms of those contracts, agreements or other documents. If we filed any of those contracts, agreements or other documents as an exhibit to the registration statement, you may read the contract, agreement or other document itself for a complete description of its terms. Each statement in this prospectus relating to a contract, agreement or other document filed as an exhibit is qualified in all respects by the filed exhibit.

You can read our SEC filings, including the registration statement, annual, quarterly and special reports and proxy statements, as well as other information over the Internet at the SEC' s website at www.secgov or by visiting our website that we maintain at *www.heartsciences.com* where you may access the same free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on, or that can be accessed through, our website does not constitute part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only. Investors should not rely on any such information in deciding whether to purchase our securities.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with them. This means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this document. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (1) after the date of the initial registration statement, as amended, and prior to effectiveness of the registration statement, and (2) after the date of this prospectus and prior to the termination of this offering. Such information will automatically update and supersede the information contained in this prospectus and the documents listed below:

(a) Our Annual Report on Form 10-K for the year ended April 30, 2022 filed with the SEC on July 29, 2022;

(b) Our Quarterly Report on Form 10-Q for the quarter ended July 31, 2022 filed with the SEC on September 12, 2022;

(b) Our Current Reports on Form 8-K filed with the SEC on June 15, 2022 (as amended by Form 8-K/A filed with the SEC on June 16, 2022), June 23, 2022, July 18, 2022, September 9, 2022 and September 20, 2022; and

(c) The description of our Common Stock, which is contained in the Registration Statement on Form 8-A, as filed with the SEC on June 14, 2022, and including any amendments or reports filed for the purpose of updating such description.

Notwithstanding the foregoing, information that we elect to furnish, but not file, or have furnished, but not filed, with the Commission in accordance with Commission rules and regulations is not incorporated into this Registration Statement, shall not be deemed "filed" under the Securities Act, and does not constitute a part hereof.

We will provide to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, a copy of any or all of the information that we have incorporated by reference into this prospectus but not delivered with this prospectus. We will provide this information upon written or oral request at no cost to the requester. You may request this information by contacting our corporate headquarters at the following address: at 550 Reserve St, Suite 360, Southlake, Texas 76092, Attn: Danielle Watson, or by calling (682)-237-7781 or at the following email address: investorrelations@heartsciences.com.

GLOSSARY OF TERMS

The following definitions shall apply to the terms used in this prospectus.

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.

"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.

"Class III" means a classification of medical devices that 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. Class III devices generally require approval of a PMA.

"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 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.

"IDE" means the FDA' s investigational device exemption. FDA regulations governing medical device clinical trials provide when an IDE may be obtained. The IDE regulations exempt investigational devices from many regulations, but otherwise govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of submission, recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators intended to encourage public health and safety and with ethical standards.

"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.

Terms Used for Other Regulators and Regulations within the U.S.

"CCPA" means the California Consumer Privacy Act.

"CPRA" means the California Privacy Rights Act.

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.

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.

"LV" means left ventricular.

"LVD" means left ventricular dysfunction.

"LVDD" means left ventricular diastolic dysfunction.

"off-label" means the use of products for a purpose other than as approved by the FDA.

"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 Our Company and 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.

"$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.

"Investor Warrants" means all outstanding warrants to purchase 56,726 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 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 225,000 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 MyoVista *wav*ECG device.

"Series A Preferred Stock" means our Series A convertible preferred stock, par value $0.001 per share.

"Series B Preferred Stock" means our Series B convertible preferred stock, par value $0.001 per share.

"Series C Preferred Stock" means our Series C convertible preferred stock, par value $0.001 per share.

"Shares" means, collectively, all of the Shares, Pre-Funded Warrants and Bridge Warrants and Pre-Funded Warrants.

"Underwriter" means The Benchmark Company LLC.

"Underwriter Warrants" means the warrants to purchase an aggregate of 105,000 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.

"Warrants" means, collectively, the Pre-Funded Warrants and the Bridge Warrants.

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 through February 2022, which were issued to such lead investor and 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 and Bridge Warrants.

"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 Senior Subordinated Convertible Loan Notes we sold to Purchasers pursuant to the Securities Purchase Agreement.

"Bridge Warrant Amendment" means Amendment No. 1 to Bridge Warrant by and between Heart Test Laboratories, Inc. and Cavalry Investment Fund, LP, dated September 8, 2022.

"Bridge Warrants" means warrants issued in connection with the purchase of Bridge Notes to purchase our Common Stock upon exercise of such warrants pursuant to the Securities Purchase Agreement.

"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%.

"Pre-Funded 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.

"Purchasers" means the accredited investors who purchased our securities pursuant to the Securities Purchase Agreement.

"Registration Rights Agreement" means the registration rights agreement we entered into with the Purchasers in conjunction with the Securities Purchase Agreement.

"Securities Purchase Agreement" means the Securities Purchase Agreement we entered into with the Purchasers in connection with the 2021 Bridge Financing.

Terms Used in Connection with this Offering Not Otherwise Listed

"FASB ASC" means the Financial Standards Accounting Board 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.

"GE" means the General Electric Company.

"Hill-Rom" means Hill-Rom Holdings, Inc.

"MD&A" means Management' s Discussion & Analysis of Financial Condition and Results of Operations.

"Nasdaq" means the Nasdaq Stock Market.

"Philips" means Koninklijke Philips N.V.

"PPP" means the Paycheck Protection Program established pursuant to the CARES Act.

1,540,492 Shares of Common Stock

Up to 1,683,470 Shares of Common Stock Issuable Upon Exercise of the Bridge Warrants

Up to 139,356 Shares of Common Stock Issuable Upon Exercise of the Pre-Funded Warrants

HEART TEST LABORATORIES, INC.

PROSPECTUS

October 7, 2022